NCTID: NCT00005795
Intervention Type: Drug
Intervention Name: arsenic trioxide
Title: Arsenic Trioxide in Treating Patients With Acute Myeloid Leukemia
Condition: Leukemia
Eligibility Criteria: DISEASE CHARACTERISTICS: Documented acute myelogenous leukemia (AML) including secondary
AML and biphenotypic leukemia Secondary AML may be either chemotherapy induced or evolving
from a myelodysplastic syndrome Bone marrow evidence of AML must include the following:
Cellularity of 20% or greater Minimum of 20% leukemic cells Signs of bone marrow failure
such as: Anemia (hemoglobin less than 12.0 g/dL) Granulocytopenia (granulocyte count less
than 1,500/mm3) Thrombocytopenia (platelet count less than 100,000/mm3) Must not be any of
the following: Acute lymphoblastic leukemia Blastic phase of chronic myelogenous leukemia
Acute promyelocytic leukemia (M3) Prior induction therapy using any conventional induction
chemotherapy regimen required In first or second relapse after successful induction therapy
OR Failed 1 attempt at reinduction relapse OR Refractory to at least 1 prior induction
therapy No prior induction therapy allowed in secondary AML or in newly diagnosed AML in
patients at least 65 years old

PATIENT CHARACTERISTICS: Age: 16 and over Performance status: ECOG 0-2 Life expectancy: At
least 6 weeks Hematopoietic: See Disease Characteristics No evidence of being platelet
transfusion refractory WBC no greater than 20,000/mm3 (leukapheresis, hydroxyurea, or both
allowed) Hepatic: Bilirubin no greater than 2.0 mg/dL unless leukemic infiltration to liver
SGOT or SGPT less than 2 times upper limit of normal Renal: Creatinine no greater than 2.0
mg/dL Cardiovascular: No evidence of symptomatic coronary atherosclerotic heart disease
Other: Not pregnant Negative pregnancy test Fertile patients must use effective
contraception No active infection and afebrile Afebrile, stable, and completing antibiotics
allowed Febrile not from infection but from blood products allowed

PRIOR CONCURRENT THERAPY: Biologic therapy: No concurrent bone marrow transplantation
Chemotherapy: See Disease Characteristics At least 3 weeks since prior chemotherapy No
other concurrent chemotherapy Endocrine therapy: Not specified Radiotherapy: No concurrent
radiotherapy Surgery: Not specified Other: No other concurrent antileukemic agents
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00005820
Intervention Type: Drug
Intervention Name: nitrocamptothecin
Title: Nitrocamptothecin in Treating Patients With Stage IV Prostate Cancer That Has Not Responded to Hormone Therapy
Condition: Prostate Cancer

Eligibility Criteria: DISEASE CHARACTERISTICS:

- Histologically confirmed adenocarcinoma of the prostate with clinically progressive stage IVA or IVB disease after at least primary androgen ablation with either orchiectomy or LHRH agonist and only one cytotoxic chemotherapy regimen
- Measurable disease with a maximum of 10 measurable lesions OR nonmeasurable disease
- Serum testosterone no greater than 50 ng/mL if no prior bilateral orchiectomy

PATIENT CHARACTERISTICS:

Age:

- Not specified

Performance status:

- ECOG 0 or 1

Life expectancy:

- Not specified

Hematopoietic:

- Absolute neutrophil count at least 1,500/mm3
- Platelet count at least 100,000/mm3 (transfusion independent)
- No disseminated intravascular coagulation

Hepatic:

- Bilirubin no greater than 1.5 times upper limit of normal (ULN)
- AST and ALT no greater than 3 times ULN

Renal:

- Creatinine no greater than 1.5 times ULN

Other:

- Fertile patients must use effective contraception
- No currently active second malignancy other than nonmelanoma skin cancers
- No active infection

PRIOR CONCURRENT THERAPY:

Biologic therapy:

- At least 4 weeks since prior immunotherapy and recovered

Chemotherapy:

- See Disease Characteristics

- At least 6 weeks since prior suramin

- At least 4 weeks since other prior chemotherapy

- No prior therapy with camptothecin or any of its analogues

Endocrine therapy:

- Prior second line hormonal therapy allowed

- At least 4 weeks since prior hormonal therapy

- Concurrent treatment with LHRH agonists allowed and required for

- patients without orchiectomy

- No concurrent hormonal therapy except for nondisease related conditions

- Concurrent corticosteroids allowed if on stable dose for at least 6 weeks

- before study

- No concurrent dexamethasone as an antiemetic

Radiotherapy:

- At least 4 weeks since prior radiotherapy and recovered

- No palliative radiotherapy

- At least 8 weeks since prior strontium 89 or samarium 153

Surgery:

- At least 3 weeks since major surgery and recovered

Overall Status: Completed
Phase: Phase 2

NCTID: NCT00005829
Intervention Type: Drug
Intervention Name: gemcitabine hydrochloride
Title: Gemcitabine in Treating Patients With Recurrent Chronic Lymphocytic Leukemia
Condition: Leukemia
Eligibility Criteria: DISEASE CHARACTERISTICS: Diagnosis of B-cell chronic lymphocytic leukemia manifested by all
of the following: Minimum threshold peripheral lymphocyte count of at least 5,000/mm3 Small
to medium sized peripheral blood lymphocytes with no greater than 55% prolymphocytes Bone
marrow aspirate and biopsy containing at least 30% lymphoid cells Immunophenotypic and
biopsy evaluation of peripheral blood lymphocytes demonstrating monoclonality of B
lymphocytes B-cell markers with CD5 antigen (e.g., T-1, T-101) in the absence of other pan
T-cell markers (e.g., CD3, CD2) Expression of CD19, CD20, and CD23 B cell surface markers
B-cell expression of kappa or lambda light chains Active disease with at least one of the

following criteria: One or more disease related symptoms: At least 10% weight loss within the past 6 months Fever greater than 100.5 F for at least 2 weeks without evidence of infection Night sweats without evidence of infection Evidence of progressive marrow failure as manifested by the development of or worsening of anemia (hemoglobin less than 11.0 g/dL) and/or thrombocytopenia (platelet count less than 100,000/mm3) (i.e., any stage III or IV disease) Autoimmune anemia and/or thrombocytopenia poorly responsive to corticosteroid therapy Massive (i.e., greater than 6 cm below the left costal margin) or progressive splenomegaly (i.e., a greater than 50% increase over two months) Massive (i.e., greater than 10 cm in longest diameter) or progressive lymphadenopathy (i.e., a greater than 50% increase over two months) Progressive lymphocytosis with an increase of greater than 50% over a 2 month period (unrelated to corticosteroids) or an anticipated doubling time of less than 6 months No marked hypogammaglobulinemia or the development of a monoclonal protein in the absence of any criteria for active disease Previously treated with at least a fludarabine or cladribine based regimen and a prior alkylating agent with evidence of recurrent or progressive disease

PATIENT CHARACTERISTICS: Age: 18 and over Performance status: ECOG 0-2 Life expectancy: Not specified Hematopoietic: See Disease Characteristics Platelet count at least 75,000/mm3 Hepatic: Bilirubin no greater than 1.5 times upper limit of normal (ULN) SGOT no greater than 1.5 times ULN (unless due to hemolysis or chronic lymphocytic leukemia) Renal: Creatinine no greater than 1.5 times ULN Cardiovascular: No New York Heart Association class III or IV heart disease No myocardial infarction within the past month Other: No uncontrolled infection HIV negative No other active malignancy Not pregnant or nursing Negative pregnancy test Fertile patients must use effective contraception

PRIOR CONCURRENT THERAPY: Biologic therapy: Not specified Chemotherapy: See Disease Characteristics At least 4 weeks since prior chemotherapy Endocrine therapy: See Disease Characteristics No concurrent corticosteroids Radiotherapy: At least 4 weeks since prior radiotherapy Surgery: At least 4 weeks since prior major surgery
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00005861
Intervention Type: Drug
Intervention Name: pegylated liposomal doxorubicin hydrochloride
Title: Liposomal Doxorubicin in Treating Patients With Advanced or Recurrent Endometrial Cancer
Condition: Endometrial Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS:

- Histologically confirmed stage III, IV, or recurrent endometrial carcinoma for which curative radiotherapy or surgery is not an option

- Bidimensionally measurable disease

  - Irradiated field as only site allowed if evidence of progression since radiotherapy

PATIENT CHARACTERISTICS:

Age:

- Not specified

Performance status:

- GOG 0-2

Life expectancy:

- Not specified

Hematopoietic:

- Absolute neutrophil count at least 1,500/mm^3

- Platelet count at least 100,000/mm^3

Hepatic:

- Bilirubin no greater than 1.5 times upper limit of normal (ULN)

- SGOT no greater than 3 times ULN

- Alkaline phosphatase no greater than 3 times ULN

Renal:

- Creatinine no greater than 1.5 times ULN

Cardiovascular:

- LVEF normal by cardiac echocardiogram or MUGA

Other:

- No concurrent active infection

- No prior or concurrent malignancy within past 5 years except nonmelanoma skin cancer

PRIOR CONCURRENT THERAPY:

Biologic therapy:

- Not specified

Chemotherapy:

- Prior chemotherapy as radiosensitizer allowed

- No prior chemotherapy for advanced or metastatic disease
- No other concurrent chemotherapy

Endocrine therapy:

- Not specified

Radiotherapy:

- See Disease Characteristics
- Recovered from prior radiotherapy

Surgery:

- See Disease Characteristics
- Recovered from prior surgery

Other:

- No prior therapy that would preclude study
- No other concurrent antineoplastic agents
- No other concurrent investigational agents

Overall Status: Completed
Phase: Phase 2

NCTID: NCT00005843
Intervention Type: Drug
Intervention Name: tipifarnib
Title: R115777 in Treating Patients Who Have Metastatic Pancreatic Cancer
Condition: Pancreatic Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS:

- Histologically confirmed adenocarcinoma of the pancreas
- Measurable metastatic disease No prior treatment for metastatic disease except immunotherapy (e.g., antibodies, vaccines, cytokines)

PATIENT CHARACTERISTICS:

- Age: 18 and over
- Performance status: ECOG 0-2
- WBC at least 4,000/mm3 OR granulocyte count at least 1,500/mm3
- Platelet count at least 100,000/mm3
- Bilirubin no greater than 2.0 mg/dL
- SGOT/SGPT no greater than 2 times normal
- Creatinine no greater than 2.0 mg/dL OR creatinine clearance at least 50 mL/min
- Not pregnant or nursing
- Fertile patients must use effective contraception during and for 3 months after the

study

- No concurrent illness or active infection which would preclude study

- No prior malignancy allowed unless disease free for the time period considered appropriate for cure of the specific cancer

- No history of allergies to imidazole compounds (e.g., fluconazole, ketoconazole, miconazole, itraconazole, clotrimazole)

PRIOR CONCURRENT THERAPY:

- No prophylactic filgrastim (G-CSF), sargramostim (GM-CSF), or thrombopoietin

- Primary neoadjuvant or adjuvant chemotherapy allowed at least 6 months prior to detection of metastatic disease

- Primary radiotherapy allowed at least 6 months prior to detection of metastatic disease

- No concurrent use of proton pump inhibitors (e.g., omeprazole)

Overall Status: Completed
Phase: Phase 2

NCTID: NCT00005837
Intervention Type: Drug
Intervention Name: oxaliplatin
Title: Oxaliplatin in Treating Patients With Recurrent or Refractory Cervical Cancer
Condition: Cervical Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS: Histologically confirmed refractory or recurrent squamous cell carcinoma of the cervix that has failed local therapeutic measures and considered incurable Bidimensionally measurable disease Must not be eligible for a higher priority GOG protocol No known brain metastases

PATIENT CHARACTERISTICS: Age: Not specified Performance status: GOG 0-2 Life expectancy: Not specified Hematopoietic: WBC at least 3,000/mm3 Platelet count at least 100,000/mm3 Granulocyte count at least 1,500/mm3 Hepatic: Bilirubin no greater than 1.5 times upper limit of normal (ULN) SGOT no greater than 3 times ULN Alkaline phosphatase no greater than 3 times ULN Renal: Creatinine normal Cardiovascular: No symptomatic congestive heart failure No unstable angina pectoris No cardiac arrhythmia Other: Not pregnant or nursing Fertile patients must use effective contraception No evidence of preexisting peripheral sensory neuropathy greater than CTC grade 1, including residual neuropathy attributed to prior chemotherapy and other chronic conditions (e.g., diabetes, venous stasis, and carpal tunnel syndrome) No history of allergy to platinum compounds or to antiemetics appropriate

for administration in conjunction with protocol directed chemotherapy No other uncontrolled concurrent illness (e.g., ongoing or active infection) No other malignancy within the past 5 years except nonmelanoma skin cancer and no other prior malignancy whose prior cancer treatment contraindicates this protocol therapy

PRIOR CONCURRENT THERAPY: Biologic therapy: No concurrent colony stimulating factors (CSFs) during first course of therapy At least 24 hours since prior CSFs during subsequent courses of therapy Chemotherapy: At least 3 weeks since prior chemotherapy and recovered No prior oxaliplatin No more than 1 prior chemotherapy regimen Endocrine therapy: Not specified Radiotherapy: At least 3 weeks since prior radiotherapy and recovered Surgery: At least 3 weeks since prior surgery and recovered Other: At least 3 weeks since prior anticancer therapy and recovered No other concurrent investigational agents No concurrent antiretroviral therapy (HAART)
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00005833
Intervention Type: Drug
Intervention Name: R115777
Title: S9923 R115777 in Treating Patients With Advanced Colorectal Cancer
Condition: Colorectal Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS: Histologically or cytologically confirmed advanced colorectal adenocarcinoma Well differentiated OR Moderately well differentiated OR Poorly differentiated Distant metastases not surgically curable Measurable disease No prior treatment for disseminated disease No known brain metastases

PATIENT CHARACTERISTICS: Age: 18 and over Performance status: Zubrod 0-1 Life expectancy: Not specified Hematopoietic: Absolute granulocyte count at least 1,500/mm3 Platelet count at least 100,000/mm3 Hepatic: Bilirubin no greater than 1.5 times upper limit of normal (ULN) SGOT or SGPT no greater than 2.5 times ULN Renal: Creatinine no greater than 2.0 mg/dL Other: Not pregnant or nursing Fertile patients must use effective contraception Must be able to swallow or receive enteral medications through gastrostomy feeding tube No intractable nausea or vomiting No other prior malignancy for the past 5 years except adequately treated basal cell or squamous cell skin cancer, carcinoma in situ of the cervix, or any adequately treated stage I or II cancer in complete remission

PRIOR CONCURRENT THERAPY: Biologic therapy: At least 4 weeks since prior adjuvant immunotherapy and recovered No concurrent immunotherapy Chemotherapy: At least 4 weeks since prior adjuvant chemotherapy and recovered No other concurrent chemotherapy Endocrine

therapy: No concurrent hormonal therapy Radiotherapy: At least 4 weeks since prior
radiotherapy and recovered No more than 25% of total area of bone marrow irradiated No
concurrent radiotherapy Surgery: At least 2 weeks since prior surgery and recovered Other:
No concurrent proton pump inhibitors No other concurrent anticancer therapy
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00005832
Intervention Type: Drug
Intervention Name: R115777
Title: S9924 R115777 in Treating Patients With Locally Advanced or Metastatic Pancreatic Cancer
Condition: Pancreatic Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS: Histologically or cytologically confirmed adenocarcinoma of the
pancreas Ductal adenocarcinoma Mucinous noncystic carcinoma Signet ring cell carcinoma
Adenosquamous carcinoma Undifferentiated (anaplastic) carcinoma Mixed ductal endocrine
carcinoma Well differentiated adenocarcinoma Moderately well or poorly differentiated
adenocarcinoma Undifferentiated ductal carcinoma No papillary cystic carcinomas, sarcomas,
or tumors arising from the endocrine pancreas Pathological confirmation of a metastatic
site allowed Clinical documentation of pancreatic involvement and no evidence of another
primary allowed Locally advanced or distant metastatic disease surgically incurable No
known brain metastases

PATIENT CHARACTERISTICS: Age: Not specified Performance status: Zubrod 0-1 Life expectancy:
Not specified Hematopoietic: Absolute granulocyte count at least 1,500/mm3 Platelet count
at least 100,000/mm3 Hepatic: Bilirubin no greater than 1.5 times upper limit of normal
(ULN) SGOT or SGPT no greater than 2.5 times ULN Renal: Creatinine no greater than 2.0
mg/dL Other: Ability to swallow and/or receive enteral medications via gastrostomy feeding
tube No intractable nausea or vomiting No other prior malignancy within the past 5 years
except adequately treated basal or squamous cell skin cancer, carcinoma in situ of the
cervix, or stage I or II cancer in remission Not pregnant or nursing Fertile patients must
use effective contraception

PRIOR CONCURRENT THERAPY: Biologic therapy: No prior or concurrent immunotherapy
Chemotherapy: No prior chemotherapy No prior adjuvant or neoadjuvant chemoradiotherapy,
including for advanced pancreatic cancer No other concurrent chemotherapy Endocrine
therapy: No prior or concurrent hormonal therapy Radiotherapy: See Chemotherapy No prior
radiotherapy, except for palliation to metastatic sites No concurrent radiotherapy Surgery:
See Disease Characteristics At least 2 weeks since prior surgery for

pancreatic cancer and
recovered Prior partial resections of the stomach and duodenum for pancreatic cancer
allowed No prior major resection of the small intestine Prior pancreaticduodenectomy for
pancreatic cancer allowed Other: No concurrent proton pump inhibitors (e.g., omeprazole)
Concurrent antacids or H2 blockers allowed No other concurrent therapy for pancreatic
cancer
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00005880
Intervention Type: Drug
Intervention Name: budesonide
Title: Budesonide in Treating Former and Current Smokers With Bronchial Dysplasia
Condition: Lung Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS: Histologically confirmed mild, moderate, or severe bronchial
dysplasia More than one suspicious area of abnormal fluorescence on bronchoscopy If only
one abnormal area, lesion must be greater than 1.5 mm Current or ex-smokers who have smoked
at least 30 pack years (e.g., 1 pack per day for at least 30 years) Sputum cells with
morphometric index at least 7 by computer-assisted image analysis No invasive cancer on
bronchoscopy or abnormal chest x-ray suspicious of lung cancer

PATIENT CHARACTERISTICS: Age: 40 to 74 Performance status: Not specified Life expectancy:
Not specified Hematopoietic: No bleeding disorder Hepatic: Not specified Renal: Not
specified Cardiovascular: No unstable angina or congestive heart failure Pulmonary: No
active pulmonary tuberculosis No acute bronchitis or pneumonia No acute or chronic
respiratory failure Other: No history of allergy to budesonide or lactose No known reaction
to lidocaine Ability to reliably take medication Not pregnant or nursing Negative pregnancy
test Fertile patients must use effective contraception

PRIOR CONCURRENT THERAPY: Biologic therapy: Not specified Chemotherapy: Not specified
Endocrine therapy: At least 6 months since prior oral glucocorticoids (e.g., prednisone) At
least 6 months since prior inhaled glucocorticoids (e.g., budesonide, Beclovent, or
Becloforte) Radiotherapy: Not specified Surgery: Not specified
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00005873
Intervention Type: Drug
Intervention Name: rubitecan
Title: Nitrocamptothecin in Treating Patients With Locally Recurrent or Metastatic Breast Cancer
Condition: Breast Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS: Histologically or cytologically confirmed locally recurrent or
metastatic breast cancer not amenable to surgery or radiotherapy

Measurable or evaluable
disease No prior radiotherapy to only target lesion Disease progression after no more than
2 prior chemotherapy treatments for metastatic disease No active CNS metastasis Prior CNS
metastasis allowed with no evidence of active disease Hormone receptor status: Not
specified

PATIENT CHARACTERISTICS: Age: Not specified Menopausal status: Not specified Performance
status: ECOG 0-2 Life expectancy: At least 12 weeks Hematopoietic: Absolute granulocyte
count greater than 1,500/mm3 Hemoglobin greater than 9.0 g/dL Platelet count greater than
100,000/mm3 Hepatic: Bilirubin no greater than 2.0 mg/dL AST/ALT no greater than 3 times
upper limit of normal (ULN) (no greater than 5 times ULN in case of liver metastases)
Renal: Creatinine no greater than 2.0 mg/dL Other: Not pregnant or nursing Negative
pregnancy test Fertile patients must use effective contraception Must be able to have daily
fluid intake of at least 3 liters No concurrent active infection No other prior malignancy
in past 5 years except adequately treated basal cell carcinoma of the skin or carcinoma in
situ of the cervix

PRIOR CONCURRENT THERAPY: Biologic therapy: Not specified Chemotherapy: See Disease
Characteristics No prior irinotecan, topotecan, or other camptothecin analogues At least 3
weeks since prior chemotherapy Endocrine therapy: No concurrent corticosteroids to control
CNS disease Radiotherapy: See Disease Characteristics At least 2 weeks since prior
radiotherapy Surgery: At least 4 weeks since prior major surgery
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00005864
Intervention Type: Drug
Intervention Name: chloroquinoxaline sulfonamide
Title: Chloroquinoxaline Sulfonamide in Treating Patients With Stage IV Colorectal Cancer
Condition: Colorectal Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS: Histologically or cytologically confirmed stage IV colorectal
cancer Measurable disease defined as lesions that measure at least 20 mm in one dimension
using conventional techniques or at least 10 mm with spiral CT scan not including: Bone
lesions Leptomeningeal disease Ascites Pleural/pericardial effusion Inflammatory breast
disease Lymphangitis cutis/pulmonis Abdominal masses that are not confirmed and followed by
imaging techniques Cystic lesions Recurrent disease allowed after adjuvant chemotherapy if
recurrence occurred at least 6 months after completion of therapy No known brain metastases

PATIENT CHARACTERISTICS: Age: 18 and over Performance status: ECOG 0-2 Karnofsky 60-100%

Life expectancy: Greater than 12 weeks Hematopoietic: WBC at least 3,000/mm3 Absolute
neutrophil count at least 1,500/mm3 Platelet count at least 100,000/mm3 Hepatic: Bilirubin
normal AST/ALT no greater than 2.5 times upper limit of normal Renal: Creatinine normal
Cardiovascular: No history of symptomatic congestive heart failure, unstable angina, or
cardiac arrhythmia (e.g., supraventricular tachycardia or atrial fibrillation) Other: Not
pregnant or nursing Negative pregnancy test Fertile patients must use effective
contraception No significant episodes of hypoglycemia in past 6 months No known allergies
to compounds of similar chemical or biologic composition to chloroquinoxaline sulfonamide
No known glucose-6 phosphate deficiency or hemolytic anemia No uncontrolled concurrent
illness (e.g., active infection) No concurrent psychiatric illness or social condition that
would preclude compliance

PRIOR CONCURRENT THERAPY: Biologic therapy: One prior biologic therapy allowed
Chemotherapy: See Disease Characteristics No more than one prior chemotherapy for
metastatic disease or adjuvant treatment At least 4 weeks since prior chemotherapy (6 weeks
for nitrosoureas or mitomycin) and recovered Endocrine therapy: No concurrent oral
hypoglycemics or insulin Radiotherapy: At least 4 weeks since prior radiotherapy and
recovered Surgery: Not specified Other: No other concurrent investigational agents No
concurrent combination antiretroviral treatment for HIV
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00005877
Intervention Type: Drug
Intervention Name: rubitecan
Title: Nitrocamptothecin in Treating Patients With Advanced or Recurrent Colorectal Cancer
Condition: Colorectal Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS: Histologically or cytologically proven colorectal cancer with
failure or relapse after at least 1 prior fluorouracil based chemotherapy regimen for
advanced disease OR metastatic disease within 6 months after completion of adjuvant therapy
No more than 1 prior fluorouracil based chemotherapy regimen for metastatic disease Prior
oral fluorouracil or combinations of other drugs with fluorouracil allowed Prior adjuvant
therapy with fluorouracil allowed and not counted as 1 regimen if given more than 1 year
prior to study At least 1 bidimensionally measurable indicator lesion that has not been
irradiated and has the following minimum dimensions: Skin nodule or superficial lymph node:
2 x 2 cm Lung lesion surrounded by aerated lung: 1 x 1 cm by chest x-ray or at least 2 cm
in 1 dimension by CT scan Liver lesion, soft tissue mass, or lymph node: at least 2 cm in 1

dimension by CT scan or sonogram

PATIENT CHARACTERISTICS: Age: Not specified Performance status: ECOG 0-2 Life expectancy:
At least 8 weeks Hematopoietic: Granulocyte count greater than 1,500/mm3 Hemoglobin greater
than 10 g/dL Platelet count greater than 100,000/mm3 Hepatic: SGOT and SGPT no greater than
3 times normal (no greater than 5 times normal if liver tumor present) Bilirubin no greater
than 2 mg/dL Renal: Creatinine no greater than 2 mg/dL Other: Not pregnant or nursing
Negative pregnancy test Fertile patients must use effective contraception during and for 6
months after study

PRIOR CONCURRENT THERAPY: Biologic therapy: At least 2 weeks since prior immunotherapy and
recovered No concurrent filgrastim (G-CSF) No concurrent immunotherapy Chemotherapy: See
Disease Characteristics No prior nitrocamptothecin, irinotecan, or other camptothecin
analog At least 2 weeks since other prior chemotherapy and recovered No other concurrent
chemotherapy Endocrine therapy: No concurrent anticancer hormonal therapy Radiotherapy: See
Disease Characteristics At least 2 weeks since prior radiotherapy and recovered No
concurrent radiotherapy Surgery: At least 2 weeks since prior surgery and recovered No
scheduled major surgery within 8 weeks following initiation of treatment Overall Status: Unknown status
Phase: Phase 2

NCTID: NCT00005884
Intervention Type: Drug
Intervention Name: eflornithine
Title: Eflornithine to Prevent Skin Cancer in Patients With Previously Treated Early Stage Skin Cancer
Condition: Non-melanomatous Skin Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS: Histologically proven previously treated stage 0, I, or II basal
or squamous cell skin cancer

PATIENT CHARACTERISTICS: Age: 21 and over Performance status: ECOG 0-1 Life expectancy: Not
specified Hematopoietic: WBC at least 3,500/mm3 Platelet count at least 100,000/mm3
Hemoglobin at least 11.0 g/dL Hepatic: Bilirubin no greater than 2 mg/dL SGOT less than 3
times normal Renal: Creatinine less than 2.0 mg/dL Other: Not pregnant or nursing Negative
pregnancy test Fertile patients must use effective contraception No significant clinical
hearing loss or use of hearing aid No family history of early retinal blindness or
ornithine diaminotransferase deficiency

PRIOR CONCURRENT THERAPY: Biologic therapy: No prior bone marrow transplant No concurrent
tamoxifen for cancer treatment or prophylaxis Chemotherapy: Greater than 4 weeks since
prior chemotherapy No concurrent cytotoxic chemotherapy Endocrine therapy: Greater than 4

weeks since prior hormonal therapy for cancer No concurrent prednisone No concurrent
hormonal therapy for cancer treatment or prophylaxis Radiotherapy: Greater than 4 weeks
since prior radiotherapy Surgery: Greater than 4 weeks since prior major surgery No prior
solid organ transplant Other: At least 4 weeks since prior topical medications (e.g.,
tretinoin, isotretinoin, psoralen ultraviolet light therapy, or fluorouracil) for skin
cancer No concurrent antiseizure medication
Overall Status: Completed
Phase: Phase 3

NCTID: NCT00005865
Intervention Type: Drug
Intervention Name: vinorelbine tartrate
Title: Vinorelbine in Treating Patients With Stage IIIB or Stage IV Non-Small Cell Lung Cancer
Condition: Lung Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS: Histologically or cytologically confirmed stage IIIB or IV
non-small cell lung cancer not amenable to combination chemotherapy, curative surgery, or
radiotherapy Bidimensionally measurable disease

PATIENT CHARACTERISTICS: Age: 18 and over Performance status: Karnofsky 60-100% Life
expectancy: At least 12 weeks Hematopoietic: Granulocyte count at least 2,000/mm3 Platelet
count at least 100,000/mm3 Hemoglobin at least 10 g/dL Hepatic: Bilirubin no greater than
1.5 times upper limit of normal (ULN) SGOT less than 2.5 times ULN Alkaline phosphatase
less than 5 times ULN (except in cases of bone or liver metastases) Renal: Creatinine no
greater than 1.5 times ULN Cardiovascular: No unstable or uncontrolled cardiac disease
Pulmonary: No history of recurrent aspiration pneumonitis within the past 3 months Other:
Not pregnant or nursing Negative pregnancy test Fertile patients must use effective
contraception during and for 9 days after study Able to swallow capsules intact No active
infection within the past 2 weeks No unstable or uncontrolled medical conditions No other
prior malignancy within the past 5 years except basal cell skin cancer or carcinoma in situ
of the cervix No history of peripheral neuropathy with severity greater than CALGB grade 1

PRIOR CONCURRENT THERAPY: Biologic therapy: No prior immunologic therapy At least 1 week
since prior hematopoietic growth factors or other blood products Chemotherapy: See Disease
Characteristics No prior chemotherapy No other concurrent chemotherapy Endocrine therapy:
Not specified Radiotherapy: See Disease Characteristics At least 4 weeks since prior
radiotherapy Surgery: See Disease Characteristics At least 2 weeks since prior surgery
Other: At least 4 weeks since prior investigational device or drug No other concurrent
anticancer therapy No other concurrent investigational device or drug

Overall Status: Completed
Phase: Phase 2

NCTID: NCT00005878
Intervention Type: Drug
Intervention Name: celecoxib
Title: Celecoxib to Prevent Cancer in Patients With Barrett's Esophagus
Condition: Esophageal Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS:

- Histologically confirmed Barrett's dysplasia with specific information on the location (level) of the highest grade of dysplasia based on biopsy from baseline endoscopy

- Short segment Barrett's esophagus must be sufficient area to allow for biopsy without complete resection

- No presence of reflux esophagitis grades 2-4

- No history of confirmed invasive carcinoma of the esophagus

- No diagnosis of esophageal, gastric, pyloric channel, or duodenal ulceration of 1 cm or more in diameter within the past 30 days

PATIENT CHARACTERISTICS:

Age:

- 18 and over

Performance status:

- ECOG 0-2

Life expectancy:

- Not specified

Hematopoietic:

- Hemoglobin at least 9 g/dL

- Platelet count greater than 125,000/mm^3

- WBC greater than 3,000/mm^3

- No significant bleeding disorder

- No other abnormal hematopoietic laboratory test result that would preclude study

Hepatic:

- PT/PTT no greater than 1.5 times upper limit of normal (ULN)

- AST/ALT less than 1.5 times ULN

- Alkaline phosphatase less than 1.5 times ULN

- No chronic or acute hepatic disorder

- No abnormal hepatic laboratory test result that would preclude study

Renal:

- Creatinine no greater than 1.5 times ULN
- No chronic or acute renal disorder
- No other abnormal renal laboratory test result that would preclude study

Other:

- Not pregnant or nursing
- Negative pregnancy test
- Fertile patients must use effective contraception
- No prior or concurrent active inflammatory bowel disease (e.g., Crohn's disease or ulcerative colitis)
- No other prior or concurrent curatively treated malignancy with a survival prognosis of less than 5 years
- No hypersensitivity or adverse reaction to COX-2 inhibitors (e.g., celecoxib), sulfonamides, salicylates, or NSAIDs
- No other significant medical, psychological, or psychosocial condition that would preclude study participation

PRIOR CONCURRENT THERAPY:

Biologic therapy:

- Not specified

Chemotherapy:

- Not specified

Endocrine therapy:

- At least 6 months since prior regular (at least 2 weeks duration) oral or intravenous corticosteroids
- At least 6 months since prior regular (at least 4 weeks duration) inhaled corticosteroids
- No concurrent regular oral or intravenous corticosteroids
- No concurrent regular inhaled corticosteroids
- Concurrent corticosteroid nasal spray allowed

Radiotherapy:

- At least 12 weeks since prior radiotherapy to the chest or upper abdomen

Surgery:

- At least 3 months since prior surgery to the esophagus or stomach except hiatal hernia repair, fundoplication, vagotomy, or pyloroplasty

- No prior complete mucosal resection using any technique

- No concurrent resection of high-grade nodule

Other:

- At least 30 days since prior chronic (at least 3 times a week for greater than 2 weeks) aspirin or other nonsteroidal antiinflammatory drugs (NSAIDs) (i.e., greater than 100 mg/day)

- No prior complete mucosal ablation using any technique

- No prior treatment on this study

- At least 30 days since prior investigational medication including shingles vaccine

- No concurrent chronic NSAIDs or COX-2 inhibitors except low-dose aspirin (i.e., no greater than 100 mg/day)

- No concurrent anticoagulants (e.g., heparin or warfarin)

- No other concurrent investigational medication
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00005883
Intervention Type: Drug
Intervention Name: phenethyl isothiocyanate
Title: Phenethyl Isothiocyanate in Preventing Lung Cancer in People Who Smoke
Condition: Lung Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS: Asymptomatic smokers who either refuse to or cannot stop smoking
Urinary cotinine levels greater than 100 ng/mL Willing to adhere to certain dietary restrictions limiting intake of cruciferous vegetables (watercress, broccoli, radishes, mustard, brussels sprouts) while on study

PATIENT CHARACTERISTICS: Age: Not specified Performance status: Not specified Life expectancy: Not specified Hematopoietic: WBC at least 3,500/mm3 Platelet count at least 100,000/mm3 Hepatic: Bilirubin less than 1.6 mg/dL Transaminases less than 2 times normal Renal: Creatinine less than 1.6 mg/dL Urinary RBC levels 0-2 Urinary WBC levels at least 0-2 Pulmonary: No dyspnea at rest Other: No concurrent illness, condition, or symptom that would preclude study Not pregnant or nursing Negative pregnancy test Fertile patients must use effective contraception

PRIOR CONCURRENT THERAPY: Not specified
Overall Status: Completed
Phase: Phase 1

NCTID: NCT00005872
Intervention Type: Drug
Intervention Name: rubitecan
Title: Nitrocamptothecin in Treating Patients With Recurrent Non-small Cell Lung Cancer
Condition: Lung Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS: Histologically or cytologically confirmed recurrent non-small cell
lung cancer No more than one prior chemotherapy treatment
Bidimensionally measurable
disease No prior radiotherapy to target lesion OR Progression since prior radiotherapy

PATIENT CHARACTERISTICS: Age: 18 and over Performance status: ECOG 0-2 Life expectancy: Not
specified Hematopoietic: Absolute neutrophil count at least 1,500/mm3 Platelet count at
least 100,000/mm3 Hepatic: Bilirubin no greater than 2.0 mg/dL ALT/AST no greater than 3
times upper limit of normal (ULN) (no greater than 5 times ULN in case of liver metastases)
Renal: Creatinine no greater than 2.0 mg/dL OR Creatinine clearance at least 50 mL/min
Other: Not pregnant or nursing Negative pregnancy test Fertile patients must use effective
contraception No uncontrolled serious medical or psychiatric illness

PRIOR CONCURRENT THERAPY: Biologic therapy: Not specified Chemotherapy: See Disease
Characteristics At least 3 weeks since prior chemotherapy and recovered No prior
camptothecin Endocrine therapy: Not specified Radiotherapy: See Disease Characteristics At
least 3 weeks since prior radiotherapy and recovered Surgery: At least 2 weeks since prior
major surgery
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00005980
Intervention Type: Drug
Intervention Name: pegylated liposomal doxorubicin hydrochloride
Title: Comparison of Two Regimens of Liposomal Doxorubicin in Treating Women With Metastatic Breast Cancer
Condition: Breast Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS:

- Histologically proven progressive or recurrent metastatic breast cancer
- Bidimensionally measurable disease with at least one target lesion
    - If previously irradiated lesions:
        - No preirradiated only lesions
        - Clear progression prior to study
        - New lesions in a previously irradiated region allowed

- Refusal of or medical contraindication to standard anthracycline containing regimen

- Hormone receptor status:

    - Not specified

PATIENT CHARACTERISTICS:

Age:

- Any age

Sex:

- Female

Menopausal status:

- Not specified

Performance status:

- ECOG 0-2

Life expectancy:

- Not specified

Hematopoietic:

- Neutrophil count at least 1,500/mm^3

- Platelet count at least 100,000/mm^3

Hepatic:

- Bilirubin normal

- Transaminases less than 2 times upper limit of normal

Renal:

- Creatinine normal

Cardiovascular:

- Left ventricular ejection fraction normal by echocardiography or MUGA scan

- No significant cardiac history including:

    - Clinically significant atrial or ventricular arrhythmias requiring treatment

    - Medically controlled congestive heart failure

    - Significant angina or clinically and/or electrocardiographically documented
      myocardial infarction within the past year

    - Clinically significant valvular disease

Other:

- No other prior or concurrent malignancy within the past 5 years except contralateral breast cancer, or adequately treated basal cell skin cancer or carcinoma in situ of the cervix
- No psychological, familial, sociological, or geographical condition that would preclude study
- Not pregnant or nursing
- Fertile patients must use effective contraception

PRIOR CONCURRENT THERAPY:

Biologic therapy:

- Not specified

Chemotherapy:

- See Disease Characteristics
- Prior adjuvant chemotherapy allowed if total doxorubicin dose is no greater than 300 mg/m2, total epirubicin dose is no greater than 450 mg/m^2, and total mitoxantrone dose is no greater than 75 mg/m^2
- No greater than one regimen of prior chemotherapy for metastatic disease
- No prior anthracyclines for metastatic disease
- No other concurrent cytotoxic therapy

Endocrine therapy:

- No concurrent hormonal therapy
- At least 4 weeks since prior progestins, estrogens, or androgens

Radiotherapy:

- See Disease Characteristics
- Concurrent palliative radiotherapy allowed if sole target lesion is outside irradiated field

Surgery:

- Not specified

Other:

- Concurrent bisphosphonates for metastatic bone disease and hypercalcemia secondary to malignancy allowed if bony lesions not only target lesion
- No other concurrent investigational therapy

Overall Status: Completed
Phase: Phase 2

NCTID: NCT00005995
Intervention Type: Drug
Intervention Name: shark cartilage extract AE-941
Title: AE-941 in Treating Patients With Metastatic Kidney Cancer
Condition: Kidney Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS: Histologically confirmed renal cell adenocarcinoma Disease
progression within 16 weeks after first-line therapy, which included interleukin-2 and/or
interferon Metastatic disease not amenable to surgery Measurable and/or evaluable disease
No more than one line of prior anticancer treatment for renal cell carcinoma No pure
papillary cell tumor, mixed tumor containing predominantly sarcomatoid cells, Bellini
carcinoma, medullary carcinoma, or chromophobe oncocytic tumor No brain metastases

PATIENT CHARACTERISTICS: Age: 18 and over Performance status: ECOG 0-1 Life expectancy:
More than 3 months Hematopoietic: Platelet count at least 100,000/mm3 WBC at least
2,500/mm3 Hemoglobin at least 8 g/dL (epoetin alfa allowed) Hepatic: Not specified Renal:
Calcium no greater than the upper limit of normal (ULN) (bisphosphonates allowed)
Creatinine no greater than 2 times ULN Other: No other prior malignancy within past 5 years
except basal cell carcinoma of the skin or carcinoma in situ of the cervix No severe
allergy to fish or seafood No medical condition that would interfere with intake and/or
absorption of study medication (e.g., gastrectomy or major intestinal resection) No
significant medical or psychiatric condition that would preclude study Not pregnant
Negative pregnancy test Fertile patients must use adequate contraception

PRIOR CONCURRENT THERAPY: Biologic therapy: See Disease Characteristics At least 1 month
but no longer than 8 months since prior immunotherapy Chemotherapy: Not specified Endocrine
therapy: At least 1 week since prior systemic corticosteroids for symptomatic treatment of
renal cell carcinoma At least 28 days since prior medroxyprogesterone acetate No concurrent
medroxyprogesterone acetate Concurrent corticosteroids for symptomatic treatment of
neurological complications caused by renal cancer allowed Radiotherapy: Concurrent
radiotherapy to symptomatic lesions for symptom relief allowed Surgery: See Disease
Characteristics Concurrent surgical removal of symptomatic lesions for symptom relief
allowed Other: At least 28 days since other prior experimental therapeutic agents At least
28 days since other prior shark cartilage products No other concurrent therapies for
metastatic renal cell carcinoma No other concurrent shark cartilage products
Overall Status: Completed

Phase: Phase 3

NCTID: NCT00005989
Intervention Type: Drug
Intervention Name: tipifarnib
Title: R115777 in Treating Patients With Recurrent or Metastatic Non-small Cell Lung Cancer
Condition: Lung Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS:

- Histologically or cytologically confirmed recurrent or metastatic non-small cell lung cancer (NSCLC)
- Measurable disease
  - At least 20 mm in at least one dimension
  - Nonmeasurable is defined as any of the following:
    - Bone lesions
    - Leptomeningeal disease
    - Ascites
    - Pleural/pericardial effusion
    - Inflammatory breast disease
    - Lymphangitis cutis/pulmonis
    - Abdominal masses not confirmed and followed by imaging techniques
    - Cystic lesions
- No CNS metastases

PATIENT CHARACTERISTICS:

Age

- 18 and over

Performance status

- ECOG 0-2

Life expectancy

- At least 12 weeks

Hematopoietic

- Absolute neutrophil count at least 1,500/mm^3
- Platelet count at least 100,000/mm^3

Hepatic

- Bilirubin no greater than 2 times upper limit of normal (ULN)
- AST no greater than 3 times ULN (no greater than 5 times ULN in

case of hepatic
metastases)

Renal

- Creatinine no greater than 2 times ULN

Cardiovascular

- No New York Heart Association class III or IV heart disease

Other

- Not pregnant or nursing

- Negative pregnancy test

- Fertile patients must use effective contraception

- No uncontrolled infection

- No other prior malignancy in past 5 years except adequately treated basal cell or
squamous cell skin cancer or other adequately treated noninvasive carcinomas

- No other concurrent severe underlying disease

PRIOR CONCURRENT THERAPY:

Biologic therapy

- No prior biologic, gene, or immunotherapy

Chemotherapy

- No prior chemotherapy for NSCLC except low dose cisplatin as radiosensitizer

Endocrine therapy

- Not specified

Radiotherapy

- Prior radiotherapy to less than 25% of bone marrow allowed

Surgery

- Not specified
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00005999
Intervention Type: Drug
Intervention Name: arsenic trioxide
Title: Arsenic Trioxide in Treating Patients With Stage IVB or Recurrent Cervical Cancer
Condition: Cervical Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS:

- Histologically confirmed stage IVB or recurrent cervical carcinoma that is not
amenable to standard curative therapies

- Squamous carcinoma OR
- Adenocarcinoma

- Measurable disease
  - At least 20 mm by conventional techniques OR
  - At least 10 mm by spiral CT scan
  - Nonmeasurable disease defined as any of the following:
    - Bone disease
    - Leptomeningeal disease
    - Ascites
    - Pleural/pericardial effusion
    - Inflammatory breast disease
    - Lymphangitis cutis/pulmonis
    - Abdominal masses not confirmed or followed by imaging techniques
    - Cystic lesions
- No active brain metastases

PATIENT CHARACTERISTICS:

Age:

- 17 and over

Performance status:

- Karnofsky 60-100%

Life expectancy:

- Greater than 3 months

Hematopoietic:

- Absolute neutrophil count at least 1,500/mm^3
- Platelet count at least 100,000/mm^3

Hepatic:

- Bilirubin no greater than 1.5 times upper limit of normal (ULN)
- AST and ALT no greater than 2.5 times ULN

Renal:

- Creatinine no greater than 2.0 mg/dL OR
- Creatinine clearance at least 50 mL/min

Cardiovascular:

- No cardiac arrhythmias, unstable angina, or conduction abnormalities

- No New York Heart Association class III or IV heart disease or clinical evidence of congestive heart failure

- Pretreatment QTc less than 500 msec

Other:

- Not pregnant or nursing

- Negative pregnancy test

- Fertile patients must use effective contraception during and for 4 months after study

- No grade 3 or greater neurologic abnormalities

- No history of seizures

- No concurrent uncontrolled active infection

PRIOR CONCURRENT THERAPY:

Biologic therapy:

- No more than 2 prior therapies for advanced disease

Chemotherapy:

- No more than 2 prior therapies for advanced disease

- At least 4 weeks since prior chemotherapy

Endocrine therapy:

- No more than 2 prior therapies for advanced disease

Radiotherapy:

- No more than 2 prior therapies for advanced disease

- At least 4 weeks since prior radiotherapy

Surgery:

- Not specified

Other:

- At least 4 weeks since prior cytotoxic therapy or investigational agents

Overall Status: Completed
Phase: Phase 2

NCTID: NCT00006008
Intervention Type: Drug
Intervention Name: arsenic trioxide
Title: Arsenic Trioxide in Treating Patients With Relapsed or Refractory Acute Lymphoblastic Leukemia

Condition: Leukemia
Eligibility Criteria: DISEASE CHARACTERISTICS:

- Morphologically proven acute lymphoblastic leukemia (ALL)
  - Subtypes L1, L2, or L3
  - Bone marrow morphology with greater than 25% lymphoblasts
  - ALL morphology and cytochemistry with myeloid markers eligible
- Refractory to induction therapy or relapsed following chemotherapy or autologous blood or bone marrow transplantation
  - Any number of prior relapses allowed
  - No relapse following allogeneic transplantation
- Prior CNS leukemia allowed if treated and currently disease-free

PATIENT CHARACTERISTICS:

Age:

- 18 and over

Performance status:

- ECOG 0-2

Life expectancy:

- At least 6 months

Hematopoietic:

- Not specified

Hepatic:

- Bilirubin no greater than 2.0 mg/dL
- SGOT/SGPT no greater than 2 times upper limit of normal (ULN)
- Alkaline phosphatase no greater than 2 times ULN

Renal:

- Creatinine no greater than 2 mg/dL

Other:

- Not pregnant or nursing
- Negative pregnancy test
- Fertile patients must use effective contraception
- No significant active infection
- No other medical conditions that would likely decrease life expectancy

- No other prior malignancy within the past 5 years except cured basal or squamous cell skin cancer or carcinoma in situ of the cervix

PRIOR CONCURRENT THERAPY:

Biologic therapy:

- See Disease Characteristics

Chemotherapy:

- See Disease Characteristics

Endocrine therapy:

- At least 2 weeks since prior systemic corticosteroids

Radiotherapy:

- Not specified

Surgery:

- Not specified

Other:

- No concurrent antibiotics for active or resolving infection

Overall Status: Completed
Phase: Phase 2

NCTID: NCT00006020
Intervention Type: Drug
Intervention Name: nelarabine
Title: S0010 506U78 in Treating Patients With Recurrent or Refractory Acute Lymphocytic Leukemia
Condition: Leukemia
Eligibility Criteria: DISEASE CHARACTERISTICS:

- Diagnosis of acute lymphocytic leukemia (ALL)
  - FAB class L1-L2
- Non-T-cell ALL (lymphocytic immunophenotype markers CD19+, CD5-, and CD7- in peripheral blood, bone marrow, or in at least 1 extramedullary disease site)
  - Coexpression of myeloid antigens CD13 or CD33 allowed
- Histologically confirmed extramedullary disease in the absence of bone marrow or blood involvement allowed
  - CD3 and myeloperoxidase marker negative
- Meeting 1 of the following criteria for recurrent/refractory disease:
  - Refractory to standard induction regimen including at least vincristine and prednisone

- Recurrence after response after prior induction therapy
- Recurrence and failure on subsequent treatment

- No CNS involvement
- Must be registered on SWOG-S9910 and SWOG-9007

PATIENT CHARACTERISTICS:

Age:

- 16 and over

Performance status:

- Zubrod 0-3

Life expectancy:

- Not specified

Hematopoietic:

- Not specified

Hepatic:

- Bilirubin no greater than 1.5 times upper limit of normal (ULN)
- SGOT or SGPT no greater than 3 times ULN

Renal:

- Creatinine no greater than 2 times ULN

Other:

- Not pregnant or nursing
- Fertile patients must use effective contraception
- No grade 2 or greater neuropathy
- No other prior malignancy within the past 5 years except adequately treated basal cell or squamous cell skin cancer, carcinoma in situ of the cervix, or any other adequately treated stage I or II cancer in complete remission

PRIOR CONCURRENT THERAPY:

Biologic therapy

- Not specified

Chemotherapy

- See Disease Characteristics

Endocrine therapy

- Not specified

Radiotherapy

- Not specified

Surgery

- Not specified

Overall Status: Completed
Phase: Phase 2

NCTID: NCT00006023
Intervention Type: Drug
Intervention Name: capecitabine
Title: Capecitabine in Treating Patients With Metastatic Prostate Cancer That Has Not Responded to Hormone Therapy
Condition: Prostate Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS: Histologically or cytologically confirmed metastatic hormone
refractory prostate cancer Disease progression after orchiectomy or during hormonal therapy
Measurable or evaluable disease At least 2 consecutive increases in PSA At least 1 week
between reference value and first increase OR Third value must be higher than second if
second value is less than reference value PSA at least 5 ng/mL No leptomeningeal or brain
metastases

PATIENT CHARACTERISTICS: Age: 18 to 85 Performance status: WHO 0-2 Life expectancy: Not
specified Hematopoietic: WBC at least 3,500/mm3 OR Granulocyte count at least 2,000/mm3
Hemoglobin at least 9.0 g/dL Platelet count at least 100,000/mm3 Hepatic: Bilirubin no
greater than 1.5 times upper limit of normal (ULN) SGOT no greater than 2.5 times ULN
Renal: Creatinine no greater than 1.5 times ULN Other: No other prior malignancies in past
5 years except curatively treated basal cell or squamous cell carcinoma of the skin No
other significant disease that would preclude study No concurrent active severe infections

PRIOR CONCURRENT THERAPY: Biologic therapy: Prior gene therapy and antibody therapy allowed
Chemotherapy: No prior cytostatic chemotherapy, including estramustine Endocrine therapy:
See Disease Characteristics At least 1 month since prior antiandrogen therapy (e.g.,
flutamide or bicalutamide) without tumor response OR Concurrent antiandrogen therapy
allowed if clinically unacceptable to discontinue use If disease progressed while receiving
hormonal agents (e.g., goserelin, leuprolide, diethylstilbestrol), therapy must continue
during study Radiotherapy: At least 4 weeks since prior radiotherapy No prior radiotherapy
to lesions to be evaluated No concurrent radiotherapy to more than one area Surgery: See
Disease Characteristics Other: Prior noncytostatic therapy allowed At least 1 month since
prior investigational drugs
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00006001
Intervention Type: Drug
Intervention Name: semaxanib
Title: SU5416 in Treating Patients With Metastatic or Locally Recurrent Colorectal Cancer
Condition: Colorectal Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS:

- Histologically confirmed metastatic or locally recurrent adenocarcinoma of the colon or rectum

- Progressive disease as defined by new or progressive radiologic lesions

- Measurable disease at least 1 dimension as at least 20 mm with conventional techniques or at least 10 mm with spiral CT scan

- Lesions seen on colonoscopic examination or barium studies, bone metastases, CNS lesions, CEA levels and ascites are not considered measurable

- Lesion accessible for biopsy which is not within prior radiation port

- Known history of CNS metastasis allowed if patients have had treatment, are neurologically stable, and do not require oral or intravenous steroids or anticonvulsants, provided brain scan (CT or MRI) shows absence of active or residual disease

- If neurologic signs or symptoms suggestive of CNS metastasis, negative brain scan required

PATIENT CHARACTERISTICS:

- Age: 18 and over

- Performance status: WHO 0-2

- Life expectancy: At least 12 weeks

- WBC at least 3,000/mm3

- Platelet count at least 75,000/mm3

- Bilirubin no greater than 1.5 mg/dL

- Transaminases no greater than 2.5 times upper limit of normal

- Creatinine no greater than 1.5 mg/dL OR creatinine clearance at least 60 mL/min

- No uncompensated coronary artery disease

- No history of myocardial infarction or severe/unstable angina within past 6 months

- No severe peripheral vascular disease associated with diabetes

mellitus

- No deep venous or arterial thrombosis within past 3 months
- No pulmonary embolism within past 3 months
- Not pregnant or nursing
- Negative pregnancy test
- Fertile patients must use effective contraception
- No other significant uncontrolled underlying medical or psychiatric illness
- No serious active infections
- No concurrent second malignancy except for nonmelanoma skin cancer or carcinoma in situ of the cervix unless completed therapy and considered to be at less than 30% risk of relapse
- No history of severe allergic or anaphylactic reactions to paclitaxel or docetaxel

PRIOR CONCURRENT THERAPY:

- No more than 2 prior chemotherapy regimens for metastatic disease
- At least 4 weeks since prior chemotherapy
- No concurrent chemotherapy
- No other concurrent investigational antineoplastic drugs
- No prior radiotherapy to only site of measurable disease
- At least 4 weeks since prior radiotherapy and recovered
- No concurrent radiotherapy
- At least 30 days since other prior investigational drugs

Overall Status: Terminated
Phase: Phase 2

NCTID: NCT00006017
Intervention Type: Drug
Intervention Name: becatecarin
Title: Two Rebeccamycin Analogue Regimens in Treating Patients With Advanced or Recurrent Non-small Cell Lung Cancer
Condition: Lung Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS:

- Histologically proven stage IIIB (with pleural effusions), IV, or recurrent non-small cell lung cancer with failure on 1 prior chemotherapy regimen
- Measurable disease

PATIENT CHARACTERISTICS:

Age:

- Not specified

Performance status:

- 0-2

Life expectancy:

- At least 12 weeks

Hematopoietic:

- WBC at least 3,000/mm^3
- Granulocyte count at least 1,500/mm^3
- Platelet count at least 100,000/mm^3
- Hemoglobin greater than 10 g/dL

Hepatic:

- Bilirubin no greater than 1.5 mg/dL
- AST and ALT less than 2 times normal

Renal:

- Creatinine normal OR
- Creatinine clearance at least 60 mL/min

Cardiovascular:

- No New York Heart Association class III or IV heart disease

Other:

- Not pregnant or nursing
- Negative pregnancy test
- Fertile patients must use effective contraception
- No concurrent illness that would preclude study

PRIOR CONCURRENT THERAPY:

Biologic therapy:

- Not specified

Chemotherapy:

- See Disease Characteristics
- No more than 1 prior chemotherapy regimen
- At least 4 weeks since prior chemotherapy

Endocrine therapy:

- Not specified

Radiotherapy:

- Not specified

Surgery:

- Not specified

Other:

- No concurrent combination antiretroviral therapy for HIV

Overall Status: Completed
Phase: Phase 2

NCTID: NCT00006053
Intervention Type: Drug
Intervention Name: imatinib mesylate
Title: STI571 in Treating Patients With Chronic Myelogenous Leukemia That Has Not Responded to Interferon Alfa
Condition: Leukemia
Eligibility Criteria: DISEASE CHARACTERISTICS: Diagnosis of chronic phase chronic myelogenous leukemia (CML)
Philadelphia (Ph) chromosome positive OR Bcr/Abl positive Refractory to or intolerant of
interferon alfa therapy Failure to achieve complete response for at least 1 month after at
least 6 months of interferon alfa therapy OR At least 65% Ph chromosome positivity in bone
marrow after at least 1 year of interferon alfa therapy OR At least 30% increase in Ph
chromosome positive bone marrow cells in samples taken at least 1 month apart or increase
to at least 65% while receiving interferon alfa therapy OR At least 100% increase in WBC
count to at least 20,000/mm3 in samples taken at least 2 weeks apart while receiving
interferon alfa therapy OR At least grade 3 nonhematologic toxicity persisting for more
than 2 weeks while receiving interferon alfa therapy (must be more than 3 months from time
of diagnosis) No greater than 15% blasts or basophils in peripheral blood or bone marrow
Less than 30% blasts plus promyelocytes in peripheral blood or bone marrow

PATIENT CHARACTERISTICS: Age: 18 and over Performance status: ECOG 0-3 Life expectancy: Not
specified Hematopoietic: Platelet count at least 100,000/mm3 Hepatic: Bilirubin no greater
than 2 times upper limit of normal (ULN) SGOT and SGPT no greater than 2 times ULN Renal:
Creatinine no greater than 2 times ULN Cardiovascular: No New York Heart Association class
III or IV heart disease Other: Not pregnant or nursing Negative pregnancy test Fertile
patients must use effective barrier contraception during and for at least 2 weeks after
study for women and at least 3 months after study for men No history of noncompliance to
prior medical regimens

PRIOR CONCURRENT THERAPY: Biologic therapy: See Disease Characteristics At least 14 days
since prior interferon alfa No other concurrent biologic therapy

Chemotherapy: At least 6
weeks since prior busulfan At least 14 days since prior cytarabine At least 7 days since
prior hydroxyurea No other concurrent chemotherapy Endocrine therapy: Not specified
Radiotherapy: Not specified Surgery: Not specified Other: At least 28 days since prior
investigational agents No other concurrent investigational agents
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00006052
Intervention Type: Drug
Intervention Name: imatinib mesylate
Title: STI571 in Treating Patients With Accelerated Phase Chronic Myelogenous Leukemia
Condition: Leukemia
Eligibility Criteria: DISEASE CHARACTERISTICS: Confirmed diagnosis of chronic myelogenous leukemia in accelerated
phase At least 15% but less than 30% blasts in blood or bone marrow At least 30% blasts
plus promyelocytes in the peripheral blood or bone marrow At least 20% peripheral basophils
Thrombocyte count less than 100,000/mm3 (unrelated to therapy) Patients must have never
been in blastic phase Ph chromosome positive OR Ph chromosome negative and Bcr/Abl positive

PATIENT CHARACTERISTICS: Age: 18 and over Performance status: ECOG 0-3 Life expectancy: Not
specified Hematopoietic: See Disease Characteristics Blood counts recovered from any prior
antileukemic agents Hepatic: Bilirubin no greater than 1.5 times upper limit of normal
(ULN) (no greater than 3 times ULN if liver involvement suspected) AST and ALT no greater
than 3 times ULN (no greater than 5 times ULN if liver involvement suspected) Renal:
Creatinine no greater than 2 times ULN Cardiovascular: No grade 3 or 4 cardiac disease
Other: No serious other concurrent medical condition Not pregnant or nursing Negative
pregnancy test Fertile patients must use effective barrier contraception during and for at
least 2 weeks after study for women and at least 3 months after study for men No history of
noncompliance with medical regimens

PRIOR CONCURRENT THERAPY: Biologic therapy: At least 48 hours since prior interferon alfa
Prior hematopoietic stem cell transplantation allowed if blood counts have recovered No
concurrent biologic therapy Chemotherapy: At least 14 days since prior homoharringtonine At
least 24 hours since prior hydroxyurea At least 7 days since prior low dose cytarabine
(less than 30 mg/m2 every 12-24 hours daily) At least 14 days since prior moderate dose
cytarabine (100-200 mg/m2 for 5-7 days) At least 28 days since prior high dose cytarabine
(1-3 g/m2 every 12-24 hours for 6-12 doses) At least 21 days since prior anthracyclines,
mitoxantrone, etoposide, methotrexate, or cyclophosphamide At least 6 weeks since prior

busulfan No concurrent chemotherapy Endocrine therapy: Not specified Radiotherapy: Not specified Surgery: Not specified Other: At least 28 days since prior other investigational agents No concurrent other investigational agents
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00006044
Intervention Type: Drug
Intervention Name: therapeutic testosterone
Title: Testosterone in Treating Patients With Progressive Prostate Cancer That No Longer Responds to Hormone Therapy
Condition: Prostate Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS:

- Histologically confirmed androgen independent metastatic prostate cancer
- Progressive disease manifested by either:
  - New osseous lesions by bone scan or a greater than 25% increase in bidimensionally measurable soft tissue disease or the appearance of new sites of disease by MRI or CT scan OR
  - Minimum of 3 rising PSA values from baseline that are obtained 1 week or more apart, or 2 rising PSA values more than 1 month apart, where the percentage increase over the range of values is at least 25%
- Castrate state by orchiectomy or gonadotropin-releasing hormone analogues for minimum of 1 year
  - Testosterone no greater than 30 ng/mL
- Measurable disease
- Metastatic disease by bone scan, MRI, or CT scan
- Rising PSA values
- If receiving antiandrogen therapy, must have shown progressive disease off treatment
- No active CNS or epidural tumor

PATIENT CHARACTERISTICS:

Age:

- 18 and over

Performance status:

- Karnofsky 60-100%

Life expectancy:

- Not specified

Hematopoietic:

- WBC at least 3,500/mm^3
- Platelet count greater than 100,000/mm^3

Hepatic:

- Bilirubin less than 2.0 mg/dL
- SGOT less than 3 times upper limit of normal
- PTT less than 14 seconds

Renal:

- Creatinine less than 2.0 mg/dL OR
- Creatinine clearance greater than 60 mL/min

Cardiovascular:

- No New York Heart Association class III or IV cardiac disease

Pulmonary:

- No severe debilitating pulmonary disease

Other:

- No infection requiring IV antibiotics
- No other severe medical problems that would increase risk for toxicity

PRIOR CONCURRENT THERAPY:

Biologic therapy:

- Recovered from prior biologic therapy
- No concurrent immunotherapy

Chemotherapy:

- Recovered from prior chemotherapy
- No concurrent chemotherapy

Endocrine therapy:

- See Disease Characteristics
- If no prior orchiectomy, must continue on gonadotropin-releasing hormone analogs to maintain castrate levels of testosterone
- No concurrent finasteride
- No other concurrent hormonal therapy

Radiotherapy:

- Recovered from prior radiotherapy

- No concurrent radiotherapy to an indicator lesion

Surgery:

- See Disease Characteristics

- Recovered from prior surgery

- No concurrent surgery on only measurable lesion

Other:

- At least 4 weeks since other prior investigational anticancer drugs and recovered

- No other concurrent investigational anticancer agents
Overall Status: Completed
Phase: Phase 1

NCTID: NCT00006075
Intervention Type: Drug
Intervention Name: Chlorhexidine gluconate
Title: A Study of Chlorhexidine in the Prevention of HIV-1 Transmission From Mothers to Their Babies
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Mothers may be eligible for this study if they:

- Receive HIV testing and counseling (both HIV-positive and HIV-negative women will be
  enrolled).

- Are at least 36 weeks pregnant.

- Are receiving routine prenatal care at the Chris Hani Baragwanath Hospital maternity
  unit in Soweto, South Africa.

Exclusion Criteria

Mothers will not be eligible if they:

- Have severe complications during the pregnancy, such as bleeding before birth.

- Have a C-section by choice.

- Have obvious genital sores at the time of labor.

- Have a baby that is positioned a certain way during delivery.

- Receive prostaglandin tablets, in the vagina, during labor.

- Have major medical conditions, such as TB or diabetes (except HIV, in HIV-positive
  women).
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00006082
Intervention Type: Drug
Intervention Name: rubitecan

Title: Nitrocamptothecin in Treating Patients With Advanced Small Cell Lung Cancer
Condition: Lung Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS:

- Histologically proven advanced (extensive stage) small cell lung cancer with progressive or recurrent disease after 1 first line chemotherapy regimen
  - Sensitive disease, defined as a response to prior chemotherapy lasting at least 3 months from the end of all prior treatment, including radiotherapy, until the time of progression OR
  - Refractory disease, defined as no response to prior chemotherapy, or a response to prior chemotherapy followed by progression within 3 months after completion of all prior therapy, including radiotherapy
- Minimum of 1 target lesion that can be accurately measured in at least 1 dimension
  - 20 mm or more with conventional techniques OR
  - 10 mm or more with spiral CT scans
- No symptomatic brain metastases

PATIENT CHARACTERISTICS:

Age:

- 18 and over

Performance status:

- ECOG 0-2

Life expectancy:

- At least 3 months

Hematopoietic:

- Neutrophil count at least 2,000/mm^3
- Platelet count at least 100,000/mm^3

Hepatic:

- Bilirubin less than 1.5 times upper limit of normal (ULN)
- Alkaline phosphatase, SGOT, and SGPT no greater than 2.5 time ULN (no greater than 5 times ULN if hepatic metastases present)

Renal:

- Creatinine no greater than 1.7 mg/dL

Cardiovascular:

- No ischemic heart disease within the past 6 months

- Normal 12 lead electrocardiogram

Other:

- Not pregnant or nursing

- Fertile patients must use effective contraception

- No other prior or concurrent malignancy except cone biopsied carcinoma of the cervix
  or adequately treated basal cell or squamous cell skin cancer

- No unstable systemic disease or active uncontrolled infection

- No psychological, familial, sociological, or geographical condition that may preclude
  compliance

PRIOR CONCURRENT THERAPY:

Biologic therapy:

- Prior maintenance therapy with biologic agents following first line chemotherapy
  allowed

- No concurrent filgrastim (G-CSF) with nitrocamptothecin

Chemotherapy:

- See Disease Characteristics

- Greater than 4 weeks since prior chemotherapy

- No more than 1 prior chemotherapy regimen for extensive disease

- Alternate or sequential use of different regimens without interruption in first line
  treatment is considered 1 first line therapy

Endocrine therapy:

- Not specified

Radiotherapy:

- See Disease Characteristics

- Greater than 4 weeks since prior radiotherapy

Surgery:

- Greater than 2 weeks since prior major surgery

Other:

- No other concurrent anticancer therapy

- No other concurrent investigational therapy

Overall Status: Completed
Phase: Phase 2

NCTID: NCT00006097
Intervention Type: Drug
Intervention Name: CC-1088
Title: Chemotherapy in Treating Patients With Chronic Lymphocytic Leukemia
Condition: Leukemia
Eligibility Criteria: DISEASE CHARACTERISTICS: Histologically or cytologically confirmed refractory, progressive,
B-cell chronic lymphocytic leukemia Failed prior first line therapy of chlorambucil or
fludarabine (or their equivalent) Progressive disease as defined by at least one of the
following: Greater than 50% increase in the sum of the products of at least 2 lymph nodes
on two consecutive determinations 2 weeks apart (at least one lymph node must be greater
than 2 cm) Appearance of new palpable lymph nodes At least a 50% increase in size of
previously palpable liver or spleen Appearance of palpable hepatomegaly or splenomegaly not
previously present At least a 50% increase in the absolute lymphocyte count to at least
5,000/mm3 Transformation to an aggressive histology (e.g., Richter's or prolymphocytic
leukemia) High risk OR Intermediate risk with active disease, as defined by the following:
Greater than 10% weight loss Extreme fatigue Fevers greater than 100.5 Fahrenheit for
greater than 2 weeks without infection Night sweats Splenomegaly greater than 6 cm
Lymphadenopathy greater than 10 cm Lymphocytosis with a doubling time less than 6 months

PATIENT CHARACTERISTICS: Age: 18 and over Performance status: ECOG or Zubrod 0-2 Life
expectancy: Not specified Hematopoietic: See Disease Characteristics Hepatic: Bilirubin no
greater than 2.5 times upper limit of normal (ULN) ALT and AST no greater than 2.5 times
ULN Renal: Creatinine no greater than 2.0 mg/dL Other: Not pregnant Negative pregnancy test
Fertile patients must use effective contraception during and for 2 weeks after study

PRIOR CONCURRENT THERAPY: Biologic therapy: Not specified Chemotherapy: See Disease
Characteristics Endocrine therapy: Not specified Radiotherapy: Not specified Surgery: Not
specified
Overall Status: Completed
Phase: Phase 1/Phase 2

NCTID: NCT00006090
Intervention Type: Drug
Intervention Name: arsenic trioxide
Title: Arsenic Trioxide in Treating Patients With Refractory or Relapsed Chronic Lymphocytic Leukemia
Condition: Leukemia
Eligibility Criteria: DISEASE CHARACTERISTICS: Relapsed or refractory chronic lymphocytic leukemia (CLL)
Previously treated with alkylating agent Refractory or intolerant to fludarabine as defined
by: Progressive disease during treatment with fludarabine Stable disease (no partial or

complete response) after at least 2 courses of fludarabine Relapse or progressive disease within 6 months of treatment with fludarabine Autoimmune hemolytic anemia or idiopathic thrombocytopenia concurrent with or within 1 month after completion of fludarabine Grade 2 pulmonary toxicity or neurotoxicity that would preclude further treatment with fludarabine OR Progressive B-cell CLL as defined by at least 1 of the following: Hemoglobin less than 11 g/dL, or progressive decline Platelet count no greater than 100,000/mm3, or progressive decline Massive (greater than 6 cm below costal margin) or progressive splenomegaly Massive lymph nodes or clusters or progressive lymphadenopathy At least 10% weight loss in past 6 months Fatigue grade 2-3 Fever (greater than 100.5 F) or night sweats for greater than 2 weeks without evidence of infection Progressive lymphocytosis greater than 50% over 2 month period, or anticipated doubling time less than 6 months Lymphocyte count greater than 100,000/mm3 No uncontrolled autoimmune hemolytic anemia or idiopathic thrombocytopenia No other uncontrolled immune phenomena related to CLL No CNS metastases

PATIENT CHARACTERISTICS: Age: 12 and over Performance status: Zubrod 0-2 Life expectancy: At least 2 years Hematopoietic: See Disease Characteristics Hepatic: Bilirubin no greater than 1.5 times upper limit of normal (ULN) (unless due to Gilbert's disease or direct CLL infiltration of liver) SGOT or SGPT no greater than 2.5 times ULN (unless due to direct CLL infiltration of liver) No hepatic disease that would preclude study Renal: Creatinine no greater than 1.5 times ULN OR Creatinine clearance at least 60 mL/min Cardiovascular: No unstable angina pectoris No cardiac arrhythmia No prior grade III or IV New York Heart Association cardiac problem No cardiovascular disease that would preclude study Other: No prior grand mal seizures (infantile febrile seizures allowed) No other active malignancy No other uncontrolled concurrent medical problem No active uncontrolled infection No prior hypersensitivity to arsenic trioxide or related drugs No neurologic, endocrine, or other systemic disease that would preclude study No other condition that would preclude study compliance Not pregnant or nursing Negative pregnancy test Fertile patients must use effective contraception

PRIOR CONCURRENT THERAPY: Biologic therapy: No concurrent stem cell transplant Chemotherapy: See Disease Characteristics At least 14 days since prior chemotherapy and recovered (unless evidence of disease progression) No concurrent chemotherapy No prior arsenic treatment Endocrine therapy: No concurrent steroidal or hormonal therapy for cancer Steroids for adrenal failures and hormones for nondisease conditions allowed Radiotherapy:

At least 14 days since prior radiotherapy and recovered (unless evidence of disease
progression) No concurrent radiotherapy Other: At least 14 days since other investigational
agents and recovered (unless evidence of disease progression) No concurrent other
investigational agents
Overall Status: Withdrawn
Phase: Phase 2

NCTID: NCT00006091
Intervention Type: Drug
Intervention Name: arsenic trioxide
Title: Arsenic Trioxide in Treating Patients With Chronic Phase Chronic Myelogenous Leukemia That Has Not Responded to Previous Treatment
Condition: Leukemia
Eligibility Criteria: DISEASE CHARACTERISTICS:

- Diagnosis of Philadelphia (Ph) chromosome positive (or breakpoint cluster region bcr
positive) chronic myelogenous leukemia in chronic phase

- Ineligible for or refused allogeneic bone marrow transplantation

- Interferon alfa refractory or intolerant as defined by the following:

- Refractory: Failure to achieve a complete hematologic response lasting for at least 1
month after prior therapy with interferon alfa based regimen for at least 3 months 65%
or more Ph positive chromosomes in bone marrow after one year of interferon alfa based
therapy

- At least a 30% increase in Ph positive chromosomes in bone marrow in samples taken at
least one month apart OR

- An increase of at least 65% in Ph positive chromosomes in bone marrow

- Intolerant: Grade 3 or greater nonhematologic toxicity Autoimmune phenomenon at any
grade

- No accelerated phase or blastic phase disease as defined by the following:

- Greater than 15% blasts or basophils in the peripheral blood or bone marrow

- Greater than 30% blasts plus promyelocytes in the peripheral blood or bone marrow

- Documented extramedullary blastic disease outside liver or spleen

- Platelet count less than 100,000/mm3 unrelated to therapy

- Clonal evolution (additional chromosomal abnormalities other than Ph chromosome) as
solitary feature is not considered accelerated disease

- No known brain metastases or central nervous system (CNS) disease

PATIENT CHARACTERISTICS:

- Age: 12 and over
- Performance status: Zubrod 0-2
- Life expectancy: At least 2 years
- Hematopoietic: See Disease Characteristics
- Hepatic: Unless due to direct disease infiltration of the liver:
- ALT and AST no greater than 2.5 times upper limit of normal (ULN)
- Bilirubin no greater than 1.5 times ULN (unless due to Gilbert's disease)
- No hepatic disease that would preclude study
- Renal: Creatinine no greater than 1.5 times ULN Creatinine clearance at least 60 mL/min
- Cardiovascular: No history of New York Heart Association grade III or IV cardiac disease
- No cardiovascular disease that would preclude study
- No unstable angina pectoris or cardiac arrhythmia that would shorten life expectancy
- Other: No history of grand mal seizures other than infantile febrile seizures
- No active secondary malignancy or other uncontrolled concurrent medical problem that would shorten life expectancy
- No neurologic, endocrine, or other major systemic disease that would preclude study
- No active infection uncontrolled by oral or IV antibiotics
- No history of hypersensitivity to the study drug or drugs with similar chemical structure
- No mental condition that would preclude study Not pregnant or nursing
- Negative pregnancy test
- Fertile patients must use effective contraception

PRIOR CONCURRENT THERAPY:

- Biologic therapy: See Disease Characteristics
- No concurrent bone marrow or peripheral blood stem cell transplantation
- Chemotherapy: At least 14 days since prior chemotherapy (48 hours

for hydroxyurea and
6 weeks for busulfan) and recovered (unless evidence of rapidly progressive disease)

- No other concurrent cytotoxic chemotherapy

- No prior arsenic trioxide

- Endocrine therapy: No concurrent steroids for the treatment of neoplasms (except for
new adrenal failures)

- No concurrent hormones for the treatment of neoplasms (except for nondisease related
conditions)

- Radiotherapy: At least 14 days since prior radiotherapy

- No concurrent radiotherapy

- Surgery: Not specified

- Other: At least 14 days since other prior investigational agent

- No other concurrent investigational or antileukemic agents
Overall Status: Withdrawn
Phase: Phase 2

NCTID: NCT00006121
Intervention Type: Drug
Intervention Name: oxaliplatin
Title: Oxaliplatin in Treating Women With Advanced or Metastatic Breast Cancer That Has Not Responded to Previous Chemotherapy
Condition: Breast Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS:

- Histologically confirmed advanced or metastatic breast cancer

- Bidimensionally measurable disease

  - At least one lesion at least 2 cm in one dimension by CT scan or MRI

- Must have failed prior anthracycline/taxane based chemotherapy as defined by one of
the following:

  - Stage IV disease treated with anthracycline/taxane combination as first line
therapy for advanced or metastatic disease

  - Stage IV disease treated with first line anthracycline therapy and second line
taxane therapy for advanced or metastatic disease

  - Any adjuvant treatment other than anthracycline based therapy followed by
anthracycline/taxane combination as first line therapy for advanced or metastatic
disease

  - Any adjuvant therapy other than anthracycline based therapy followed by first
line anthracycline based therapy and second line taxane based

therapy for
advanced or metastatic disease

- Adjuvant anthracycline based therapy followed by relapse after 6 months treated
with anthracycline/taxane combination as first line therapy or first line
anthracycline based therapy and second line taxane based therapy for advanced or
metastatic disease

- Adjuvant anthracycline based therapy followed by relapse within 6 months treated
with first line taxane based therapy for advanced or metastatic disease

- Disease progression within 6 months of last taxane based chemotherapy

- No brain metastases

- Hormonal receptor status:

- Not specified

PATIENT CHARACTERISTICS:

Age:

- 18 and over

Sex:

- Female

Menopausal status:

- Not specified

Performance status:

- WHO 0-2

Life expectancy:

- At least 3 months

Hematopoietic:

- Absolute neutrophil count greater than 2,000/mm^3

- Platelet count greater than 100,000/mm^3

Hepatic:

- Bilirubin less than 1.5 times upper limit of normal (ULN)

- Alkaline phosphatase and transaminases no greater than 2.5 times ULN (no greater than
5 times ULN in case of liver metastases)

Renal:

- Creatinine less than 1.25 times ULN

Cardiovascular:

- LVEF at least 50% if prior total dose of doxorubicin 550 mg/m2 or greater, epirubicin 900 mg/m2 or greater, or pirarubicin 700 mg/m2 or greater
- No prior or active congestive heart failure, myocardial infarction, or angina
- No uncontrolled hypertension or arrhythmia

Other:

- No unstable systemic disease
- No active infection
- No grade 2 or greater peripheral neuropathy
- No psychological, familial, sociological, or geographical condition that would preclude study

PRIOR CONCURRENT THERAPY:

Biologic therapy:

- No prior high dose chemotherapy with hematopoietic rescue
- No concurrent immunotherapy
- No concurrent filgrastim (G-CSF) or sargramostim (GM-CSF) for prevention of neutropenia

Chemotherapy:

- See Disease Characteristics
- At least 4 weeks since prior chemotherapy
- At least 1 prior taxane based chemotherapy for advanced or metastatic disease
- No prior high dose chemotherapy with hematopoietic rescue
- No prior platinum based chemotherapy
- No prior taxane chemotherapy other than docetaxel or paclitaxel
- No prior adjuvant or neoadjuvant therapy with taxane/anthracycline based combination chemotherapy

Endocrine therapy:

- No concurrent steroids except in case of allergy prevention, emesis prophylaxis, or long term treatment for more than 3 months prior to study
- No concurrent hormonal anticancer therapy

Radiotherapy:

- No prior radiotherapy to study site unless evidence of disease progression

- Concurrent local radiotherapy allowed for pain relief

Surgery:

- At least 4 weeks since prior major surgery

Other:

- At least 4 weeks since prior anticancer and/or investigational drug

- No concurrent bisphosphonates unless started at least 2 months prior to study

- No other concurrent anticancer therapy

- No other concurrent experimental drugs

Overall Status: Terminated
Phase: Phase 2

NCTID: NCT00006092
Intervention Type: Drug
Intervention Name: Arsenic Trioxide
Title: Arsenic Trioxide for Induction Therapy of Adult Patients With Leukemia
Condition: Leukemia
Eligibility Criteria: DISEASE CHARACTERISTICS:

- Diagnosis of one of the following:

  - Acute lymphoblastic leukemia

    - Philadelphia chromosome (Bcr-abl) positive

    - Refractory to initial therapy OR recurrent following 1 induction therapy regimen with or without consolidation therapy and/or bone marrow transplantation

  - Blastic phase chronic myelogenous leukemia

    - Philadelphia chromosome (Bcr-abl) positive

    - Previously untreated OR recurrent or refractory following 1 induction therapy regimen with or without consolidation therapy including imatinib mesylate

- Must not be eligible for bone marrow transplant

PATIENT CHARACTERISTICS:

Age:

- 18 and over

Performance status:

- Eastern Cooperative Oncology Group (ECOG) 0-2

Life expectancy:

- At least 8 weeks

Hematopoietic:

- Not specified

Hepatic:

- Bilirubin no greater than 2.0 times upper limit of normal (ULN)
- AST/ALT no greater than 2 times ULN

Renal:

- Creatinine no greater than 2.0 times ULN
- Creatinine clearance greater than 70 mL/min

Cardiovascular:

- No uncontrolled angina
- No New York Heart Association class III or IV heart disease
- No second degree heart block without pacemaker

Other:

- Not pregnant or nursing
- Negative pregnancy test
- Fertile patients must use effective contraception during and for 6 months after study
- HIV negative
- No uncontrolled infection or other serious concurrent illness
- No peripheral neuropathy
- No potassium less than 3.0 or greater than 5.5 mEq/L that can not be corrected OR
- No magnesium less than 1.2 or greater than 2.5 mEq/L that can not be corrected
- Electrolyte imbalances must be corrected prior to study entry

PRIOR CONCURRENT THERAPY:

Biologic therapy:

- See Disease Characteristics

Chemotherapy:

- See Disease Characteristics
- At least 28 days since prior chemotherapy
- At least 24 hours since prior hydroxyurea

- No prior arsenic trioxide

- No other concurrent cytotoxic chemotherapy except intrathecal chemotherapy for CNS leukemia

Endocrine therapy:

- Not specified

Radiotherapy:

- At least 28 days since prior radiotherapy

- No concurrent radiotherapy including for palliation

Surgery:

- Not specified

Other:

- At least 14 days since prior imatinib mesylate

- No other concurrent investigational agents

- No concurrent amphotericin B

Overall Status: Terminated
Phase: Phase 2

NCTID: NCT00006143
Intervention Type: Drug
Intervention Name: Somatropin
Title: Growth Hormone Treatment of Children With HIV-Associated Growth Failure
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Children may be eligible for this study if they:

- Are 4 to 12 years of age for girls, and 4 to 13 years of age for boys (consent of parent/guardian is required).

- Are HIV-positive.

- Are not growing normally.

- Have a normal intake of food each day.

- Are able to walk.

- Have been on stable anti-HIV therapy for at least 24 weeks before study entry and will continue therapy for the entire duration of the study with no anticipated change in therapy for the first 48 weeks of the study. (These therapy requirements reflect a change.)

- Are willing and able to follow study requirements.

Exclusion Criteria

Children may not be eligible for this study if they:

- Had steady fever of 101 degrees F or higher during the 2 weeks before study entry.

- Have a serious infection requiring medications within 30 days prior to study entry.

- Are being fed through a vein.

- Have severe diarrhea, intestinal bleeding or blockage, or are unable to absorb food.

- Have cancer.

- Have taken medications that may interfere with the study drug or have had radiation.

- Have diabetes or a history of sugar intolerance.

- Have carpal tunnel syndrome (unless it has been surgically repaired).

- Have heart or kidney problems, or serious swelling of any kind.

- Have any condition other than HIV infections that may have affected growth or that
  makes it difficult to measure height.

- Have any known allergies to the study drug.

Overall Status: Completed
Phase: nan

NCTID: NCT00006203
Intervention Type: Drug
Intervention Name: naltrexone (Revia)
Title: Naltrexone, Craving, and Drinking
Condition: Alcoholism
Eligibility Criteria: Inclusion Criteria:

- Drink at least 4 days per week with 2 heavy drinking days (more than 6 standard drinks
  for men, more than 5 drinks for women) per week on average during the month prior to
  the study.

Exclusion Criteria:

- Current interest in treatment or a history of treatment for alcohol problems.

- History of liver disease or current liver function tests greater than five times
  normal.

- Opiate abuse or dependence, any opiate use two weeks before the study or a urine test
  screen that is positive for opiates.

- Females, who are pregnant, nursing, or not using reliable birth control method.

- Daily use of acetaminophen.

- Living with someone who participated in this study.

Overall Status: Completed
Phase: Phase 4

NCTID: NCT00006224
Intervention Type: Drug
Intervention Name: gemcitabine hydrochloride
Title: Gemcitabine in Treating Patients With Persistent or Recurrent Cancer of the Cervix
Condition: Cervical Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS:

- Diagnosis of persistent or recurrent nonsquamous cell carcinoma of the cervix that has failed local therapeutic measures and is considered incurable
  - Eligible subtypes:
    - Adenocarcinoma
    - Adenosquamous carcinoma
    - Undifferentiated carcinoma
  - Must have documented disease progression
  - Histologic confirmation of original primary tumor required
- Bidimensionally measurable disease
- Ineligible for higher priority GOG protocol

PATIENT CHARACTERISTICS:

Age:

- 18 and over

Performance status:

- GOG 0-2

Life expectancy:

- Not specified

Hematopoietic:

- Platelet count at least 100,000/mm^3
- Granulocyte count at least 1,500/mm^3

Hepatic:

- Bilirubin no greater than 1.5 times normal
- SGOT and alkaline phosphatase no greater than 3 times normal

Renal:

- Creatinine no greater than 1.5 mg/dL

Other:

- No significant infection

- Not pregnant

- Fertile patients must use effective contraception

- No other invasive malignancy within the past 5 years except nonmelanomatous skin cancer

PRIOR CONCURRENT THERAPY:

Biologic therapy:

- No concurrent filgrastim (G-CSF)

Chemotherapy:

- No prior gemcitabine

- At least 3 weeks since other prior chemotherapy for cervical cancer and recovered

- No more than 1 prior chemotherapy regimen (single or combination cytotoxic therapy)

Endocrine therapy:

- Not specified

Radiotherapy:

- At least 3 weeks since prior radiotherapy for cervical cancer and recovered

Surgery:

- At least 3 weeks since prior surgery for cervical cancer and recovered

Other:

- No prior cancer treatment that would preclude study

Overall Status: Terminated
Phase: Phase 2

NCTID: NCT00006207
Intervention Type: Drug
Intervention Name: PRO 2000
Title: Safety and Tolerability of the Vaginal Gel PRO 2000/5
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Volunteers may be eligible for this study if they:

- Are female and 18-45 years of age.

- Are willing and able to complete daily study records.

- Are willing to undergo clinical exams and testing.

- Either have regular menstrual periods or do not menstruate due to use of hormones.

- Agree to stop using female barrier methods of birth control during the study.

- Additionally, volunteers may be eligible for HIV-negative groups in this study if they:

- Have not changed their use of hormonal birth control over the last 3 months.

- Are HIV-negative.

- Have a single male partner at low-risk for HIV infection and agree that he can be asked for his consent.

- Agree to the following: To have vaginal intercourse 2 or more times a week; to use condoms provided by the study for each act of intercourse; to use the gel as directed; not to be in similar studies; not to receive oral sex; not to use IV drugs, except for medical treatment; not to use any other vaginal products; not to douche; and not to use vaginal drying agents.

- Additionally, volunteers may be eligible for the HIV-positive group in this study if they:

- Are HIV-positive.

- Have a CD4 count greater than 200 cells/mm3.

- Have a normal Pap smear at screening.

- Are on stable anti-HIV drug therapy.

- Agree to have no sexual intercourse during the study.

- Have HIV care by qualified medical caregivers.

- Agree to allow study staff access to their HIV medical care information.

- Agree to the following: To use the gel as directed; not to use IV drugs other than for medical treatment; not to use any other vaginal products; not to participate in similar studies; not to receive oral sex; not to douche; and not to use any vaginal drying agents.

Exclusion Criteria

Volunteers will not be eligible for this study if they:

- Are menopausal.

- Have certain liver, kidney, or blood problems.

- Have genital problems such as sores.

- Are allergic to anything used in the study, including latex.

- Have used spermicides or condoms treated with spermicides within the week before enrollment.

- Have been in another drug study within the past 30 days.

- Have participated in this trial before and study gel has been permanently discontinued.

- Have had an IUD or begun using hormonal birth control, or had an abnormal Pap smear, a pregnancy, an abortion, gynecologic surgery, breakthrough menstrual bleeding, or vaginal bleeding during or following sexual intercourse, in the last 3 months.

- Have had or received treatment for sexually transmitted diseases in the past 3 months.

- Show signs, on a pelvic exam, indicating a sexually transmitted disease or other genital tract problems.

- Used IV drugs, except for medical reasons, within the past year.

- Received antibiotics in the last 14 days.

- Have had a reaction to an anticoagulant (such as warfarin or heparin).

- Are pregnant or breast-feeding.

- Have a positive urine culture.

Overall Status: Completed
Phase: Phase 1

NCTID: NCT00006209
Intervention Type: Drug
Intervention Name: Tucaresol
Title: A Study of Tucaresol in HIV-Infected Patients Who Are Taking Other Anti-HIV Drugs
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Patients may be eligible for this study if they:

- Are at least 18 years old.

- Are HIV-positive.

- Have more than 300 CD4 T cells/microL at screening.

- Are taking certain anti-HIV drugs.

- Have been taking these anti-HIV drugs successfully for at least 6 months.

- Do not expect to change their anti-HIV therapy while they are in the study.

- Have had plasma viral load less than 50 copies/ml while on their anti-HIV therapy.

- Have viral load that cannot be detected at screening and baseline tests.

- Are able to complete weekly visits.

Exclusion Criteria

Patients will not be eligible for this study if they:

- Cannot give informed consent.

- Have abnormal laboratory test results at baseline.

- Are pregnant or breast-feeding.

- Have had certain short-term or long-term illnesses (such as heart disease, sickle cell
  disease, anemia, or lung problems).

- Have received a vaccination within the 30 days prior to enrollment.

- Have received any other experimental drug within 60 days of enrollment.

- Are taking abacavir (Ziagen, GW1592) or drugs that affect the immune system, such as
  IL-2, GM-CSF, corticosteroids, or cyclosporine.

- Have a history of tumors.

- Are actively using illegal drugs (methadone is allowed).

- Have hepatitis B or hepatitis C.

Overall Status: Unknown status
Phase: Phase 1

NCTID: NCT00006230
Intervention Type: Drug
Intervention Name: rubitecan
Title: Nitrocamptothecin in Treating Patients With Advanced Ovarian Cancer
Condition: Ovarian Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS:

- Histologically proven metastatic or unresectable locally advanced progressive ovarian
  cancer that has failed first line platinum and taxane based regimen

  - Refractory disease defined by a relapse within 1 year after completion of first
    line therapy

  - Sensitive disease defined by a relapse greater than 1 year after completion of
    first line therapy

- Minimum of 1 target lesion that can be accurately measured in at least 1 dimension

  - At least 20 mm by conventional techniques OR

  - At least 10 mm by spiral CT scan

- No symptomatic brain metastases

PATIENT CHARACTERISTICS:

Age:

- 18 and over

Performance status:

- ECOG 0-2

Life expectancy:

- At least 3 months

Hematopoietic:

- Neutrophil count at least 2,000/mm^3
- Platelet count at least 100,000/mm^3

Hepatic:

- Bilirubin less than 1.5 times upper limit of normal (ULN)
- Alkaline phosphatase, SGOT, and SGPT no greater than 2.5 times ULN (no greater than 5 times ULN if hepatic metastases present)

Renal:

- Creatinine no greater than 1.7 mg/dL

Cardiovascular:

- No ischemic heart disease within the past 6 months
- Normal 12 lead electrocardiogram

Other:

- Not pregnant or nursing
- Fertile patients must use effective contraception
- No unstable systemic disease or active uncontrolled infections
- No other prior or concurrent malignancy except adequately treated basal cell or squamous cell skin cancer or cone biopsied carcinoma of the cervix
- No psychological, familial, sociological, or geographical condition that would preclude compliance

PRIOR CONCURRENT THERAPY:

Biologic therapy:

- No concurrent filgrastim (G-CSF) with nitrocamptothecin

Chemotherapy:

- See Disease Characteristics

- Greater than 4 weeks since prior chemotherapy

Endocrine therapy:

- Not specified

Radiotherapy:

- Greater than 4 weeks since prior radiotherapy

Surgery:

- Greater than 2 weeks since prior major surgery

Other:

- No other concurrent anticancer agents

- No other concurrent investigational therapy

Overall Status: Completed
Phase: Phase 2

NCTID: NCT00006262
Intervention Type: Drug
Intervention Name: becatecarin
Title: Rebeccamycin Analogue in Treating Patients With Refractory Stage III or Stage IV Ovarian Epithelial Cancer
Condition: Ovarian Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS: Histologically or cytologically confirmed stage III or IV ovarian
epithelial cancer Platinum resistant disease as defined by disease progression during or
within 6 months of receiving prior paclitaxel combined with cisplatin or carboplatin No
elevated CA-125 as only evidence of disease recurrence Measurable disease At least 20 mm in
diameter by conventional techniques OR At least 10 mm in diameter by spiral CT scan No
known brain metastases

PATIENT CHARACTERISTICS: Age: 21 and over Performance status: ECOG 0-2 Life expectancy:
Greater than 3 months Hematopoietic: WBC at least 3,000/mm3 Absolute neutrophil count at
least 1,500/mm3 Platelet count at least 100,000/mm3 Hepatic: Bilirubin normal AST and ALT
no greater than 2.5 times upper limit of normal Renal: Creatinine normal OR Creatinine
clearance greater than 60 mL/min Other: No history of allergic reactions to compounds of
similar chemical or biologic composition to rebeccamycin analogue No other prior cancer
within the past 5 years except nonmelanomatous skin cancer No other medical problems that
would preclude study Not pregnant or nursing Negative pregnancy test Fertile patients must
use effective contraception

PRIOR CONCURRENT THERAPY: Biologic therapy: Not specified Chemotherapy: See Disease
Characteristics At least 4 weeks since prior chemotherapy Endocrine therapy: Not specified
Radiotherapy: Not specified Surgery: Not specified Other: No other

concurrent therapeutic
agents for cancer
Overall Status: Terminated
Phase: Phase 2

NCTID: NCT00006279
Intervention Type: Drug
Intervention Name: Nevirapine
Title: The Safety of Nevirapine When Given to Breast-Feeding Babies From Birth to Age 6 Months
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Mothers may be eligible for this study if they:

- Receive prenatal care at King Edward VIII Hospital, Durban, or St. Mary's Hospital, Marianhill, South Africa; or polyclinics in Chitungwiza District, Zimbabwe.

- Are pregnant for at least 30 weeks before giving birth.

- Are at least 18 years of age.

- Are HIV-positive by 2 ELISA tests.

- Have no serious current or previous problems in pregnancy (e.g., seizures).

- Have a fixed home and/or work address.

- Plan to deliver the baby at a hospital or clinic where the study is based.

- Plan to breast-feed their babies.

- Infants may be eligible for this study if they:

- Are born to women participating in this study.

- Weigh at least 2.5 kg at birth.

- Begin breast-feeding by 48 hours.

Exclusion Criteria

Mothers will not be eligible for this study if they:

- Have AIDS or any other serious illness.

- Are using illegal drugs or have been using alcohol for a long time.

- Are sensitive to NVP.

- Have taken any nonnucleoside reverse transcriptase inhibitors in the past.

- Are using rifampin, rifabutin, ketoconazole, macrolides, or cimetidine.

- Infants will not be eligible for this study if they:

- Have jaundice (yellowing of the skin and whites of eyes) that requires a blood

transfusion.

- Have any serious or life-threatening condition(s).

Overall Status: Completed
Phase: Phase 1

NCTID: NCT00006325
Intervention Type: Drug
Intervention Name: Peginterferon alfa-2b
Title: Safety, Tolerability, and Anti-HIV Activity of PEG-Intron in HIV-Positive Children
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Patients may be eligible for this study if they:

- Are HIV-infected infants and children aged 3 months to 16 years.

- Have been on stable anti-HIV drugs for at least 16 weeks if over 6 months of age.
  Infants aged 3 to 6 months must be on stable anti-HIV drugs for at least 6 weeks.
  Children should be receiving at least 3 anti-HIV drugs.

- Have a viral load of more than 5,000 copies/ml.

- Have written informed consent from parent or guardian and, if able, can give written
  consent themselves.

- Are able to follow the schedule in the protocol.

- Have a parent/guardian who is willing to comply with study requirements.

- (This study has been changed to allow any combination of 3 anti-HIV drugs and to
  remove CD4 requirements.)

Exclusion Criteria

Patients will not be eligible for this study if they:

- Are breast-feeding or pregnant or not using birth control, if a female.

- Have abnormal thyroid activity.

- Have severe HIV symptoms.

- Have opportunistic (AIDS-related) infections or history of such infections within the
  preceding 2 months.

- Have participated in a clinical trial of an experimental drug in the previous month.

- Have a positive test result for hepatitis B or C.

- Have an allergy to E. coli.

- Have a mental disorder.

- Have a history of drug dependence and measure positive when

screened.
Overall Status: Completed
Phase: Phase 1

NCTID: NCT00006369
Intervention Type: Drug
Intervention Name: ERA-923
Title: ERA-923 in Treating Postmenopausal Women With Metastatic Breast Cancer
Condition: Breast Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS: Diagnosis of metastatic breast cancer Prior tamoxifen therapy
failure within 1 year of study defined as follows: Prior tamoxifen therapy for metastatic
disease with prior response and progression of disease while still on treatment or within 1
year of last treatment Prior adjuvant tamoxifen therapy for a minimum of 2 years with
subsequent progression of disease while still on treatment or within 1 year of last
treatment Postmenopausal Must be amenorrheic for at least 12 months Removal of both ovaries
or chemotherapy induced menopause allowed At least 1 bideminsionally measurable lesion No
disease restricted only to bone No symptomatic CNS metastases untreated by surgery or
radiotherapy Hormone receptor status: Estrogen or progesterone receptor positive

PATIENT CHARACTERISTICS: Age: Not specified Menopausal status: Postmenopausal Performance
status: ECOG 0-2 Life expectancy: At least 6 months Hematopoietic: Absolute neutrophil
count at least 1,500/mm3 Platelet count at least 100,000/mm3 Hemoglobin greater than 9.0
g/dL Hepatic: Bilirubin no greater than 1.5 times upper limit of normal (ULN) AST no
greater than 3 times ULN (no greater than 5 times ULN if liver metastases present) PT and
PTT no greater than 1.25 times ULN Renal: Creatinine no greater than 1.5 times ULN
Cardiovascular: No deep vein thrombosis, retinal vein thrombosis, or stroke within past
year No unstable angina or myocardial infarction within past 6 months Pulmonary: No
pulmonary embolism within past year Other: Not pregnant or nursing No other major illness
or condition that would preclude study

PRIOR CONCURRENT THERAPY: Biologic therapy: No concurrent trastuzumab (Herceptin)
Chemotherapy: No more than 2 prior chemotherapy regimens, including trastuzumab One regimen
in adjuvant setting and one in metastatic setting OR Two regimens in metastatic setting No
concurrent chemotherapy Endocrine therapy: See Disease Characteristics At least 6 months
since prior raloxifene for osteoporosis No prior hormonal, antiestrogen, or aromatase
inhibitors other than tamoxifen for breast cancer At least 4 weeks since prior tamoxifen No
concurrent hormonal replacement therapy, other antiestrogens (including raloxifene),
aromatase inhibitors, or systemic steroids (except physiologic replacement doses)

Radiotherapy: See Disease Characteristics Surgery: See Disease Characteristics Other: At least 4 weeks since prior investigational drug No concurrent warfarin exept low dose warfarin for port maintenance No other concurrent investigational agent No concurrent immunosuppressive therapy
Overall Status: Unknown status
Phase: Phase 2

NCTID: NCT00006462
Intervention Type: Drug
Intervention Name: gemcitabine hydrochloride
Title: Gemcitabine in Treating Children With Relapsed or Refractory Acute Lymphoblastic Leukemia or Acute Myelogenous Leukemia
Condition: Leukemia
Eligibility Criteria: DISEASE CHARACTERISTICS:

- Diagnosis of relapsed acute lymphoblastic leukemia or acute myelogenous leukemia
    - M3 marrow (at least 25% blasts in bone marrow aspirate)
    - Refractory to conventional therapy

PATIENT CHARACTERISTICS:

Age:

- 21 and under at diagnosis

Performance status:

- ECOG 0-2 OR
- Zubrod 0-2

Life expectancy:

- At least 2 months

Hematopoietic:

- Not specified

Hepatic:

- Bilirubin normal
- SGOT or SGPT no greater than 2.5 times upper limit of normal

Renal:

- Creatinine normal OR
- Creatinine clearance or radioisotope glomerular filtration rate at least 70 mL/min

Other:

- Not pregnant or nursing
- Negative pregnancy test

- Fertile patients must use effective contraception

PRIOR CONCURRENT THERAPY:

Biologic therapy:

- No concurrent immunomodulating agents

Chemotherapy:

- At least 2 weeks since prior chemotherapy

- No other concurrent chemotherapy for cancer

Endocrine therapy:

- No concurrent corticosteroids except for treatment of adrenal crises with suppressed pituitary/adrenal response

- Concurrent low-dose hydrocortisone (less than 100 mg/m2) allowed for allergic reactions to amphotericin or transfusions

Radiotherapy:

- Concurrent radiotherapy to localized painful lesions allowed

Surgery:

- Not specified

Other:

- Recovered from any prior therapy

Overall Status: Completed
Phase: Phase 2

NCTID: NCT00006457
Intervention Type: Drug
Intervention Name: oltipraz
Title: Oltipraz in the Prevention of Lung Cancer in People Who Smoke
Condition: Lung Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS:

- Current cigarette smokers

  - At least 20 cigarettes a day

  - No variation of more than 10 in the number of cigarettes smoked per day within the past 3 months

  - At least 10 years of smoking any amount

  - Failed to stop smoking after at least one attempt to quit within the last 3 years

- Prior stage I non-small cell lung cancer allowed if surgically resected with at least a lobectomy

- No concurrent evidence of lung cancer

- Willing to undergo 2 bronchoscopies

PATIENT CHARACTERISTICS:

Age:

- 18 and over

Performance status:

- ECOG 0

Life expectancy:

- Not specified

Hematopoietic:

- CBC normal
- Hemostasis normal

Hepatic:

- PT and PTT normal

Renal:

- Blood chemistries normal
- Nonfasting glucose no greater than 200 mg/dL
- No active renal disease
- No urinary tract infection by urinalysis (trace protein allowed)

Cardiovascular:

- EKG normal
- No coronary artery disease requiring continuous medication

Pulmonary:

- Chest radiograph normal (postsurgical changes allowed)
- No acute or significant chronic abnormality
- FEV1 greater than 1.8 L or 75% predicted
- No chronic obstructive pulmonary disease requiring continuous medication

Other:

- No known hypersensitivity or prior adverse reaction to oltipraz
- No inmates or prisoners
- No medical or psychological condition that would preclude study (e.g., acute psychosis)
- No prior malignancy except nonmelanomatous skin cancer, cervical

dysplasia, or
curatively treated stage I or II cancer of the head and neck

- Not pregnant or nursing

- Negative pregnancy test

- Fertile patients must use effective contraception during and for 6 months after study

PRIOR CONCURRENT THERAPY:

Biologic therapy:

- Not specified

Chemotherapy:

- At least 3 months since prior potential chemoprevention agent (e.g., oltipraz,
retinoids, or acetylcysteine)

Endocrine therapy:

- Not specified

Radiotherapy:

- Not specified

Surgery:

- See Disease Characteristics

Overall Status: Completed
Phase: Phase 1

NCTID: NCT00006471
Intervention Type: Drug
Intervention Name: Fenretinide
Title: Fenretinide in Treating Patients With Recurrent or Metastatic Head and Neck Cancer
Condition: Head and Neck Cancer
Eligibility Criteria: Inclusion Criteria:

1. Biopsy-proven recurrent squamous cell carcinoma of the head and neck

2. Stage 4 disease, either at initial presentation or at recurrence. Patients with
metastatic disease at initial presentation must have received at least one prior
course of cytotoxic chemotherapy.

3. Patients who present with metastatic disease should have received no more than one
prior regimen of chemotherapy or biologic therapy to be eligible. Patients who
initially received adjuvant or induction chemotherapy and then recurred may have
received one additional cycle of chemotherapy or biologic therapy at the time of
recurrence. Patients may have received any number of cycles of a particular regimen of
chemotherapy.

4. Patients must have a life expectancy of at least 3 months

5. Biopsy of the recurrent lesion(s) is encouraged but not mandatory for enrollment.

6. Performance status grade 0-2.

7. Serum creatinine <= 1.5 mg/dL.

8. Serum transaminases and bilirubin <= 1.5 time normal.

9. Age >= 18 years.

10. White blood cell count >= 3,000; platelets >= 100,000; hemoglobin >= 9mg/dl.

11. Signed informed consent.

12. Women of childbearing potential must agree to utilize two methods of effective birth control, one barrier, one hormonal, or should abstain from sexual intercourse that could result in pregnancy. Contraceptive measures should be continued for at least one month after fenretinide administration has been discontinued.

13. It is recommended that male patients with female partners of childbearing potential use barrier contraception while on fenretinide.

Exclusion Criteria:

1. Pregnant women (women of childbearing potential must have a negative pregnancy test within 24 hours prior to enrollment in the study); women who are currently breast-feeding.

2. Grade 2 or greater peripheral neuropathy

3. Concurrent treatment with cytotoxic chemotherapy or radiation

4. Serious infection or other intercurrent illness requiring immediate therapy.

5. Inability to take oral medications, or other medical or social factors interfering with compliance.

6. Patients on high dose synthetic or natural Vitamin A derivatives (>= 10,000 per day).

7. Patients should not take any anti-oxidants such as Vitamin C or E.

Overall Status: Completed
Phase: Phase 2

NCTID: NCT00006475
Intervention Type: Drug
Intervention Name: imatinib mesylate
Title: STI571 in Treating Patients With Chronic Myelogenous Leukemia in Blast Crisis
Condition: Leukemia
Eligibility Criteria: DISEASE CHARACTERISTICS: Diagnosis of chronic myelogenous

leukemia (CML) in blast crisis,
defined by at least one of the following: 30% blasts in peripheral blood and/or bone marrow
Flow cytometry criteria Extramedullary disease other than spleen, lymph node, and/or liver
involvement Newly diagnosed CML in blast crisis OR CML in blast crisis with prior therapy
for accelerated or blastic phases Philadelphia (Ph) chromosome positive OR Ph chromosome
negative and Bcr/Abl positive

PATIENT CHARACTERISTICS: Age: 18 and over Performance status: ECOG 0-2 Life expectancy: Not
specified Hematopoietic: See Disease Characteristics Hepatic: SGOT and SGPT no greater than
3 times upper limit of normal (ULN) (no greater than 5 times ULN if liver involvement)
Bilirubin no greater than 3 times ULN Renal: Creatinine no greater than 2 times ULN
Cardiovascular: No grade 3 or 4 cardiac disease Other: Not pregnant or nursing Negative
pregnancy test Fertile patients must use effective barrier contraception during and for at
least 2 weeks after study for women and for at least 3 months after study for men No
history of noncompliance with medical regimens No serious concurrent medical condition

PRIOR CONCURRENT THERAPY: Biologic therapy: At least 48 hours since prior interferon alfa
At least 6 weeks since prior hematopoietic stem cell transplantation No concurrent
anticancer biologic therapy Chemotherapy: At least 6 weeks since prior busulfan At least 24
hours since prior hydroxyurea At least 2 weeks since prior homoharringtonine At least 1
week since prior low-dose cytarabine (less than 30 mg/m2 every 12-24 hours daily) At least
2 weeks since prior moderate-dose cytarabine (100-200 mg/m2 for 5-7 days) At least 4 weeks
since prior high-dose cytarabine (1-3 g/m2 every 12-24 hours for 6-12 doses) At least 3
weeks since prior anthracyclines, mitoxantrone, or etoposide No concurrent anticancer
chemotherapy Endocrine therapy: Not specified Radiotherapy: Not specified Surgery: Not
specified Other: At least 4 weeks since other prior investigational agents No other
concurrent anticancer investigational agents
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00006519
Intervention Type: Drug
Intervention Name: Capravirine
Title: Capravirine to Treat Children With HIV Infection
Condition: HIV Infection
Eligibility Criteria: INCLUSION CRITERIA:

Age: Two age groups will be enrolled and studied separately.

Group 1: 4 months to less than 2 years.

Group 2: 2 years to less than 21 years.

Gender and Ethnicity: There will be no restriction as to genderor ethnicity. A resonable effort will be made to include chldren of both genders and all ethnic backgrounds.

HIV-infected children between the ages of 4 months and 21 years.

An indication for treatment with antiretrovirals.

One of the following: Children failing current treatment after at least 12 weeks of therapy as defined by the most recent Guidelines for the Use of Antiretroviral Agents in n Pediatric HIV Infection or accepted practice OR Intolerant to or are showing evidence of toxicity from other antiretroviral treatments.

HIV RNA greater than or equal to 5,000 copies per/mL within the past 3 months (may be from outside institution).

Women of childbearing age must agree to avoid becoming pregnant while on study and for 4 months afterwards.

Hematologic Function:

Total WBC greater than 1,500/mm(3),

Absolute neutrophil count greater than 750/mm(3),

Hemoglobin greater than 8.0 gm/dL, and

Platelet count greater than 75,000/mm(3) at study entry.

Hepatic Function:

Liver transaminases must be less than or equal to 3.0 times the upper limit of normal;

Serum amylase less than 1.5 times the upper limit of normal and if abnormal, fractionated pancreatic amylase less than 45 U/L;

Lipase less than 1.5 times the upper limit of normal;

Creatinine phosphokinase (CPK) less than 2.5 times the upper limit of normal.

Renal Function:

Patients must have an age-adjusted normal serum creatinine OR a creatinine clearance greater than or equal to 70 mL/min/1.73:

EXCLUSION CRITERIA:

Therapeutic regimens including:

Immunomodulating agents (within 30 days of entry), other than GCSF, erythropoeitin, corticosteroids, IVIG, or anti-D;

Treatment with chemotherapeutic agents (including hydroxyurea) or radiation therapy within
the past 6 weeks;

Current chronic use of medications known to inhibit or induce cytochrome P450, including
but not limited to: isoniazid, rifampin, rifabutin, astemizole, terfenadine, cisapride,
triazolam, midazolam, nifedipine, diltiazem, verapamil, cimetidine, dexamethasone,
carbamazepine, phenytoin, phenobarbital, propoxyphene, quinidine, amiodarone, or ergot
alkaloids, azole antifungals (ketoconazole, fluconazole, itraconazole), or macrolide
antibiotics (erythromycin, clarithromycin);

Current use of highly plasma protein bound drugs including but not limited to, warfarin and
phenytoin;

Current use, or use within the last 28 days, of any investigational agent.

Clinically significant, unrelated systemic illness (serious infections or significant
cardiac, pulmonary, hepatic or other organ dysfunction) which in the judgement of the
Principal Investigator or Chairperson would compromise the patient's ability to tolerate
this therapy or is likely to interfere with the study procedures or results will be
excluded.

Weighting less than 10 kg.

Pregnant or breast feeding females will be excluded.
Overall Status: Completed
Phase: Phase 1

NCTID: NCT00006877
Intervention Type: Drug
Intervention Name: temozolomide
Title: Temozolomide in Treating Patients With Metastatic Non-small Cell Lung Cancer
Condition: Lung Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS: Histologically proven metastatic non-small cell lung cancer
Eligible subtypes: Adenocarcinoma Squamous cell carcinoma Large cell carcinoma At least 1
bidimensionally measurable lesion, at least 2 cm by 2 cm in perpendicular diameter on
radiologic study Previously irradiated bony lesions are not considered measurable unless
there is evidence of disease progression at that site prior to study No brain metastases

PATIENT CHARACTERISTICS: Age: 18 and over Performance status: ECOG 0-2 Life expectancy:
More than 12 weeks Hematopoietic: Absolute neutrophil count at least 1,500/mm3 Platelet
count at least 100,000/mm3 Hemoglobin at least 9 g/dL Hepatic: Bilirubin no greater than 2
times upper limit of normal (ULN) SGOT and SGPT no greater than 2 times ULN (5 times ULN if

documented liver metastases) Alkaline phosphatase no greater than 2 times ULN (5 times ULN
if documented liver metastases) Renal: Blood urea nitrogen no greater than 1.5 times ULN
Creatinine no greater than 1.5 times ULN Other: No active nonmalignant systemic disease
that would increase risk No frequent vomiting or medical condition that would interfere
with oral medication intake (e.g., partial bowel obstruction) No other malignancy within
the past 5 years except surgically cured carcinoma in situ of the cervix or basal cell or
squamous cell skin cancer HIV negative No AIDS-related illness Not pregnant or nursing
Negative pregnancy test Fertile patients must use effective contraception

PRIOR CONCURRENT THERAPY: Biologic therapy: No concurrent immunotherapy or biologic therapy
No concurrent growth factors or epoetin alfa Chemotherapy: At least 4 weeks since prior
chemotherapy No more than 1 prior chemotherapy regimen for metastatic disease No other
concurrent chemotherapy Endocrine therapy: Not specified Radiotherapy: See Disease
Characteristics Prior radiotherapy for local control or as palliative therapy for a painful
bony lesion allowed No prior radiotherapy to 50% or more of bone marrow At least 4 weeks
since prior radiotherapy to 15% or more of bone marrow (2 weeks for radiotherapy to less
than 15% of bone marrow) and recovered No concurrent radiotherapy Surgery: Not specified
Other: Recovered from any prior therapy No other concurrent investigational drugs
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00007436
Intervention Type: Drug
Intervention Name: Tenofovir disoproxil fumarate
Title: The Safety of Tenofovir Disoproxil Fumarate Taken With Other Anti-HIV Drugs to Treat HIV-Infected Patients
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Patients may be eligible for this study if they:

- Have completed another study on tenofovir DF without toxicity.

- Are willing to use intrauterine or effective barrier methods of birth control, both
men and women, during the study and for 30 days following tenofovir DF treatment.

Exclusion Criteria

Patients will not be eligible for this study if they:

- Are taking drugs that may damage the kidney (nephrotoxic) including aminoglycoside
antibiotics, amphotericin B, cidofovir, cisplatin, foscarnet, IV pentamidine,
vancomycin, and oral or IV ganciclovir.

- Are taking agents that affect kidney function, such as probenecid.

- Are receiving systemic chemotherapy.

- Are taking systemic corticosteroids.

- Are taking experimental drugs except those that are approved by Gilead.

- Are currently participating in the GS-99-908 or GS-00-912 (expanded access) studies.

- Are pregnant or breast-feeding.

Overall Status: Unknown status
Phase: Phase 3

NCTID: NCT00007449
Intervention Type: Drug
Intervention Name: DPC 083
Title: Safety and Effectiveness of the Drug DPC 083 in Combination With Nucleoside Analogue Reverse Transcriptase Inhibitors in HIV-1-Infected Patients Who Are Failing Treatment With Nonnucleoside Reverse Transcriptase Inhibitors
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Patients may be eligible for this study if they:

- Have HIV infection.

- Are at least 18 years old.

- Weigh at least 50 kg.

- Have documented evidence of virologic failure.

- Have screening HIV genotype done while receiving NNRTI treatment, or within 2 weeks after stopping the treatment.

- Have a viral load (amount of HIV in the blood) of at least 1,000 copies/ml within 45 days prior to Day 1 of study.

- Are willing to use an effective barrier method of birth control during the study. Birth control agents taken by mouth or placed under the skin should not be used as the only method of birth control. If the patient stops taking the study drug, he or she should continue to use birth control for the following 3 months.

Exclusion Criteria

Patients will not be eligible for this study if they:

- Had virologic failure of any treatment containing an HIV protease inhibitor drug.

- Had virologic failure of more than 1 treatment containing an NNRTI drug.

- Have participated in any study using DPC 083.

- Were treated with any experimental NNRTI.

- Have cancer that requires systemic therapy.

- Have a history of blood clotting problems.

- Have attempted suicide or are in danger of hurting themselves.

- Used illegal injection drugs within 6 months of study entry.

- Do not expect to complete 12 months on the study.

- Have not met requirements for HIV genotyping results.

- Have any disease other than HIV infection or other medical problems that the researchers think may interfere with the study.

- Have difficulty swallowing capsules/tablets.

- Have had treatment with immunomodulatory agents such as interferons, interleukins, or thalidomide within 30 days prior to study entry.

- Are using or have used systemic drugs, including glucocorticoids, that suppress the immune system, for over 2 weeks. (Low levels of prednisone are allowed.)

- Have used carbamazepine, phenytoin, or Hypericum perforatum (St. John's wort) within 30 days of beginning study treatment.

- Have had any vaccination within 3 weeks before study screening.

- Have received any experimental therapy within 30 days of beginning study treatment.

- Are pregnant or breast-feeding.

- Abuse alcohol or drugs.

Overall Status: Unknown status
Phase: Phase 2

NCTID: NCT00007943
Intervention Type: Drug
Intervention Name: gemcitabine hydrochloride
Title: Gemcitabine in Treating Patients With Advanced Colorectal Cancer
Condition: Colorectal Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS: Histologically confirmed advanced colorectal cancer that has failed at least 1

prior course of fluoropyrimidine-based chemotherapy

Measurable and/or evaluable disease

PATIENT CHARACTERISTICS:

Age:

- 18 and over

Performance status:

- 0-2

Life expectancy:

- At least 3 months

Hematopoietic:

- WBC at least 3,000/mm3
- Platelet count at least 100,000/mm3

Hepatic:

- Bilirubin no greater than 2.5 times upper limit of normal (ULN)
- ALT and/or AST no greater than 3 times ULN (no greater than 10 times ULN if
- secondary to hepatic involvement by tumor

Renal:

- Creatinine no greater than 2.0 mg/dL

Cardiovascular:

- No history of cardiac arrhythmias requiring chronic treatment beyond an
- acute event (e.g., arrhythmias during severe electrolyte abnormalities
- allowed)
- No active cardiac disease requiring treatment other than hypertension,
- stable angina, or chronic valvular disease

Other:

- No other malignancy within the past 5 years except curatively treated
- (including surgically cured) cancer
- No serious medical or psychiatric illness that would preclude study
- No active uncontrolled bacterial, fungal, or viral infection
- Not pregnant or nursing
- Negative pregnancy test
- Fertile patients must use effective contraception

PRIOR CONCURRENT THERAPY:

Biologic therapy:

- Not specified

Chemotherapy:

- See Disease Characteristics
- No more than 3 prior chemotherapy regimens
- Must have 1 prior fluorouracil-based regimen and 1 other cytotoxic agent
- (e.g., irinotecan)
- More than 4 weeks since prior chemotherapy
- Prior gemcitabine allowed
- No other concurrent antineoplastic therapy

Endocrine therapy:

- Not specified

Radiotherapy:

- More than 4 weeks since prior radiotherapy

Surgery:

- More than 4 weeks since prior surgery

Overall Status: Completed
Phase: Phase 2

NCTID: NCT00008333
Intervention Type: Drug
Intervention Name: vinorelbine tartrate
Title: Vinorelbine in Treating Older Patients With Stage IIIB or Stage IV Non-small Cell Lung Cancer
Condition: Lung Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS: Histologically confirmed stage IIIB or IV non-small cell lung cancer Measurable disease At least 1 lesion that is 2.0 cm or more in longest diameter CNS metastases allowed if previously treated and clinically stable for at least 8 weeks prior to study No meningeal carcinomatosis Participation in translational research component of this study is mandatory

PATIENT CHARACTERISTICS: Age: 65 and over Performance status: ECOG 0-2 Life expectancy: At least 12 weeks Hematopoietic: Platelet count at least 100,000/mm3 Hemoglobin at least 10.0 g/dL Absolute neutrophil count at least 1,500/mm3 Hepatic: Bilirubin no greater than 2.0 mg/dL Renal: Creatinine no greater than 2 times upper limit of normal Other: No dysphagia or inability to swallow capsules intact No peripheral neuropathy grade 2 or greater No other significant medical condition that would preclude study No active infection within the past 2 weeks No other malignancy within the past 5 years

PRIOR CONCURRENT THERAPY: Biologic therapy: Not specified Chemotherapy: No prior chemotherapy for this disease within the past 5 years Endocrine therapy:

Not specified
Radiotherapy: At least 3 weeks since prior radiotherapy and recovered No prior radiotherapy
to more than 25% of bone marrow No prior radiotherapy to measurable lesion unless
documented progression after therapy No concurrent radiotherapy, including palliative
radiotherapy Surgery: At least 3 weeks since prior major surgery
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00008489
Intervention Type: Drug
Intervention Name: Didanosine
Title: Comparing Side Effects of Two Forms of Videx in HIV-Infected Adults
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Patients may be eligible for this study if they:

- Are HIV-positive.

- Are at least 16 years old (consent of parent or guardian required if under 18).

- Are taking a stable Videx-containing anti-HIV regimen, using Videx tablets either once
or twice a day, for at least 2 weeks prior to the screening visit.

- Score 2 or higher on the GSRS questionnaire for 1 or more of the following symptoms at
the first 2 study visits: abdominal pain, nausea and vomiting, borborygmus, abdominal
distension, and loose stools.

- Agree to use an effective barrier method of birth control during the study.

- Are available for at least 8 weeks.

Exclusion Criteria

Patients will not be eligible for this study if they:

- Are pregnant or breast-feeding.

- Are taking Videx in liquid form, nelfinavir, or amprenavir.

- Have a history of pancreatitis or gallstones.

- Abuse alcohol or require drugs which, in the opinion of the investigator, may increase
the risk of pancreatitis.

- Have had treatment for an active opportunistic (AIDS-related) infection within 4 weeks
of the screening visit. Patients with chronic candidiasis (yeast infection) or
bacterial infection will be allowed.

- Are receiving or plan to receive chemotherapy for cancer.

- Plan to change their medications within 8 weeks following the screening visit.

- Are receiving investigational drugs or are participating in a clinical trial involving anti-HIV medications. Patients in Phase IV studies (studies that evaluate the long-term safety and effectiveness of a drug, usually after the drug has been approved by the FDA) may be eligible.

- Have an active, ongoing gastrointestinal disease or infection such as colitis, diverticulitis, Crohn's disease, peptic ulcer disease, giardiasis, or cryptosporidiosis.

- Are unable to take medications by mouth.

- Have severe diarrhea.

- Have peripheral neuropathy (a condition affecting the nervous system) or other condition or prior therapy that, in the opinion of the investigator, would affect the study.

Overall Status: Unknown status
Phase: Phase 3

NCTID: NCT00008528
Intervention Type: Drug
Intervention Name: Enfuvirtide
Title: T-20 With Anti-HIV Combination Therapy for Patients With Prior Anti-HIV Drug Treatment and/or Drug Resistance to Each of the Three Classes of Approved Anti-HIV Drugs
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Patients may be eligible for this study if they:

- Are HIV-infected.

- Are at least 16 years old (have consent of parent or guardian if under 18).

- Have a viral load (level of HIV in the blood) of 5,000 copies/ml or more.

- Have received anti-HIV drugs for at least 6 months and/or have shown resistance to each of the 3 types of anti-HIV drugs as follows: nucleoside reverse transcriptase inhibitors (resistant to 1 or more); nonnucleoside reverse transcriptase inhibitors (resistant to 1 or more); and protease inhibitors (resistant to 2 or more, taken either together or 1 after the other for at least 6 months total).

Overall Status: Completed
Phase: Phase 3

NCTID: NCT00008372
Intervention Type: Drug
Intervention Name: chloroquinoxaline sulfonamide
Title: Chloroquinoxaline Sulfonamide in Treating Patients With Small Cell Lung Cancer
Condition: Lung Cancer

Eligibility Criteria: DISEASE CHARACTERISTICS: Histologically confirmed platinum-refractory small cell lung
cancer No response or progression during or within 6 months of completing platinum based
therapy Measurable disease No symptomatic brain or leptomeningeal metastases

PATIENT CHARACTERISTICS: Age: 18 and over Performance status: SWOG 0-2 Life expectancy: At
least 12 weeks Hematopoietic: Granulocyte count at least 1,500/mm3 Platelet count at least
100,000/mm3 No hemolytic anemia Hepatic: Bilirubin normal AST no greater than 2.5 times
upper limit of normal Renal: Creatinine no greater than 1.5 mg/dL OR Creatinine clearance
at least 60 mL/min Cardiovascular: No history of cardiac arrhythmias Other: No other active
malignancy requiring concurrent treatment No allergy to sulfonamides Not pregnant or
nursing Negative pregnancy test Fertile patients must use effective contraception

PRIOR CONCURRENT THERAPY: Biologic therapy: Not specified Chemotherapy: See Disease
Characteristics No more than 2 prior chemotherapy regimens At least 3 weeks since prior
chemotherapy and recovered Endocrine therapy: No concurrent corticosteroids to control
symptoms of brain and/or leptomeningeal metastases Radiotherapy: At least 4 weeks since
prior radiotherapy No concurrent radiotherapy to measurable lesions Surgery: Not specified
Other: No concurrent hypoglycemic agents (including insulin)
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00008320
Intervention Type: Drug
Intervention Name: ceramide
Title: Ceramide Cream in Treating Women With Cutaneous Breast Cancer
Condition: Breast Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS: Histologically or cytologically confirmed cutaneous breast cancer
for which no curative or significantly palliative therapy exists including chest wall
radiotherapy Measurable disease Disease progression after at least 1 hormonal therapy for
estrogen receptor positive disease and after radiotherapy if chest wall disease has been
previously irradiated No infection at site of cutaneous metastatic disease Hormone receptor
status: Estrogen receptor status known

PATIENT CHARACTERISTICS: Age: 18 and over Sex: Female Menopausal status: Not specified
Performance status: ECOG 0-3 Life expectancy: At least 12 weeks Hematopoietic: Not
specified Hepatic: Not specified Renal: Not specified Other: Not pregnant or nursing
Negative pregnancy test Fertile patients must use effective contraception

PRIOR CONCURRENT THERAPY: Biologic therapy: No concurrent biologic therapy during first 2

months of study Chemotherapy: No other concurrent local antineoplastic therapy for cutaneous disease No concurrent systemic chemotherapy during first 2 months of study Endocrine therapy: See Disease Characteristics Radiotherapy: See Disease Characteristics At least 4 weeks since prior radiotherapy No concurrent radiotherapy during first 2 months of study except for CNS disease Surgery: Not specified
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00008697
Intervention Type: Drug
Intervention Name: arsenic trioxide
Title: Arsenic Trioxide in Treating Patients With Refractory or Recurrent Acute Promyelocytic Leukemia
Condition: Leukemia
Eligibility Criteria: INCLUSION CRITERIA

1. APML diagnosis based upon morphological, histochemical, and/or flow cytometric criteria, confirmed upon review by a central, study-designated hematologic pathologist;

OR

any relapsed acute leukemia bearing a t(15:17) translocation or variant APML translocations involving the retinoic acid receptor alpha gene on chromosome 15q22, based on cytogenetics or PCR.

2. disease in first or subsequent relapse, following standard induction and consolidation chemotherapy (with all-trans retinoic acid) and/or allogeneic bone marrow/stem cell transplantation;

OR

failure to achieve initial complete remission with ATRA and standard chemotherapy.

EXCLUSION CRITERIA

1. Availability of a fully HLA-matched sibling donor for patients otherwise felt to be candidates for allogeneic bone marrow/stem cell transplantation; patients with only a partially HLA-matched sibling or matched unrelated donor will remain eligible for study entry.

2. pregnancy.

3. Patients with significantly impaired left ventricular ejection fraction (<40%) will be ineligible for the study.

Patients with renal failure and a creatinine clearance of less than 25 ml/min or requiring hemodialysis will be ineligible for the study. Otherwise, there are no

rigid exclusion
criteria based upon age, performance status, or co-morbidity. Decisions regarding
enrollment of patients for whom these factors may be relevant will be individualized and
left to the discretion of the investigators. Central venous access will be required for all
patients. Patients of child-bearing potential must agree to use contraception during sexual
intercourse while undergoing treatment with arsenic trioxide.
Overall Status: Completed
Phase: Phase 1/Phase 2

NCTID: NCT00009555
Intervention Type: Drug
Intervention Name: Testosterone
Title: Testosterone for HIV-Positive Men With Reduced Serum Testosterone Levels and Abdominal Fat
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Patients may be eligible for this study if they:

- Are HIV-positive.

- Have been taking anti-HIV medications for at least 12 weeks before study entry and
plan to continue taking them for an additional 24 weeks.

- Are male and between 18 and 70 years old.

- Have a measurement of greater than 100 cm around the abdomen.

- Can report an increase in abdominal size after taking antiretroviral drugs.

- Have a viral load less than 10,000 copies/ml within 6 weeks prior to screening.

- Have a serum total testosterone between 125 and 400 ng/dl. If serum total testosterone
is greater than 400 ng/dl, bioavailable testosterone must be less than 115 ng/dl or
free testosterone must be less than 50 pg/ml.

Exclusion Criteria

Patients will not be eligible for this study if they:

- Take certain drugs, including testosterone derivatives, glucocorticoids, appetite
stimulants, dronabinol, megestrol acetate, androstenediols, oxandrolone, or other
anabolic agents such as dehydroepiandrosterone (DHEA) or growth hormone within 12
weeks prior to study entry.

- Take hydroxyurea within 30 days of study entry.

- Take drugs for diabetes.

- Have diabetes.

- Take granulocyte-macrophage colony-stimulating factor (GM-CSF).

(Granulocyte
colony-stimulating factor (G-CSF) is allowed.)

- Take cytokines, cytokine inhibitors, or ketoconazole.

- Take ritonavir with simvastatin or lovastatin.

- Have an active opportunistic infection. Patients on treatment for at least 12 weeks
will be allowed.

- Have 5-7 loose stools per day or diarrhea for more than 1 week, within 6 weeks of
study entry.

- Have a blood pressure greater than 160 over 100.

- Have certain heart problems.

- Have a breast mass that has not been diagnosed.

- Have active cancer.

- Have had prostate cancer or certain other prostate problems.

- Are allergic to any part of the testosterone gel.

- Have a history of blood clots.

- Have a history of sleep apnea.

- Are receiving experimental treatment.

- Are receiving experimental drugs in other studies and do not know if they are taking
the drug or placebo.

- Abuse drugs or alcohol in a way that would interfere with the study.

- Are dieting or doing heavy exercising.

- Have a viral load of 10,000 copies/ml or more at screening
Overall Status: Completed
Phase: Phase 4

NCTID: NCT00009971
Intervention Type: Drug
Intervention Name: fenretinide
Title: Fenretinide in Treating Patients With Recurrent Small Cell Lung Cancer
Condition: Lung Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS:

- Histologically or cytologically confirmed recurrent small cell lung cancer (SCLC)
after platinum-containing chemotherapy regimen with or without thoracic radiotherapy

  - Limited stage or extensive stage SCLC

- Measurable disease

  - At least 20 mm by conventional techniques OR

- At least 10 mm with spiral CT scan

- No pleural effusions, bone metastases, brain metastases, or abnormal radionucleotide scans as sole evidence of disease

- No symptomatic or uncontrolled brain or leptomeningeal disease

- Previously treated brain metastases allowed if neurologically stable

PATIENT CHARACTERISTICS:

Age:

- 18 and over

Performance status:

- Zubrod 0-2

Hematopoietic:

- WBC at least 2,500/mm^3

- Platelet count at least 70,000/mm^3

Hepatic:

- Bilirubin no greater than 1.5 mg/dL

- SGOT no greater than 2 times upper limit of normal

Renal:

- Creatinine no greater than 1.5 mg/dL OR

- Creatinine clearance at least 60 mL/min

Cardiovascular:

- No symptomatic heart disease

- No myocardial infarction within the past 6 months

Other:

- Not pregnant or nursing

- Negative pregnancy test

- Fertile patients must use effective contraception for 1 month before, during, and for 2 months after study

- No pre-existing retinal degenerative disease (e.g., retinitis pigmentosa or associated disorders)

- No other serious concurrent illness

- No other malignancy within the past 5 years except localized nonmelanoma skin cancer or carcinoma in situ

PRIOR CONCURRENT THERAPY:

Chemotherapy:

- At least 3 weeks since prior chemotherapy

- No more than 2 prior chemotherapy regimens

Endocrine therapy:

- Concurrent steroids allowed at stable dose

Radiotherapy:

- No prior radiotherapy to study lesions

Other:

- At least 3 weeks since prior systemic retinoid or carotenoid therapy

- No concurrent anticonvulsants

Overall Status: Completed
Phase: Phase 2

NCTID: NCT00004429
Intervention Type: Drug
Intervention Name: growth hormone
Title: Randomized Study of Recombinant Human Growth Hormone in Patients on Chronic Hemodialysis or Peritoneal Dialysis
Condition: Kidney Failure, Chronic
Eligibility Criteria: PROTOCOL ENTRY CRITERIA:

--Disease Characteristics--

- On hemodialysis or peritoneal dialysis for more than 3 months

- Optimally dialyzed (urea reduction ratio greater than 65%)

- Suboptimal nutritional status identified by one of the following criteria: -Protein catabolic rate less than 0.85 g/kg/d calculated by three point urea kinetic modeling on at least 2 occasions over the past 6 months -Progressive unintentional weight loss of more than 2.5% of the initial or ideal body weight and/or patient weighs less than 90% of ideal body weight -Biochemical parameters of malnutrition defined by two or more of the following measurements over the past 3 months: Serum albumin no greater than 3.7 g/dL Serum transferrin concentration less than 250 mg/dL Serum prealbumin concentration less than 30 mg/dL Serum IGF-1 concentration less than 0.250 mg/mL

--Patient Characteristics--

- No active autoimmune, inflammatory, or infectious disease At least 6 months since any documented malignancy

- No unusual dietary restrictions At least 3 months since peritonitis

Overall Status: Completed
Phase: nan

NCTID: NCT00004552
Intervention Type: Drug
Intervention Name: acamprosate (Campral)
Title: Acamprosate Treatment: Mechanisms of Action
Condition: Alcoholism
Eligibility Criteria: Inclusion Criteria:

- Meets criteria for alcohol abuse or dependence.

- Able to read English at 6th grade level or higher and to complete study evaluations.

- Average weekly alcohol consumption of standard drinks of at least 25 drinks for men and 20 drinks for women.

- No more than 3 days abstinence/week.

Exclusion Criteria:

- Current abuse or dependence on other substances, other than nicotine and marijuana.

- Positive test results for opiates, cocaine, benzodiazepines and barbiturates.

- Regular use of psychoactive drugs including anxiolytics and antidepressants.

- Psychiatrically disabled.

- Hepatocellular disease or a history of cirrhosis.

- Medical conditions that would prevent the consumption of alcohol, increase the risk of complicated alcohol withdrawal, or prevent the use of acamprosate such as a history of neurological trauma or disease, seizures, delirium, or hallucinations, hepatic, cardiovascular, metabolic, endocrine, gastrointestinal, or kidney disease.

- Individuals who have had any significant physical illnesses during the two weeks prior to receiving study medication or during the medication treatment period prior to the withdrawal study.

- Medically detoxified from alcohol more than once within the past five years.

- Alcohol withdrawal symptoms requiring management with benzodiazepines.

- Females who are pregnant, nursing or not using a reliable method of birth control.

- Individuals who are seeking alcohol treatment or have been in alcohol treatment within the past six months.

- Individuals who report disliking spirits and have taken investigational drug or naltrexone within 4 weeks immediately preceding admission to study.

- Individuals who report any daily drug use during the thirty days prior to randomization for the following: anxiolytics, beta blockers, central nervous system stimulants, hypnotics, non-therapeutic doses of neuroleptics and antidepressants, drugs with psychotropic activity or drugs which cause excessive sedation.

- Subjects who have donated blood within the past six weeks.

Overall Status: Completed
Phase: Phase 2

NCTID: NCT00004739
Intervention Type: Drug
Intervention Name: Antiretroviral therapy
Title: The Metabolic Effects of Protease Inhibitors in HIV Infected Children
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria:

- Inclusion criteria for HIV infected children- a) The participants may be either antiretroviral treatment naive, or experienced. Those individuals who are experienced will be treated with at least one new drug in addition to the protease inhibitor. The selection of the new antiretroviral regimen will be directed by a review of the patient's previous drug treatment history and/or the genetic or phenotypic characteristics of the patient's virus; b) We will recruit subjects from all CDC categories. Disease severity will subsequently be analyzed as a covariate; c) There will be no height, weight or other anthropometric inclusion criterion (these factors will be analyzed as covariates); d) All subjects will be studied when they have not had an acute superinfection for at least four weeks.

- Inclusion criteria for controls- Control volunteers will be normal healthy children who are matched to the HIV infected population for age, weight and race. Normal health and non-HIV infected status will be determined by history and by medical record review. Ethical considerations preclude HIV testing in normal children. Separate informed consent and assent forms will be utilized for the control and HIV population.

Exclusion Criteria:

- Exclusion criteria for HIV infected children- Use of Megace@ or another progestational agent, use of anabolic steroids, acute superinfection

- Exclusion criteria for controls- Previous medical history of any chronic disease or glucocorticoid use in the last six weeks. Adopted children who have

no knowledge of
family history.
Overall Status: Completed
Phase: nan

NCTID: NCT00004866
Intervention Type: Drug
Intervention Name: exatecan mesylate
Title: DX-8951f in Treating Women Who Have Advanced or Recurrent Cancer of the Cervix
Condition: Cervical Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS:

- Histologically confirmed advanced or recurrent squamous cell carcinoma of the cervix
not curable by surgery or radiotherapy

- Measurable disease

- No known brain metastases

PATIENT CHARACTERISTICS:

Age:

- 18 and over

Performance status:

- ECOG 0-2

Life expectancy:

- At least 12 weeks

Hematopoietic:

- Absolute neutrophil count at least 1,500/mm3

- Platelet count at least 100,000/mm3

Hepatic:

- Bilirubin no greater than 1.5 mg/dL

- SGOT or SGPT no greater than 2 times upper limit of normal (ULN) (5 times ULN if liver
metastases present)

Renal:

- Creatinine no greater than 2.0 mg/dL

Cardiovascular:

- No active congestive heart failure

- No uncontrolled angina

- No myocardial infarction within the past 6 months

Other:

- Not pregnant or nursing

- Negative pregnancy test
- Fertile patients must use effective contraception
- No concurrent serious infection
- No other malignancy within the past 5 years except nonmelanomatous skin cancer
- No other life threatening illness
- No psychosis, mental disability, or incompetence

PRIOR CONCURRENT THERAPY:

Biologic therapy:

- No concurrent biologic therapy

Chemotherapy:

- At least 4 weeks since prior chemotherapy
- No more than 1 prior chemotherapy regimen (except chemotherapy for radiosensitization)
- No prior camptothecin
- No other concurrent chemotherapy

Endocrine therapy:

- Not specified

Radiotherapy:

- At least 4 weeks since prior radiotherapy
- No concurrent radiotherapy

Surgery:

- At least 4 weeks since prior surgery
- No concurrent surgery

Other:

- At least 4 weeks since other prior investigational drugs (including analgesics or antiemetics)
- No other concurrent investigational drugs during or within 28 days after final dose of study drug
- No concurrent drugs that induce or inhibit CYP3A enzyme

Overall Status: Completed
Phase: Phase 2

NCTID: NCT00004932
Intervention Type: Drug
Intervention Name: imatinib mesylate

Title: STI571 in Treating Patients With Recurrent Leukemia
Condition: Leukemia
Eligibility Criteria: DISEASE CHARACTERISTICS:

- Recurrent Philadelphia (Ph) chromosome-positive leukemia
  - Recurrent or refractory acute lymphoblastic or myeloblastic leukemia OR
  - Chronic myelogenous leukemia with resistance to interferon alfa with any of the following:
    - WBC at least 20,000/mm^3 after at least 3 months of interferon therapy
    - At least 100% increase in WBC to at least 20,000/mm^3 confirmed over 2 weeks while receiving interferon alfa
    - At least 66% Ph chromosome-positive cells after 1 year of interferon therapy
    - At least 30% increase in number of Ph chromosome-positive cells after an interferon-induced response while continuing interferon therapy

PATIENT CHARACTERISTICS:

Age:

- Under 22

Performance status:

- Karnofsky 50-100% if over 10 years of age OR
- Lansky 50-100% if 10 years of age and under

Life expectancy:

- At least 8 weeks

Hematopoietic:

- See Disease Characteristics

Hepatic:

- Bilirubin no greater than 1.5 times normal
- SGPT less than 3 times normal
- Albumin greater than 2 g/dL

Renal:

- Creatinine no greater than 1.5 times normal OR
- Creatinine clearance or radioisotope glomerular filtration rate at least 70 mL/min

Other:

- Not pregnant or nursing
- Negative pregnancy test
- Fertile patients must use effective contraception
- If prior allogeneic stem cell transplantation, no uncontrolled graft-versus -host disease
- No seizure disorder if on anticonvulsants
- No uncontrolled infection
- No CNS toxicity greater than grade 2

PRIOR CONCURRENT THERAPY:

Biologic therapy:

- See Disease Characteristics
- At least 1 week since prior biologic therapy and recovered
- At least 3 months since prior stem cell transplantation (SCT)
- At least 1 week since prior growth factors
- At least 1 week since prior interferon alfa

Chemotherapy:

- Recovered from prior chemotherapy
- At least 6 weeks since prior busulfan and nitrosoureas
- At least 2 weeks since prior homoharringtonine
- At least 1 week since low-dose cytarabine
- At least 2 weeks since prior moderate-dose cytarabine
- At least 4 weeks since prior high-dose cytarabine
- At least 3 weeks since all other prior cytotoxic chemotherapies
- No prior hydroxyurea

Endocrine therapy:

- Must be on a stable dose of steroids if received prior allogeneic SCT

Radiotherapy:

- Recovered from prior radiotherapy
- At least 2 weeks since prior local palliative radiotherapy (small port)
- At least 6 months since prior craniospinal radiotherapy
- At least 6 months since prior radiotherapy to 50% or more of the

pelvis

- At least 6 weeks since other prior substantial bone marrow radiotherapy

Surgery:

- Not specified

Other:

- No other concurrent investigational agents

- No concurrent anticonvulsants

Overall Status: Completed
Phase: Phase 1

NCTID: NCT00004978
Intervention Type: Drug
Intervention Name: Recombinant interleukin-2 (rIL-2)
Title: An International Study to Evaluate Recombinant Interleukin-2 in HIV Positive Patients Taking Anti-retroviral Therapy
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria:

- HIV positive

- Have a CD4 cell count of 300 cells/mm3 or more within 45 days of study entry

- Are on combination anti-HIV therapy or are beginning anti-HIV therapy at the time of study entry

- Are at least 18 years old

Exclusion Criteria:

- Have received IL-2 before

- Have cancer requiring chemotherapy

- Have evidence of active clinical disease within the past year for any AIDS-defining illness or certain other conditions such as herpes zoster or Chagas disease. (This study has been changed. Previously, patients were ineligible if they had a history of any AIDS-defining illness or certain other conditions.)

- Have used certain medications, such as corticosteroids or drugs affecting the immune system, in the 45 days before study entry

- Have a nervous system disorder requiring antiseizure medication

- Have an autoimmune or inflammatory disease such as inflammatory bowel disease (e.g., Crohn's disease or ulcerative colitis), psoriasis, optic neuritis, or any autoimmune/inflammatory diseases with potentially life-threatening complications

- Are pregnant or breastfeeding

Overall Status: Completed
Phase: Phase 3

NCTID: NCT00004915
Intervention Type: Drug
Intervention Name: raloxifene
Title: Raloxifene in Treating Patients With Persistent or Recurrent Endometrial Cancer
Condition: Endometrial Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS: Recurrent endometrial cancer Evidence of persistent or recurrent
disease 4 weeks following primary treatment with radiation and surgery Bidimensionally
measurable disease Not a candidate for curative salvage radiotherapy

PATIENT CHARACTERISTICS: Age: 18 and over Performance status: ECOG 0-3 Life expectancy: Not
specified Hematopoietic: Not specified Hepatic: Not specified Renal: Not specified
Cardiovascular: No history of unexplained or uncontrolled thromboembolic disease No active
thromboembolic disease Other: No active or uncontrolled second malignancy HIV negative

PRIOR CONCURRENT THERAPY: Biologic therapy: Not specified Chemotherapy: At least 4 weeks
since prior chemotherapy for early stage or advanced endometrial cancer Endocrine therapy:
At least 4 weeks since prior hormonal therapy for early stage or advanced endometrial
cancer Radiotherapy: See Disease Characteristics Surgery: See Disease Characteristics
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00004987
Intervention Type: Drug
Intervention Name: Dextrin 2-sulfate
Title: Treatment of Advanced AIDS Patients With Dextrin Sulfate
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Patients may be eligible for this trial if they:

- Are HIV-positive.

- Have been diagnosed with AIDS and are under treatment to prevent opportunistic
(AIDS-related) infection.

- Have had a CD4 cell count greater than 50 microL for at least the past 3 months.

- Have had a viral load of at least 50,000 copies/ml for at least the past 3 months.

- Have used up all other treatment options.

- Are able to understand and give written consent.

Exclusion Criteria

Patients may not be eligible for this trial if they:

- Have been in any other study in the 6 weeks before beginning this study.

- Have an active, opportunistic infection or other infection.

- Have any other long-term medical condition or nervous disorder that might make it difficult for them to finish the study.

Overall Status: Unknown status
Phase: Phase 1

NCTID: NCT00005012
Intervention Type: Drug
Intervention Name: Peginterferon alfa-2b
Title: Safety and Effectiveness of PEG-Intron in HIV-Infected Patients
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Patients may be eligible for this study if they:

- Have HIV levels of more than 2000 copies/ml.

- Have failed their current HAART (had a significant increase in their HIV levels with HAART).

- Have a CD4 cell count greater than 200 cells/microL.

- Have had more than 6 months of HAART.

- Have been on their current HAART for at least 6 weeks.

- Agree to use an effective method of birth control during the study.

Exclusion Criteria

Patients will not be eligible for this study if they:

- Have a history of a serious mental disorder.

- Are allergic to interferons.

- Are pregnant or breast-feeding.

- Are taking certain medications such as ribavirin, hydroxyurea, and ganciclovir.

Overall Status: Completed
Phase: Phase 2

NCTID: NCT00005045
Intervention Type: Drug
Intervention Name: carboxyamidotriazole
Title: Carboxyamidotriazole in Treating Patients With Advanced Kidney Cancer
Condition: Kidney Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS: Histologically proven advanced renal cell cancer Locally recurrent or metastatic lesions not amenable to current resection Progressive disease defined as 25% increase from last measurement or new lesions Bidimensionally measurable disease No brain metastases

PATIENT CHARACTERISTICS: Age: 18 and over Performance status: ECOG 0-2 Life expectancy: Not

specified Hematopoietic: WBC greater than 3,000/mm3 OR Absolute neutrophil count greater
than 1,500/mm3 Platelet count greater than 100,000/mm3 Hepatic: Bilirubin less than 1.5
mg/dL SGOT and/or SGPT less than 2 times upper limit of normal Renal: Creatinine less than
2.0 mg/dL Other: Not pregnant or nursing Fertile patients must use effective contraception
No other serious medical illness or active infection that would preclude chemotherapy
compliance No other prior malignancy unless curatively treated and disease free for the
past 5 years

PRIOR CONCURRENT THERAPY: Biologic therapy: At least 4 weeks since prior biologic therapy
At least 1 (but no more than 2) prior biologic regimen(s) (i.e., interleukin-2, interferon
alfa, or combination) and recovered Regimen defined as at least 8 weeks of treatment Prior
sargramostim allowed Chemotherapy: No prior chemotherapy Endocrine therapy: At least 4
weeks since prior hormonal therapy (i.e., megestrol or tamoxifen) and recovered
Radiotherapy: No prior radiotherapy to study lesions At least 4 weeks since prior
radiotherapy and recovered No concurrent palliative radiotherapy Surgery: Prior nephrectomy
allowed Recovered from any recent surgery
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00005031
Intervention Type: Drug
Intervention Name: irofulven
Title: Irofulven in Treating Patients With Persistent or Recurrent, Refractory Endometrial Cancer
Condition: Endometrial Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS: Histologically confirmed endometrial carcinoma refractory to
curative therapy or established treatments Clinically or histologically confirmed
persistent or recurrent disease Bidimensionally measurable disease (ascites or pleural
effusions not considered measurable) Not eligible for higher priority GOG protocol

PATIENT CHARACTERISTICS: Age: 18 and over Performance status: GOG 0-2 Life expectancy: Not
specified Hematopoietic: Platelet count at least 100,000/mm3 Absolute neutrophil count at
least 1,500/mm3 Hepatic: Bilirubin normal Renal: Creatinine no greater than 1.5 mg/dL OR
Creatinine clearance greater than 60 mL/min Cardiovascular: No clinically uncontrolled
dysrhythmia or signs of ischemia per ECG No congestive heart failure requiring medication
No uncontrolled hypertension Other: No significant active infection No other prior or
concurrent malignancy within the past 5 years except nonmelanomatous skin cancer

PRIOR CONCURRENT THERAPY: Biologic therapy: Not specified Chemotherapy: At least 3 weeks

since prior chemotherapy and recovered No more than 1 prior chemotherapy regimen allowed
(either single or combination cytotoxic drug therapy) No prior 6-hydroxymethylacylfulvene
No prior chemotherapy for other malignancy Endocrine therapy: Not specified Radiotherapy:
At least 3 weeks since prior radiotherapy and recovered No prior radiotherapy for other
malignancy Surgery: At least 3 weeks since prior surgery and recovered
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00005035
Intervention Type: Drug
Intervention Name: oxaliplatin
Title: Oxaliplatin in Treating Patients With Advanced Head and Neck Cancer
Condition: Head and Neck Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS: Histologically or cytologically confirmed squamous cell carcinoma
of the head and neck Recurrent or metastatic OR Locally advanced and judged incurable by
surgery or radiotherapy Bidimensionally measurable disease New and unirradiated lesion
within prior radiation field acceptable as measurable disease if at least 3 months since
prior radiotherapy No known brain metastases

PATIENT CHARACTERISTICS: Age: 18 and over Performance status: ECOG 0-2 OR Karnofsky 50-100%
Life expectancy: Not specified Hematopoietic: WBC at least 3,000/mm3 Absolute neutrophil
count at least 1,500/mm3 Platelet count at least 100,000/mm3 Hepatic: Bilirubin normal
AST/ALT no greater than 2.5 times upper limit of normal Renal: Creatinine normal OR
Creatinine clearance at least 60 mL/min Cardiovascular: No symptomatic congestive heart
failure, unstable angina pectoris, or cardiac arrhythmia Other: Not pregnant or nursing
Negative pregnancy test Fertile patients must use effective contraception No evidence of
neuropathy No history of allergy to platinum compounds or to antiemetics appropriate for
administration in conjunction with protocol therapy No other concurrent uncontrolled
illness (e.g., ongoing or active infection) Not HIV positive AND receiving antiretroviral
therapy (HAART)

PRIOR CONCURRENT THERAPY: Biologic therapy: No prior immunotherapy for head and neck cancer
No concurrent colony stimulating factors during first course of therapy Chemotherapy: No
prior chemotherapy for recurrent or metastatic disease At least 3 months since prior
chemotherapy as initial treatment Endocrine therapy: No prior hormonal therapy for head and
neck cancer Radiotherapy: See Disease Characteristics At least 3 months since prior
radiotherapy as initial treatment Surgery: See Disease Characteristics Prior surgery
allowed Other: No other concurrent investigational or commercial agents or therapies
Overall Status: Completed

Phase: Phase 2

NCTID: NCT00005027
Intervention Type: Drug
Intervention Name: becatecarin
Title: Rebeccamycin Analog in Treating Patients With Advanced Kidney Cancer
Condition: Kidney Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS:

- Histologically or cytologically confirmed locally advanced unresectable, locally recurrent, or metastatic renal cell carcinoma not eligible for a higher priority trial

- Measurable disease

  - Longest diameter at least 20 mm with conventional techniques or at least 10 mm with spiral CT scan

- No nonmeasurable disease only including:

  - Bone lesions

  - Leptomeningeal disease

  - Ascites

  - Pleural/pericardial effusion

  - Lymphangitis cutis/pulmonis

  - Abdominal masses not confirmed and followed by imaging techniques

  - Cystic lesions

- No known brain metastases

  - History of brain metastases that have been resected and/or irradiated with subsequent normal brain CT scan allowed

PATIENT CHARACTERISTICS:

Age:

- 18 and over

Performance status:

- ECOG 0-2 OR

- Karnofsky 60-100%

Life expectancy:

- Greater than 12 weeks

Hematopoietic:

- Absolute neutrophil count at least 1,500/mm^3

- Platelet count at least 100,000/mm^3

Hepatic:

- Bilirubin no greater than 1.5 mg/dL
- AST/ALT no greater than 2.5 times upper limit of normal

Renal:

- Creatinine no greater than 1.5 mg/dL OR
- Creatinine clearance at least 60 mL/min

Cardiovascular:

- No symptomatic congestive heart failure, unstable angina pectoris, or cardiac arrhythmia

Other:

- Not pregnant or nursing
- Fertile patients must use effective contraception
- No other prior malignancy within the past 2 years except nonmelanoma skin cancer or carcinoma in situ of any site
- No history of allergic reactions attributed to compounds of similar chemical or biologic composition to rebeccamycin analogue
- No other concurrent uncontrolled illness (e.g., ongoing or active infection)
- No concurrent psychiatric illness or social situation that would preclude study compliance
- HIV negative

PRIOR CONCURRENT THERAPY:

Biologic therapy:

- Prior biologic therapy allowed
- Recovered from toxic effects

Chemotherapy:

- No prior chemotherapy

Endocrine therapy:

- Not specified

Radiotherapy:

- See Disease Characteristics
- At least 4 weeks since prior radiotherapy and recovered

Surgery:

- See Disease Characteristics

Other:

- No other concurrent investigational or commercial agents or therapies for renal cell cancer

Overall Status: Completed
Phase: Phase 2

NCTID: NCT00005041
Intervention Type: Drug
Intervention Name: tipifarnib
Title: R115777 in Treating Patients With Relapsed Small Cell Lung Cancer
Condition: Lung Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS: Histologically confirmed small cell lung cancer for which no potentially curative therapy exists Confirmation at relapse required only if sole relapse site is within previous radiation port No mixed histology Bidimensionally measurable disease by CT scan At least 1 measurable lesion at least 2 cm At least a partial response to front line chemotherapy Single regimen or alternating regimen allowed No initial course exceeding 8 courses or lasting more than 6 months No uncontrolled, untreated brain metastases No extensive liver metastases such that greater than 50% of liver parenchyma is replaced with metastatic disease

PATIENT CHARACTERISTICS: Age: 18 and over Performance status: ECOG 0 or 1 Life expectancy: Not specified Hematopoietic: Absolute neutrophil count greater than 1,500/mm3 Platelet count greater than 100,000/mm3 Hepatic: Bilirubin normal SGOT/SGPT no greater than 2.5 times upper limit of normal (ULN) (5 times ULN if documented liver metastases) Renal: Creatinine less than 2.5 mg/dL Other: Not pregnant or nursing Negative pregnancy test Fertile patients must use effective contraception during and for 3 months after study Adequate unassisted oral or adequate enteral intake to maintain reasonable state of nutrition No other concurrent medical condition that would preclude study therapy

PRIOR CONCURRENT THERAPY: Biologic therapy: No prior bone marrow transplantation No concurrent immunotherapy No concurrent myeloid colony stimulating factors (e.g., filgrastim (G-CSF), sargramostim (GM-CSF), interleukin-11) Chemotherapy: See Disease Characteristics At least 3 months since prior chemotherapy measured from day 1 of last course of front line therapy No prior high dose chemotherapy with marrow or stem cell rescue No more than 1 prior chemotherapy regimen No other concurrent chemotherapy Endocrine therapy: No concurrent hormonal therapy Radiotherapy: At least 2 weeks since prior radiotherapy No

prior extensive radiotherapy (greater than 25% of bone marrow) No concurrent radiotherapy
except for patients who are responding and develop brain metastases
Surgery: Not specified
Other: At least 30 days since prior investigational drugs No concurrent participation in
another investigational trial No other concurrent experimental agents No other concurrent
anticancer therapy No prophylactic oral or IV antibiotics for neutropenia
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00005073
Intervention Type: Drug
Intervention Name: zoledronic acid
Title: Zoledronate Plus Standard Therapy Compared With Placebo Plus Standard Therapy to Prevent Bone Metastases in Patients With Recurrent Prostate Cancer That Has No Symptoms
Condition: Prostate Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS: Histologically proven asymptomatic recurrent prostate cancer Prior
local treatment status Curatively treated OR Locally advanced disease noncuratively treated
with LHRH agonist therapy Currently receiving 1 line of hormonal therapy (with LHRH
agonists or surgical castration) and failing treatment with rising PSA only Patients who
received LHRH agonists instead of surgical castration continue to receive LHRH agonist
during study Biochemical progression documented by 3 consecutively rising PSA measurements,
each at least 2 weeks apart, with the last measurement being 50% or greater than the nadir
PSA achieved after the last therapeutic maneuver (first line hormonal therapy as noted
above) PSA (50% increased values) greater than 4 ng/mL for patients with intact prostates
and greater than 0.8 ng/mL for post-prostatectomy patients Rising PSA for less than 10
months Castrate levels of testosterone (less than 30 ng/dL) No bone or visceral metastases
by bone scan and CT scan of abdomen and pelvis (except localized abnormalities and pelvic
lymph node and soft tissue disease) No CNS or leptomeningeal involvement

PATIENT CHARACTERISTICS: Age: 18 and over Performance status: Karnofsky 90-100% Life
expectancy: Greater than 6 months Hematopoietic: WBC at least 3,000/mm3 Absolute neutrophil
count at least 1,500/mm3 Hemoglobin at least 8.0 g/dL Platelet count at least 75,000/mm3
Hepatic: Liver function tests no greater than 2.5 times upper limit of normal (ULN) Renal:
Creatinine no greater than 1.5 times ULN Cardiovascular: No New York Heart Association
class III or IV heart disease with uncontrolled and/or unstable cardiac or coronary artery
disease Other: No other malignancy within the past 5 years that would confound the etiology
of metastatic disease except curatively treated nonmelanomatous skin cancer No other
nonmalignant disease that would confound evaluation or preclude compliance Fertile patients

must use effective contraception

PRIOR CONCURRENT THERAPY: Biologic therapy: No prior systemic biologic anticancer therapy
Chemotherapy: No prior chemotherapy Concurrent chemotherapy such as estramustine containing
regimens or mitoxantrone allowed at the discretion of the protocol investigator Endocrine
therapy: See Disease Characteristics No prior systemic hormonal anticancer therapy except
LHRH antagonists and/or nonsteroidal antiandrogens (e.g., flutamide, bicalutamide, or
nilutamide) Concurrent aminoglutethimide, prednisone, or diethylstilbestrol or other
estrogens allowed at the discretion of the protocol investigator Radiotherapy: At least 6
weeks since prior palliative radiotherapy Surgery: See Disease Characteristics Other: No
other prior systemic anticancer therapy At least 4 weeks since other prior investigational
drugs No other concurrent bisphosphonate agent
Overall Status: Terminated
Phase: Phase 3

NCTID: NCT00005085
Intervention Type: Drug
Intervention Name: becatecarin
Title: Rebeccamycin Analog in Treating Patients With Metastatic or Locally Recurrent Colorectal Cancer
Condition: Colorectal Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS:

- Histologically or cytologically confirmed metastatic or locally recurrent
  adenocarcinoma of the colon or rectum

- No curable stage of disease

- At least 1 unidimensionally measurable lesion

- At 20 mm by conventional techniques OR at least 10 mm by spiral CT scan

- No tumor lesions in previously irradiated area except clearly measurable lesion
  documented histologically to be consistent with recurrent tumor in previously
  irradiated bed within pelvis

- The following are considered nonmeasurable disease:

  - Bone lesions Leptomeningeal disease

  - Ascites

  - Pleural/pericardial effusion

  - Inflammatory breast disease

  - Lymphangitis cutis/pulmonis

  - Abdominal masses not confirmed and followed by imaging techniques

- Cystic lesions
- No known brain metastases

PATIENT CHARACTERISTICS:

- Age: 18 and over
- Performance status: ECOG 0-2 OR Karnofsky 60-100%
- Life expectancy: More than 12 weeks
- WBC at least 3,000/mm3
- Absolute neutrophil count at least 1,500/mm3
- Platelet count at least 100,000/mm3
- Bilirubin normal
- AST/ALT no greater than 2.5 times upper limit of normal
- Creatinine normal OR creatinine clearance at least 60 mL/min
- No symptomatic congestive heart failure
- No unstable angina pectoris
- No cardiac arrhythmia
- Not pregnant or nursing
- Negative pregnancy test
- Fertile patients must use effective contraception during and for 6 months after study
- Eligible for placement of a central venous catheter
- No prior allergic reactions attributed to compounds of similar chemical or biologic composition to rebeccamycin analogue
- No other uncontrolled concurrent illness
- No ongoing or active infection
- No psychiatric illness or social situation that would preclude study compliance

PRIOR CONCURRENT THERAPY:

- No concurrent prophylactic growth factors (e.g., epoetin alfa) except for clinically defined indication (e.g., filgrastim (G-CSF) for febrile neutropenia)
- At least 4 weeks since prior chemotherapy (e.g., fluorouracil, oral fluoropyrimidines, irinotecan, or oxaliplatin) (6 weeks for nitrosoureas or mitomycin)
- No other concurrent chemotherapy
- No concurrent hormones except for clinically defined indication

- At least 4 weeks since prior radiotherapy (including to bony sites, whole pelvis, lung, liver, or spinal cord/brain) and recovered

- No prior total dose of radiotherapy more than 7,000 cGy

- No prior radiotherapy to 40% or more of total bone marrow

- No prior radiotherapy to only site of measurable disease

- No concurrent radiotherapy

- Recovered from prior therapy 1 prior adjuvant treatment allowed 1 prior treatment for advanced disease allowed

- At least 4 weeks since prior investigational agents

- No other concurrent investigational antineoplastic drugs

- No other concurrent investigational agents

- No concurrent commercial agents for colorectal cancer

- No concurrent combination antiretroviral therapy for HIV-positive patients

Overall Status: Completed
Phase: Phase 2

NCTID: NCT00005054
Intervention Type: Drug
Intervention Name: temozolomide
Title: Temozolomide in Treating Women With Advanced Breast Cancer
Condition: Breast Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS: Histologically proven advanced carcinoma of the breast with documented progression on first line chemotherapy Measurable disease Hormone receptor status: Not specified

PATIENT CHARACTERISTICS: Age: 18 and over Sex: Female Menopausal status: Not specified
Performance status: Not specified Life expectancy: Not specified Hematopoietic: Absolute neutrophil count at least 1,500/mm3 Platelet count at least 100,000/mm3 Hemoglobin at least 10 g/dL Hepatic: Bilirubin less than 1.5 times upper limit of normal (ULN) AST no greater than 3 times ULN Alkaline phosphatase less than 2 times ULN unless arising from bone Renal: Creatinine less than 1.5 times ULN Other: Not pregnant or nursing Negative pregnancy test Fertile patients must use effective contraception No other clinically significant disease that would interfere with study evaluations No uncontrolled vomiting that would preclude administration of oral medications HIV negative

PRIOR CONCURRENT THERAPY: Biologic therapy: At least 4 weeks since prior biologic therapy and recovered Chemotherapy: See Disease Characteristics At least 4 weeks since prior chemotherapy and recovered Endocrine therapy: Not specified

Radiotherapy: Recovered from
prior radiotherapy Surgery: Recovered from prior surgery Other: No other concurrent
experimental drugs
Overall Status: Unknown status
Phase: Phase 2

NCTID: NCT00005056
Intervention Type: Drug
Intervention Name: bryostatin 1
Title: Bryostatin 1 In Treating Patients With Progressive Kidney Cancer
Condition: Kidney Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS: Histologically proven progressive hypernephroma Bidimensionally
measurable disease with documented progression within 2 months prior to study entry Sites
of measurable or evaluable disease must be outside prior radiation ports No active
symptomatic CNS disease

PATIENT CHARACTERISTICS: Age: 18 and over Performance status: WHO 0-2 Life expectancy:
Greater than 3 months Hematopoietic: Granulocyte count greater than 1,500/mm3 Platelet
count greater than 100,000/mm3 Hepatic: Bilirubin less than 1.17 mg/dL SGOT or SGPT less
than 2.5 times normal Renal: Creatinine less than 1.70 mg/dL Other: No other prior or
concurrent malignancy except adequately treated cone biopsied carcinoma in situ of the
cervix or basal cell or squamous cell skin cancer No severe or uncontrolled nonmalignant
systemic disease that would make the patient a poor medical risk No uncontrolled active
infection Not pregnant or nursing Fertile patients must use effective contraception during
and for 4 weeks after study

PRIOR CONCURRENT THERAPY: Biologic therapy: At least 4 weeks since prior immunotherapy and
recovered Chemotherapy: No prior chemotherapy Endocrine therapy: At least 4 weeks since
prior endocrine therapy or steroids and recovered No concurrent systemic steroids
Radiotherapy: See Disease Characteristics At least 4 weeks since prior radiotherapy and
recovered No concurrent radiotherapy Surgery: Not specified
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00005055
Intervention Type: Drug
Intervention Name: glufosfamide
Title: Glufosfamide With of Without Hydration in Treating Patients With Advanced Non-small Cell Lung Cancer
Condition: Lung Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS: Histologically or cytologically confirmed non-small cell lung
cancer not amenable to curative surgery or radiotherapy Metastatic or inoperable locally
advanced progressive disease At least 1 target lesion accurately measurable in at least 1
dimension Longest diameter at least 20 mm with conventional techniques or at least 10 mm

with spiral CT scans Must have failed and completed 1 and only 1 platinum based regimen in
the first line setting for metastatic/inoperable locally advanced disease No symptomatic
brain metastases

PATIENT CHARACTERISTICS: Age: 18 and over Performance status: ECOG 0-2 Life expectancy: At
least 3 months Hematopoietic: Absolute neutrophil count at least 1,500/mm3 Platelet count
at least 100,000/mm3 Hepatic: Bilirubin less than 1.5 times upper limit of normal (ULN)
Alkaline phosphatase no greater than 2.5 times ULN (5 times ULN if liver metastases
present) SGOT/SGPT no greater than 2.5 times ULN (5 times ULN if liver metastases present)
Renal: Creatinine no greater than 1.7 mg/dL Creatinine clearance at least 60 mL/min
Cardiovascular: Clinically normal cardiac function No history of ischemic heart disease No
congestive heart failure within the past 6 months Normal 12 lead ECG Other: Not pregnant or
nursing Negative pregnancy test Fertile patients must use effective contraception No other
prior or concurrent malignancies except cone biopsied carcinoma of the cervix or adequately
treated basal or squamous cell skin carcinoma No unstable systemic diseases No active
uncontrolled infections No psychological, familial, sociological, or geographical condition
that would preclude study compliance and follow-up

PRIOR CONCURRENT THERAPY: Biologic therapy: No concurrent prophylactic filgrastim (G-CSF)
No concurrent prophylactic growth factors Chemotherapy: See Disease Characteristics At
least 4 weeks since prior chemotherapy Endocrine therapy: Not specified Radiotherapy: At
least 4 weeks since prior radiotherapy Concurrent radiotherapy allowed provided not all
target lesions are in irradiated field Surgery: At least 14 days since prior major surgery
Other: No other concurrent anticancer agents No other concurrent investigational therapy No
concurrent prophylactic antiemetics during course 1
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00005053
Intervention Type: Drug
Intervention Name: glufosfamide
Title: Glufosfamide With or Without Hydration in Treating Patients With Advanced Pancreatic Cancer
Condition: Pancreatic Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS: Histologically proven metastatic or inoperable locally advanced
pancreatic adenocarcinoma At least 1 target lesion accurately measurable in at least 1
dimension Longest diameter at least 20 mm with conventional techniques or at least 10 mm
with spiral CT scan No symptomatic brain metastases

PATIENT CHARACTERISTICS: Age: 18 and over Performance status: ECOG 0-2 Life expectancy: At

least 3 months Hematopoietic: Absolute neutrophil count at least 1,500/mm3 Platelet count
at least 100,000/mm3 Hepatic: Bilirubin less than 1.5 times upper limit of normal (ULN)
Alkaline phosphatase and transaminases no greater than 2.5 times ULN (no greater than 5
times ULN for liver metastases) Renal: Creatinine no greater than 1.7 mg/dL Creatinine
clearance at least 60 mL/min Cardiovascular: Normal cardiac function No history of ischemic
heart disease No history of congestive heart failure within the past 6 months Normal 12
lead electrocardiogram Other: Not pregnant or nursing Negative pregnancy test Fertile
patients must use effective contraception No other prior or concurrent malignancy, except:
Cone biopsied carcinoma of the cervix Adequately treated basal or squamous cell skin cancer
No unstable systemic disease No active uncontrolled infection No psychological, familial,
sociological, or geographical condition that would preclude study compliance

PRIOR CONCURRENT THERAPY: Biologic therapy: No concurrent prophylactic filgrastim (G-CSF)
No concurrent prophylactic growth factors Chemotherapy: No prior chemotherapy for
metastatic or advanced disease Endocrine therapy: Not specified Radiotherapy: At least 4
weeks since prior radiotherapy Concurrent radiotherapy allowed provided not all target
lesions are in irradiated field Surgery: At least 2 weeks since prior major surgery Other:
No other concurrent anticancer agents No other concurrent investigational therapy
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00005069
Intervention Type: Drug
Intervention Name: arsenic trioxide
Title: Arsenic Trioxide in Treating Patients With Metastatic Kidney Cancer
Condition: Kidney Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS: Histologically confirmed metastatic renal cell cancer
Bidimensionally measurable disease No brain metastases

PATIENT CHARACTERISTICS: Age: Not specified Performance status: Karnofsky 70-100% Life
expectancy: Greater than 3 months Hematopoietic: WBC at least 3,000/mm3 Absolute neutrophil
count at least 1,500/mm3 Platelet count at least 100,000/mm3 Hepatic: Bilirubin normal ALT
or AST no greater than 2.5 times upper limit of normal (ULN) Renal: Creatinine no greater
than 1.5 times ULN (no greater than 1.95 mg/dL at MSKCC) Other: Not pregnant or nursing
Negative pregnancy test Fertile patients must use effective contraception during and for 4
months after study No other prior malignancy unless curatively treated and disease free for
the past 5 years and considered low risk for recurrence

PRIOR CONCURRENT THERAPY: Biologic therapy: At least 4 weeks since prior

biologic therapy
and recovered No concurrent biologic therapy Chemotherapy: At least 4 weeks since prior
cytotoxic chemotherapy and recovered No other concurrent cytotoxic chemotherapy Endocrine
therapy: At least 4 weeks since prior hormonal therapy and recovered No concurrent hormonal
therapy Radiotherapy: At least 4 weeks since prior radiotherapy No concurrent radiotherapy
Surgery: At least 4 weeks since prior major surgery
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00005070
Intervention Type: Drug
Intervention Name: irofulven
Title: Irofulven in Treating Patients With Stage IVB or Recurrent Cervical Cancer
Condition: Cervical Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS: Histologically confirmed primary metastatic (stage IVB) or
recurrent cervical carcinoma not amenable to curative therapy Squamous Adenocarcinoma
Adenosquamous Bidimensionally measurable disease No active brain metastases

PATIENT CHARACTERISTICS: Age: Not specified Performance status: Karnofsky 70-100% Life
expectancy: Not specified Hematopoietic: Absolute neutrophil count at least 1,500/mm3
Platelet count at least 100,000/mm3 Hepatic: Bilirubin normal ALT/AST no greater than 2.5
times upper limit of normal (ULN) Renal: Creatinine no greater than 1.5 times ULN (1.95
mg/dL at MSKCC) OR Creatinine clearance at least 50 mL/min Cardiovascular: No New York
Heart Association class III or IV congestive heart failure No ECG evidence of acute
ischemia No significant conduction abnormality (e.g., bifascicular block, 2nd or 3rd degree
AV blocks) Other: Not pregnant or nursing Negative pregnancy test Fertile patients must use
effective contraception No other malignancy within the past 5 years and deemed low risk for
recurrence No other concurrent clinical circumstances that would compromise safety or
integrity of trial

PRIOR CONCURRENT THERAPY: Prior multimodality therapy at diagnosis allowed (i.e.,
concurrent chemotherapy and radiotherapy, neoadjuvant chemotherapy followed by surgery
and/or radiotherapy, adjuvant chemotherapy and/or radiotherapy following surgery, or
adjuvant chemotherapy following radiotherapy) Biologic therapy: Not specified Chemotherapy:
No prior chemotherapy for metastatic or recurrent disease Endocrine therapy: Not specified
Radiotherapy: At least 4 weeks since prior radiotherapy Surgery: At least 4 weeks since
prior major surgery
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00005120
Intervention Type: Drug
Intervention Name: Calanolide A
Title: The Safety and Effectiveness of (+)-Calanolide A in HIV-Infected Patients Who Have Never Taken Anti-HIV Drugs
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Patients may be eligible for this study if they:

- Are at least 18 years old.
- Agree to use effective methods of birth control during the study.
- Have a CD4 cell count of 200 cells/mm3 or more.
- Have HIV levels of 5000 copies/ml or more.

Exclusion Criteria

Patients will not be eligible for this study if they:

- Have abnormal blood tests.
- Have had a reaction to study medication.
- Have a history of opportunistic (AIDS-related) infection or cancer.
- Are being treated for active pulmonary tuberculosis.
- Have a fever of 39 degrees C or more within 14 days of beginning study treatment.
- Are unable to take medications by mouth.
- Have an abnormal chest X-ray or ECG within 30 days of beginning study treatment.
- Have hepatitis, hemophilia, or other blood disorder.
- Have significant heart, stomach, intestinal, liver, nerve, or kidney problems.
- Have a condition which may affect ability to participate in this study, such as drug or alcohol abuse or a serious mental disorder.
- Have taken anti-HIV drugs in the past.
- Are taking certain medications.
- Have had a blood transfusion within the 3 months prior to entering the study.
- Have had radiation or chemotherapy within 16 days before the screening visit or plan to receive such treatment during the study.
- Are pregnant or breast-feeding.

Overall Status: Unknown status
Phase: Phase 1

NCTID: NCT00005091
Intervention Type: Drug

Intervention Name: exatecan mesylate
Title: DX-8951f in Treating Previously Untreated Patients With Stage IIIB or Stage IV Non-small Cell Lung Cancer
Condition: Lung Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS: Histologically or cytologically confirmed unresectable,
metastatic, or recurrent non-small cell lung cancer Stage IIIB or IV Measurable disease No
known brain metastases

PATIENT CHARACTERISTICS: Age: 18 and over Performance status: ECOG 0-2 Life expectancy: At
least 12 weeks Hematopoietic: Absolute neutrophil count greater than 1,500/mm3 Platelet
count greater than 100,000/mm3 Hepatic: Bilirubin no greater than 1.5 mg/dL SGOT or SGPT no
greater than 2 times upper limit of normal (ULN) (no greater than 5 times ULN if liver
metastases present) Renal: Creatinine no greater than 2.0 mg/dL Cardiovascular: No active
congestive heart failure Other: Not pregnant or nursing Negative pregnancy test Fertile
patients must use effective contraception No concurrent serious infection No other
malignancy within past 5 years except nonmelanomatous skin cancer No overt psychosis,
mental disability, or incompetence No life threatening illness

PRIOR CONCURRENT THERAPY: Biologic therapy: No concurrent biologic therapy Chemotherapy: No
prior chemotherapy No other concurrent chemotherapy Endocrine therapy: Not specified
Radiotherapy: No prior radiotherapy to greater than 25% of the bone marrow No concurrent
radiotherapy Surgery: No concurrent surgery Other: At least 28 days since prior
investigational drugs No other concurrent investigational drugs during or within 28 days
after final dose of study drug No concurrent drugs that induce or inhibit CYP3A enzyme
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00005096
Intervention Type: Drug
Intervention Name: docetaxel
Title: Docetaxel in Treating Patients With Stage II or Stage III Prostate Cancer
Condition: Prostate Cancer
Eligibility Criteria: Eligibility Criteria:

- Histologically confirmed adenocarcinoma of the prostate
- Potential candidate for radical prostatectomy
- Any of the following:
  - Clinical stage T3 patients
  - Serum PSA at least 20 ng/mL
  - Gleason score 8-10
  - Clinical T2 disease and either of the following:

- MRI evidence of seminal vesicle involvement

- Gleason 4+3 cancer with either 5 or 6 biopsies positive

- CALGB 0-1

- WBC greater than 3,000/mm3

- Hematocrit greater than 30%

- Platelet count greater than 100,000/mm3

- SGOT, total bilirubin within normal limits

- Signed Informed consent

Exclusion Criteria:

- No prior hormones, radiation or chemotherapy for prostate cancer

- Evidence of serious active infection

Overall Status: Completed
Phase: Phase 2

NCTID: NCT00005097
Intervention Type: Drug
Intervention Name: Polyphenon E and Placebo
Title: Green Tea Extract in Treating Patients With Actinic Keratosis
Condition: Non-melanomatous Skin Cancer
Eligibility Criteria: Inclusion Criteria:

1. participants multiple sites of actinic keratosis identified by clinical examination and the histologic confirmation of one lesion (Grade 1-3 as defined previously in "Clinical Grading") are eligible.

2. No history of invasive cancer within 5 years (though non-melanoma skin cancer, stage I cervical cancer, or chronic lymphocytic leukemia (CLL) stage 0 will not be reason to exclude a patient); no severe metabolic disorders or other life-threatening acute or chronic disease; no additional x-ray or chemotherapy anticipated.

3. Not requiring use of topical medications in areas being studied.

4. Subjects must meet the Southwest Oncology Group performance status criteria of 0 - 1 (0= fully active, able to carry on all pre-disease activities without restriction [Karnofsky scale 90 - 100]; 1 = restricted in physically strenuous activity, but ambulatory and able to carry out work of a light or sedentary nature, i.e. light housework or office work [Karnofsky scale 70 - 80]).

5. Signed informed consent approved by the local Human Subjects Committee (Institutional Review Board).

Exclusion Criteria:

1. Use of the following systemic or local therapies for the periods

specified, prior to
entry into the study:

Within 2 weeks: topical medications, e.g. corticosteroids, alpha-hydroxyacids
(glycolic acid, lactic acid) or retinoids (Retin-A) to the target lesions Within 4
weeks: systemic steroid therapy. Within 2 months: cryotherapy to the target lesions,
laser resurfacing, chemical peels, topical application of 5-fluorouracil (5-FU) or
masoprocol (Actinex) for treatment of actinic keratoses. Systemic treatment with
chemotherapeutic agents, psoralens, immunotherapy, retinoids (Tegison, Accutane).

2. Any medical condition which , in the opinion of the investigator, could preclude study
participation

3. Active infectious diseases such as tuberculosis (TB) or HIV that may affect the
patient systemically and may also affect the immune system. Localized, minor
infections such as sinusitis, uncomplicated urinary tract infection, otitis media,
etc. will not be criteria for exclusion from the study.

4. Use of any investigational drug in the previous 30 days.

5. Any history of keloid formation.

6. Pregnant or nursing patients.

7. Participants who may be unreliable for the study, including those engaging in
excessive alcohol intake or drug abuse, or participants who are unable to return for
scheduled follow-up visits
Overall Status: Terminated
Phase: Phase 2

NCTID: NCT00005594
Intervention Type: Drug
Intervention Name: ISIS 2503
Title: ISIS 2503 in Treating Patients With Advanced Cancer of the Pancreas
Condition: Pancreatic Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS: Histologically confirmed advanced adenocarcinoma of the pancreas
that is considered inoperable Measurable disease with at least 1 lesion measuring at least
2 cm in widest diameter identifiable on CT or MRI scan

PATIENT CHARACTERISTICS: Age: 18 and over Performance status: ECOG 0-1 Life expectancy: Not
specified Hematopoietic: Absolute neutrophil count greater than 1,500/mm3 Platelet count
greater than 100,000/mm3 Hepatic: Bilirubin no greater than 2.0 mg/dL Renal: Creatinine no
greater than 2.0 mg/dL Other: Not pregnant or nursing Negative pregnancy test Fertile
patients must use effective barrier contraception during and for 6 months after study No
underlying disease state associated with active bleeding No active

infection requiring
therapy No other prior malignancy within the past 5 years except nonmelanoma skin cancer

PRIOR CONCURRENT THERAPY: Biologic therapy: No concurrent biologic therapy for pancreatic
cancer Chemotherapy: No prior chemotherapy for pancreatic cancer except for fluorouracil
and/or gemcitabine administered as a radiosensitizer No other concurrent chemotherapy for
pancreatic cancer Endocrine therapy: Not specified Radiotherapy: Prior radiotherapy allowed
provided indicator lesions not within prior radiation port Recovered from toxicity No
concurrent radiotherapy for pancreatic cancer Surgery: See Disease Characteristics Other:
No concurrent anticoagulation therapy with heparin No other concurrent approved or
experimental cancer therapy
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00005614
Intervention Type: Drug
Intervention Name: Gemcitabine hydrochloride
Title: Management of Metastatic Breast Cancer in Frail Patients
Condition: Breast Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS: Metastatic breast cancer Measurable disease No progression after 3
or more different forms of chemotherapy Hormone receptor positive breast cancer must be
refractory to at least two forms of hormonal treatment (including antiestrogen, aromatase
inhibitor, and/or progestin) unless there is life threatening metastases (e.g.,
lymphangitic metastases to the lung or liver metastases) Must meet at least one of the
following characteristics for frailty: ECOG 2-4 Dependence in at least one activity of
daily living 85 and over History of three or more falls in the past 6 months Mild dementia
(must be oriented in time, space, and location) Three or more comorbid conditions Hormone
receptor status: Not specified

PATIENT CHARACTERISTICS: Age: 65 and over Sex: Female Menopausal status: Not specified
Performance status: See Disease Characteristics Life expectancy: Greater than 12 weeks
Hematopoietic: Absolute neutrophil count at least 1,500/mm3 Platelet count at least
100,000/mm3 Neutropenia or thrombocytopenia secondary to myelophthisis from breast cancer
allowed Hepatic: Increased bilirubin allowed Renal: Renal insufficiency allowed
Cardiovascular: Congestive heart failure allowed Other: No known allergy to gemcitabine

PRIOR CONCURRENT THERAPY: Biologic therapy: Not specified Chemotherapy: See Disease
Characteristics Endocrine therapy: See Disease Characteristics Radiotherapy: At least 4
weeks since prior radiotherapy to bony areas or CNS metastases Surgery: Not specified

Other: Concurrent bisphosphonates allowed No concurrent participation in other
investigational studies
Overall Status: Withdrawn
Phase: Phase 2

NCTID: NCT00005618
Intervention Type: Drug
Intervention Name: arsenic trioxide
Title: Arsenic Trioxide in Treating Patients With Relapsed or Refractory Chronic Myelogenous Leukemia
Condition: Leukemia
Eligibility Criteria: DISEASE CHARACTERISTICS: Chronic myelogenous leukemia (CML) confirmed by: Cytogenetic
testing demonstrating presence of t(9:22) OR RT-PCR demonstrating presence of BCR/ABL
rearrangement Chronic phase Blast count less than 15% OR Accelerated phase defined by 1 or
more of the following: Blast count greater than 15% but less than 30% Blast count and
promyelocytes greater than 30% Basophils greater than 20% Thrombocytopenia less than
100,000/mm3 not related to therapy Cytogenetic clonal evolution (13) OR Blastic phase Blast
count greater than 30% OR Evidence of extramedullary blasts Relapse from or failure to
achieve a major cytogenetic response to at least 1 course of standard anti-CML therapy
including interferon alfa or cytotoxic chemotherapy Must have failed adequate trial of
interferon alfa unless intolerance to or contraindication to interferon alfa Not eligible
for allogeneic stem cell transplant

PATIENT CHARACTERISTICS: Age: Not specified Performance status: Karnofsky 70-100% Life
expectancy: Not specified Hematopoietic: See Disease Characteristics Hepatic: Bilirubin no
greater than 1.5 times upper limit of normal (ULN) Renal: Creatinine no greater than 1.5
times ULN Other: Not pregnant or nursing Negative pregnancy test Fertile patients must use
effective contraception during and for 4 months after study No active serious infections
that are not controlled by antibiotics

PRIOR CONCURRENT THERAPY: Biologic therapy: See Disease Characteristics At least 4 weeks
since prior interferon alfa Chemotherapy: See Disease Characteristics At least 4 weeks
since prior chemotherapy (1 day for hydroxyurea) No other concurrent chemotherapy Endocrine
therapy: Not specified Radiotherapy: No concurrent radiotherapy Surgery: Not specified
Other: No other concurrent investigational agents
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00005646
Intervention Type: Drug
Intervention Name: paclitaxel
Title: Paclitaxel in Treating Patients With Extensive-Stage Small Cell Lung Cancer
Condition: Lung Cancer

Eligibility Criteria: DISEASE CHARACTERISTICS: Histologically or cytologically confirmed extensive stage small
cell carcinoma of the bronchus Extrathoracic metastatic disease, malignant pleural
effusion, bilateral or contralateral supraclavicular adenopathy or contralateral hilar
adenopathy Measurable disease One lesion that measures at least 20 mm in diameter using
conventional techniques or at least 10 mm with spiral CT scan Lesions not considered
measurable include: Bone lesions Leptomeningeal disease Ascites Pleural/pericardial
effusion Cystic lesions Tumor lesions situated in a previously irradiated area Abdominal
masses not confirmed and followed by imaging techniques No disease restricted to one
hemithorax with regional lymph node metastases, including hilar, ipsilateral and
contralateral mediastinal, and/or ipsilateral supraclavicular nodes

PATIENT CHARACTERISTICS: Age: 18 and over Performance status: CTC 0-2 Life expectancy: Not
specified Hematopoietic: Granulocyte count at least 1,500/mm3 Platelet count at least
100,000/mm3 Hepatic: SGOT less than 2 times upper limit of normal Bilirubin less than 1.5
mg/dL Renal: Not specified Other: Not pregnant or nursing Fertile patients must use
effective contraception

PRIOR CONCURRENT THERAPY: Biologic therapy: Not specified Chemotherapy: No prior
chemotherapy Endocrine therapy: No concurrent hormonal therapy except steroids for renal
failure or hormones administered for nondisease related conditions Radiotherapy: At least
two weeks since prior radiotherapy No concurrent palliative radiotherapy Surgery: Not
specified
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00003179
Intervention Type: Drug
Intervention Name: medroxyprogesterone
Title: Surgery Plus Medroxyprogesterone in Preventing Endometrial Cancer
Condition: Endometrial Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS:

- Histologically confirmed atypical endometrial hyperplasia with recommended treatment
with either:

- An immediate hysterectomy (Part A) OR

- A three-month delay prior to hysterectomy and a randomized choice of treatment
with oral medroxyprogesterone acetate (Provera) or medroxyprogesterone acetate
suspension (Depo-Provera) during the 3 months (Part B with arms I and II)

- Diagnosed by dilation and curettage, Novak curettage, Vabra aspirate or Pipelle

endometrial biopsy

- No recognized endometrial carcinoma
- Must not be considered inoperable

PATIENT CHARACTERISTICS:

Age:

- Not specified

Performance status:

- GOG 0-2

Life expectancy:

- Not specified

Hematopoietic:

- WBC at least 3,000/mm^3
- Platelet count at least 100,000/mm^3
- Granulocyte count at least 1,500/mm^3

Hepatic:

- Bilirubin no greater than 1.5 times normal
- SGOT no greater than 3 times normal
- Alkaline phosphatase no greater than 3 times normal

Renal:

- Creatinine no greater than 2 times normal

Cardiovascular

- No prior thrombophlebitis or thromboembolic phenomena
- No prior cerebrovascular disorders

Other:

- No prior or concurrent malignancy except nonmelanoma skin cancer or carcinoma in situ of the uterine cervix
- Not pregnant or nursing
- Negative pregnancy test
- Fertile patients must use effective contraception

PRIOR CONCURRENT THERAPY:

Biologic therapy:

- Not specified

Chemotherapy:

- Not specified

Endocrine therapy:

- See Disease Characteristics

Radiotherapy:

- Not specified

Surgery:

- See Disease Characteristics

Overall Status: Terminated
Phase: Phase 2

NCTID: NCT00003220
Intervention Type: Drug
Intervention Name: bryostatin 1
Title: Bryostatin 1 in Treating Patients With Metastatic Colorectal Cancer
Condition: Colorectal Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS: Histologically or cytologically confirmed colorectal cancer
Unresectable disease Measurable disease No uncontrolled brain metastases

PATIENT CHARACTERISTICS: Age: Any age Performance status: SWOG 0-2 Life expectancy: At
least 12 weeks Hematopoietic: Absolute neutrophil count at least 1,500/mm3 Platelet count
at least 100,000/mm3 Hepatic: Bilirubin no greater than 1.5 times upper limit of normal
(ULN) AST no greater than 2.5 times ULN Renal: Creatinine no greater than 1.5 times ULN
Other: No active infection Not pregnant or nursing Negative pregnancy test for
premenopausal women Fertile patients must use effective contraception No concurrent
uncontrolled systemic disorders No prior malignant disease within the past year except in
situ carcinoma of the cervix or curatively treated basal cell carcinoma of the skin No
history of allergy to bryostatin 1 or its vehicle

PRIOR CONCURRENT THERAPY: Biologic therapy: No concurrent immunotherapy Chemotherapy: Only
one prior chemotherapy regimen in the adjuvant or metastatic setting allowed At least 3
weeks since prior chemotherapy (6 weeks for nitrosoureas) No other concurrent chemotherapy
Endocrine therapy: No concurrent hormonal therapy (except contraceptives, appetite
stimulants and replacement steroids) Radiotherapy: At least 3 weeks since prior
radiotherapy No concurrent radiation therapy No concurrent palliative radiation therapy to
only site of measurable disease Surgery: Not specified Other: At least 1 month since prior
use of any other investigational agent No concurrent use of experimental medications
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00003219
Intervention Type: Drug
Intervention Name: perillyl alcohol
Title: Perillyl Alcohol in Treating Patients With Metastatic Breast Cancer
Condition: Breast Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS: Microscopically confirmed metastatic breast cancer Must be
refractory or have recurred after at least 1 systemic chemotherapy regimen Estrogen
receptor positive tumors must have failed or recurred after hormonal therapy At least 1
site of measurable disease required Previously radiated lesions are not considered
measurable unless there is evidence of disease progression after completion of radiation
therapy No known brain metastases Hormone receptor status: Unspecified

PATIENT CHARACTERISTICS: Age: 18 and over Menopausal status: Not specified Performance
status: Zubrod 0-2 Life expectancy: At least 12 weeks Hematopoietic: WBC at least 4000/mm3
Platelet count at least 100,000/mm3 Absolute neutrophil count at least 1500/mm3 Hepatic:
Bilirubin no greater than 1.5 mg/dL SGOT no greater than 2 times normal Renal: Creatinine
no greater than 1.5 mg/dL BUN no greater than 30 mg/dL Other: Effective birth control must
be used by fertile patients (barrier method preferred) Not pregnant or nursing

PRIOR CONCURRENT THERAPY: Recovered from toxic effects of prior treatment Biologic therapy:
No immunologic therapy within the past 2 weeks Chemotherapy: No chemotherapy within the
past 4 weeks (6 weeks for mitomycin or nitrosoureas) See Disease Characteristics Endocrine
therapy: No hormonal therapy within the past 2 weeks See Disease Characteristics
Radiotherapy: No radiotherapy within the past 4 weeks See Disease Characteristics Surgery:
Not specified Other: No concurrent cholesterol lowering agents, supplemental vitamins, or
other antioxidants
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00003205
Intervention Type: Drug
Intervention Name: bryostatin 1
Title: Bryostatin 1 in Treating Patients With Stage IV Breast Cancer
Condition: Breast Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS:

- Unequivocal diagnosis of metastatic breast cancer

- Bidimensionally measurable disease

- No uncontrolled CNS metastases

- No disease that is evaluable only, including blastic bone disease, malignant ascites,
and malignant pleural effusion

- Hormone receptor status:

- Not specified

PATIENT CHARACTERISTICS:

Age:

- 18 and over

Menopausal status:

- Not specified

Performance status:

- SWOG 0-2 OR
- Karnofsky 60-100%

Life expectancy:

- At least 18 weeks

Hematopoietic:

- Platelet count at least 50,000/mm^3
- PT and PTT within normal limits
- Neutrophil count at least 2,000/mm^3

Hepatic:

- Bilirubin no greater than 1.2 mg/dL
- Transaminases no greater than 3 times normal

Renal:

- Creatinine no greater than 1.6 mg/dL OR
- Creatinine clearance at least 70 mL/min

Other:

- No active infections requiring antibiotics
- No viral hepatitis allowed
- Seronegative for hepatitis B or C
- Not pregnant or nursing
- Fertile patients must use effective contraception during and for 2 months following study participation

PRIOR CONCURRENT THERAPY:

Biologic therapy:

- No concurrent immunotherapy

Chemotherapy:

- 2 prior chemotherapy regimens for metastatic disease allowed as adjuvant therapy or for advanced disease (may include high dose chemotherapy with stem cell support)

- At least 4 weeks since prior chemotherapy

- At least 6 weeks since prior nitrosourea or mitomycin therapy

- No other concurrent chemotherapy

Endocrine therapy:

- 2 prior hormonal therapy regimens for metastatic disease as adjuvant therapy or for advanced diseases allowed

- At least 2 weeks since prior hormonal therapy (at least 4 weeks in case of disease progression while receiving hormonal therapy after initial response)

- No concurrent hormonal therapy except oral contraceptives

- No concurrent use of steroids except for management of severe or life- threatening toxic effects arising from bryostatin 1

Radiotherapy:

- At least 2 weeks since prior radiotherapy

- No concurrent radiotherapy

Surgery:

- Not specified

Other:

- No concurrent use of drugs known to interfere with platelet function, such as aspirin or NSAIDs (including ibuprofen)

- No concurrent use of anticoagulants

- At least 2 weeks since prior use of aspirin

- At least 2 days since prior use of NSAIDS

- Concurrent use of acetaminophen to control pain is allowed

- If acetaminophen inadequate for pain control, concurrent use of oral narcotics such as codeine or oxycodone is allowed

Overall Status: Completed
Phase: Phase 2

NCTID: NCT00003223
Intervention Type: Drug
Intervention Name: fenretinide
Title: SWOG-9507, Fenretinide in Treating Patients With Neoplasia of the Mouth
Condition: Head and Neck Cancer

Eligibility Criteria: DISEASE CHARACTERISTICS: Histologically proven oral mucosal intraepithelial neoplasia Stage
II: moderate dysplasia, keratosis with atypia Stage III: severe keratinizing or
nonkeratinizing dysplasia No myelodysplastic syndrome No retinopathies

PATIENT CHARACTERISTICS: See General Eligibility Criteria

PRIOR CONCURRENT THERAPY: Biologic therapy: No concurrent biologic therapy Chemotherapy: No
concurrent chemotherapy Endocrine therapy: No concurrent endocrine therapy Radiotherapy: No
concurrent radiotherapy Surgery: Prior surgical ablation of prior dysplastic sites allowed
Other: At least 2 months since prior therapy toxicities Patient Characteristics-- Age: Not
specified Performance Status: SWOG 0-1 Life Expectancy: Not specified Hematopoietic: Not
specified Hepatic: Not specified Renal: Not specified Other: Not pregnant or nursing
Negative pregnancy test Fertile patients must use effective contraception at least 1 month
before, during, and at least 2 months after study
Overall Status: Terminated
Phase: Phase 2

NCTID: NCT00003230
Intervention Type: Drug
Intervention Name: paclitaxel
Title: Paclitaxel in Treating Patients With Refractory or Recurrent Acute Leukemia or Chronic Myelogenous Leukemia
Condition: Leukemia
Eligibility Criteria: DISEASE CHARACTERISTICS: Histologically confirmed acute myelogenous leukemia (AML), acute
lymphoblastic leukemia (ALL) of B-cell or T-cell type, or blast crisis of chronic
myelogenous leukemia (CML) Must fulfill one of the following criteria: - Newly diagnosed,
previously untreated AML or ALL in elderly patients (65 75) - First or subsequent relapse
of AML or ALL after standard chemotherapy, autologous or allogeneic bone marrow
transplantation, or high-dose treatment with peripheral blood stem cell support - AML or
ALL that is refractory to standard chemotherapy (no complete remission achieved after 2
courses of conventional induction chemotherapy) - CML in blast crisis of any subtype (i.e.,
myelogenous or lymphoblastic) with or without previously known chronic phase No leukemic
involvement of the central nervous system

PATIENT CHARACTERISTICS: Age: 18 to 75 Performance status: WHO 0-3 Life expectancy: Not
specified Hematopoietic: Not specified Hepatic: Bilirubin less than 1.25 times upper limit
of normal (ULN) Renal: Creatinine less than 1.25 times ULN Cardiovascular: No history of
atrial or ventricular arrhythmias No history of congestive heart failure, even if medically
controlled No history of documented myocardial infarction Neurologic: No motor or sensory
neuropathy grade 2 or more No dementia or significantly altered mental status Other: HIV

negative No active infection or other serious underlying medical condition No prior
allergic reaction to a drug containing Cremophor EL No complete bowel obstruction Not
pregnant or nursing Adequate contraception required of all fertile patients

PRIOR CONCURRENT THERAPY: Biologic therapy: No required concurrent cytoreductive treatment
in addition to paclitaxel No concurrent growth factors or cytokine No concurrent
immunotherapeutic drugs Chemotherapy: No prior paclitaxel or related compounds for a
malignancy other that leukemia No required concurrent cytoreductive treatment in addition
to paclitaxel Endocrine therapy: Not specified Radiotherapy: Not specified Surgery: Not
specified
Overall Status: Completed
Phase: Phase 1/Phase 2

NCTID: NCT00003238
Intervention Type: Drug
Intervention Name: perillyl alcohol
Title: Perillyl Alcohol in Treating Patients With Metastatic Prostate Cancer That Has Not Responded to Hormone Therapy
Condition: Prostate Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS: Histologically confirmed progressive metastatic or progressive
regional nodal adenocarcinoma of the prostate Regression of tumor following hormone therapy
If on antiandrogen therapy, must fail to respond to withdrawal or have progressive disease
following withdrawal of antiandrogen No CNS disease

PATIENT CHARACTERISTICS: Age: Not specified Performance status: WCCC 0-2 Life expectancy:
At least 3 months Hematopoietic: WBC at least 3000/mm3 Absolute neutrophil count at least
1200/mm3 Platelet count at least 100,000/mm3 Hemoglobin at least 8 g/dL Hepatic: Bilirubin
no greater than 1.5 mg/dL SGOT no greater than 2.5 times normal Renal: Creatinine no
greater than 1.5 times upper limit of normal Other: At least 5 years since prior malignancy
other than: Inactive nonmelanoma skin cancer Adequately treated stage I or II cancer in
complete remission No other serious illness No spinal cord compression symptoms

PRIOR CONCURRENT THERAPY: Biologic therapy: Not specified Chemotherapy: Prior chemotherapy
required Endocrine therapy: Failed one secondary hormonal manipulation for metastatic
disease Concurrent testicular androgen suppression (LHRH) allowed No concurrent hormonal
therapy other than LHRH agonist At least 4 weeks since antiandrogen treatment in order to
evaluate for response withdrawal Radiotherapy: At least 4 weeks since prior radiation
therapy No prior strontium therapy Surgery: No prior orchiectomy Other: No concurrent
cholesterol lowering agents No concurrent supplemental vitamins No concurrent antioxidants

Overall Status: Completed
Phase: Phase 2

NCTID: NCT00003259
Intervention Type: Drug
Intervention Name: vinorelbine tartrate
Title: Vinorelbine in Treating Patients With Metastatic Prostate Cancer
Condition: Prostate Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS: Histologically or cytologically proven metastatic stage IV
prostate cancer Proven hormonal resistance Measurable or evaluable disease PSA at least 3
times upper limit of normal No leptomeningeal or brain metastases

PATIENT CHARACTERISTICS: Age: 18 to 85 Performance status: WHO 0-2 Life expectancy: Greater
than 12 weeks Hematopoietic: WBC at least 3500/mm3 OR Granulocyte count at least 2000/mm3
Hemoglobin at least 9 g/dL Platelet count at least 100,000/mm3 Hepatic: Bilirubin no
greater than 1.5 times upper limit of normal (ULN) SGOT no greater than 2.5 times ULN
Renal: Creatinine no greater than 1.5 times ULN Other: No acute severe infections No other
neoplastic diseases except curatively treated basal cell or squamous cell carcinoma of the
skin, or relapse free for more than 5 years after curative treatment of a neoplasm

PRIOR CONCURRENT THERAPY: Biologic therapy: Not specified Chemotherapy: No prior cytostatic
chemotherapy Endocrine therapy: At least 1 month since antiandrogens Prior hormonal therapy
required Radiotherapy: No radiotherapy within the past 4 weeks No radiotherapy to the
lesions used to evaluate activity of the study drug Surgery: Prior orchiectomy allowed
Other: No other investigational drugs during the last month No prior therapy with
cytostatic agents
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00003256
Intervention Type: Drug
Intervention Name: alvocidib
Title: Flavopiridol in Treating Patients With Recurrent Prostate Cancer
Condition: Prostate Cancer
Eligibility Criteria: PATIENT CHARACTERISTICS:

- Performance Status: ECOG 0-2
- Life Expectancy: At least 3 months
- WBC at least 3,000/mm3
- Absolute neutrophil count at least 1,200/mm3
- Platelet count at least 100,000/mm3
- Hemoglobin at least 8 g/dL
- Bilirubin no greater than 1.5 mg/dL

- SGOT no greater than 2.5 times normal

- Creatinine no greater than 1.5 mg/dL

- Prostate-specific antigen at least 10 ng/mL (if bone only disease)

- No prior or concurrent maligancies within 5 years, except nonmelanoma skin cancer

- No serious medical illness

- No cord compression symptoms

PRIOR CONCURRENT THERAPY:

- No prior chemotherapy

- No prior suramin therapy

- Prior or concurrent use of luteinizing hormone-releasing hormone allowed (no other concurrent hormonal therapy)

- No prior anti-androgen therapy within 4 weeks of study

- At least 4 weeks since prior radiotherapy

- No prior strontium therapy

Overall Status: Completed
Phase: Phase 2

NCTID: NCT00003276
Intervention Type: Drug
Intervention Name: irinotecan hydrochloride
Title: Irinotecan in Treating Patients With Advanced Gallbladder or Bile Duct Cancer
Condition: Gallbladder Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS: Histologically or cytologically proven gallbladder or bile duct carcinoma with metastatic or recurrent disease deemed unresectable and not considered a candidate for potentially curative therapy Measurable or evaluable disease No known active CNS disease Closed to bile duct carcinoma as of July 1999

PATIENT CHARACTERISTICS: Age: 18 and over Performance status: ECOG 0-2 Life expectancy: At least 12 weeks Hematopoietic: Absolute neutrophil count at least 1500/mm3 Platelet count at least 100,000/mm3 Hepatic: SGOT no greater than 5 times upper limit of normal (ULN) Bilirubin no greater than 1.5 mg/dL OR Bilirubin no greater than 2 times ULN in patients with biliary stents or percutaneous biliary catheters Renal: Creatinine no greater than 1.5 mg/dL Cardiovascular: No New York Heart Association class III or IV heart disease Other: Nutritional intake at least 1200 kcal/day No uncontrolled infection or chronic debilitating disease Not pregnant or nursing Fertile patients must use effective contraception No uncontrolled seizure disorder No prior malignancy within 5 years except adequately treated basal cell/squamous cell carcinomas and adequately treated noninvasive

carcinomas

PRIOR CONCURRENT THERAPY: Biologic therapy: No prior biological therapy or immunotherapy for recurrent or metastatic disease No concurrent biologic therapy Chemotherapy: No prior chemotherapy for recurrent or metastatic disease Prior adjuvant chemotherapy allowed if used as a radiation sensitizer for completely resected disease No other concurrent chemotherapy Endocrine therapy: Not specified Radiotherapy: No prior radiotherapy for recurrent or metastatic disease Prior adjuvant radiotherapy allowed if used as a radiation sensitizer for completely resected disease No radiotherapy to greater than 25% of bone marrow No radiotherapy within the past 4 weeks No concurrent radiotherapy Concurrent CNS radiation allowed Surgery: No post abdominal exploration (with or without resection) within the past 4 weeks Other: No concurrent medication for other medical conditions except for: Analgesics Chronic treatments for preexisting conditions Agents required for life-threatening medical conditions No laxatives
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00003326
Intervention Type: Drug
Intervention Name: paclitaxel
Title: Paclitaxel in Treating Patients With Metastatic, Recurrent, or Unresectable Cancer of the Esophagus
Condition: Esophageal Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS: Histologically proven metastatic, locally recurrent, or unresectable squamous cell carcinoma or adenocarcinoma of the esophagus The bulk of the tumor must involve the esophagus or gastroesophageal (GE) junction (for tumors extending between the GE junction into the proximal stomach) Gastric cancers with only minor GE junction or distal esophagus involvement are not eligible Measurable or evaluable disease No prior treatment for metastatic disease No brain metastases No osseous metastases as only site of disease

PATIENT CHARACTERISTICS: Age: 18 and over Performance status: ECOG 0-2 Life expectancy: At least 3 months Hematopoietic: Absolute granulocyte count at least 1,500/mm3 Platelet count at least 100,000/mm3 Hepatic: Bilirubin no greater than 2 mg/dL AST or ALT no greater than 2 times upper limit of normal (ULN) Renal: Creatinine no greater than 2 times ULN Calcium no greater than 12 mg/dL Cardiovascular: No New York Heart Association class III/IV heart disease No myocardial infarction within 6 months of study No congestive heart failure No unstable angina No clinically significant pericardial effusion or arrhythmia Neurologic: No concurrent peripheral neuropathy greater than grade 1 Other: Not pregnant or nursing

Negative pregnancy test Fertile patients must use effective contraception No active serious infection or medical illness No history of hypersensitivity to drugs containing Cremophor (teniposide, cyclosporine, or vitamin K) No invasive malignancies within 5 years, except: Curatively treated basal or squamous cell carcinoma of the skin Curatively treated carcinoma in situ of the cervix

PRIOR CONCURRENT THERAPY: Biologic therapy: No prior immunotherapy within 4 weeks of study No concurrent immunotherapy Chemotherapy: No more than 1 prior chemotherapy regimen or chemotherapy/radiation therapy given in a neoadjuvant or adjuvant setting No prior chemotherapy within 4 weeks of study No concurrent chemotherapy Endocrine therapy: No prior hormonal therapy within 4 weeks of study Concurrent megestrol (Megace) allowed No other concurrent hormonal therapy Radiotherapy: No prior radiotherapy within 4 weeks of study No prior radiation to greater than 30% of bone marrow No more than 1 prior chemotherapy/radiation therapy regimen given in a neoadjuvant or adjuvant setting No concurrent radiotherapy Surgery: No prior surgery within 2 weeks of study Other: No prior parenteral antibiotics within 1 week of study
Overall Status: Unknown status
Phase: Phase 2

NCTID: NCT00003327
Intervention Type: Drug
Intervention Name: paclitaxel
Title: Paclitaxel in Treating Patients With Recurrent or Refractory Head and Neck Cancer
Condition: Head and Neck Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS: Histologically proven recurrent or refractory head and neck cancer Measurable or evaluable disease At least one prior chemotherapy regimen for recurrent or metastatic disease

PATIENT CHARACTERISTICS: Age: 18 and over Performance status: ECOG 0-2 Life expectancy: At least 3 months Hematopoietic: Absolute granulocyte count at least 1,500/mm3 Platelet count at least 100,000/mm3 Hepatic: Bilirubin no greater than 2 mg/dL AST or ALT no greater than 2 times upper limit of normal (ULN) Renal: Creatinine no greater than 2 times ULN Calcium within normal limits Cardiovascular: No New York Heart Association class III-IV heart disease No myocardial infarction within 6 months No congestive heart failure No unstable angina No clinically significant pericardial effusions or arrhythmias Neurologic: No peripheral neuropathy greater than grade 1 Other: Not pregnant or nursing Fertile patients must use effective contraceptive method Negative pregnancy test No active infection or serious underlying medical condition No history of hypersensitivity to drugs containing Cremophor (teniposide, cyclosporine, or vitamin K) No prior invasive

malignancies within
the past 2 years, except: Curatively treated basal or squamous cell carcinoma of the skin
Carcinoma in situ of the cervix

PRIOR CONCURRENT THERAPY: Biologic therapy: At least 3 weeks since prior immunotherapy No
concurrent immunotherapy Chemotherapy: See Disease Characteristics At least 5 weeks since
prior nitrosoureas, melphalan, or mitomycin At least 3 weeks since other prior chemotherapy
Prior taxane therapy allowed only if administered on a 3 week or greater schedule No
concurrent chemotherapy Endocrine therapy: At least 3 weeks since prior hormonal therapy
Concurrent megestrol (Megace) allowed No other concurrent hormonal therapy Radiotherapy: At
least 3 weeks since prior radiotherapy No prior radiotherapy to greater than 30% of bone
marrow No concurrent radiotherapy Surgery: At least 3 weeks since major surgery Other: At
least 1 week since prior parenteral antibiotics
Overall Status: Unknown status
Phase: Phase 2

NCTID: NCT00003351
Intervention Type: Drug
Intervention Name: irinotecan hydrochloride
Title: Irinotecan in Treating Patients With Refractory Metastatic Breast Cancer
Condition: Breast Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS: Histologically confirmed adenocarcinoma of the breast with
progressing locoregional or metastatic disease Measurable or evaluable indicator lesion No
uncontrolled CNS metastases

PATIENT CHARACTERISTICS: Age: 18 and over Performance status: ECOG 0-2 Life expectancy:
Greater than 3 months Hematopoietic: Absolute neutrophil count at least 1,500/mm3 Platelet
count at least 100,000/mm3 Hepatic: Bilirubin no greater than 0.3 mg/dL above upper limit
of normal (ULN) AST no greater than 3 times ULN Renal: Creatinine no greater than 1.0 mg/dL
above ULN Cardiovascular: No New York Heart Association class III or IV heart disease
Other: No uncontrolled infection No chronic debilitating disease Not pregnant or lactating
Fertile patients must use effective contraception

PRIOR CONCURRENT THERAPY: Biologic therapy: Not specified Chemotherapy: At least 4 weeks
since chemotherapy No more than 2 prior chemotherapy regimens for metastatic disease No
more than 1 prior chemotherapy regimen in the adjuvant setting At least 1 prior regimen
containing taxane or doxorubicin for metastatic disease or in the adjuvant setting
Endocrine therapy: Not specified Radiotherapy: No radiotherapy to greater than 25% of bone
marrow No prior treatment with strontium 89 Surgery: At least 4 weeks since major surgery
Other: No concurrent metoclopramide
Overall Status: Completed

Phase: Phase 2

NCTID: NCT00003390
Intervention Type: Drug
Intervention Name: irofulven
Title: 6-Hydroxymethylacylfulvene in Treating Patients With Metastatic Kidney Cancer
Condition: Kidney Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS: Histologically confirmed renal cell carcinoma and evidence of
metastatic disease Bidimensionally measurable disease No active brain metastases

PATIENT CHARACTERISTICS: Age: 18 and over Performance status: Karnofsky 70-100% Life
expectancy: Greater than 3 months Hematopoietic: WBC at least 3,000/mm3 Absolute neutrophil
count at least 1,500/mm3 Platelet count at least 100,000/mm3 Hepatic: Bilirubin within
normal range ALT/AST no greater than 2.5 times upper limit of normal (ULN) Renal:
Creatinine within 1.5 times ULN AND Creatinine clearance at least 50 mL/min Other: Not
pregnant or lactating Fertile patients must use effective contraception No prior malignancy
within 5 years and at low risk for recurrence Must have undergone potentially curative
therapy for prior malignancy

PRIOR CONCURRENT THERAPY: Biologic therapy: At least 4 weeks since biological therapy and
recovered Chemotherapy: No prior cytotoxic chemotherapy Endocrine therapy: At least 4 weeks
since hormone therapy and recovered Radiotherapy: At least 4 weeks since radiotherapy
Surgery: At least 4 weeks since major surgery
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00003424
Intervention Type: Drug
Intervention Name: tamoxifen citrate
Title: Tamoxifen in Treating Patients With Primary Liver Cancer
Condition: Liver Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS: Histologically or radiologically confirmed inoperable
hepatocellular carcinoma Serum alfa-feto protein level at least 500 ug/L OR Positive
lipiodol uptake

PATIENT CHARACTERISTICS: Age: 10 to 90 Performance status: ECOG 0-3 Life expectancy: Not
specified Hematopoietic: Not specified Hepatic: Not specified Renal: Creatinine less than
1.7 mg/dL Other: No encephalopathy

PRIOR CONCURRENT THERAPY: Biologic therapy: Not specified Chemotherapy: No prior
chemoembolization therapy for disease No prior systemic chemotherapy for disease Endocrine
therapy: Not specified Radiotherapy: Not specified Surgery: No prior surgery for disease
Other: No prior percutaneous injection
Overall Status: Completed

Phase: Phase 3

NCTID: NCT00003428
Intervention Type: Drug
Intervention Name: arzoxifene hydrochloride
Title: Hormone Therapy in Treating Women With Breast Cancer
Condition: Breast Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS: Histologically proven locally advanced or metastatic breast cancer
and meeting one of the following criteria: No prior systemic therapy OR Relapsed more than
12 months after stopping adjuvant tamoxifen (tamoxifen- sensitive) OR Relapsed while
receiving adjuvant tamoxifen for more than 12 months (tamoxifen-refractory) OR Disease
progression while receiving tamoxifen as first-line treatment for metastatic breast cancer
(tamoxifen-refractory) Evaluable or bidimensionally measurable disease No rapid disease
progression requiring chemotherapy Brain metastases allowed if stable for at least 6 months
after surgery or radiotherapy, with no increase in corticosteroids Hormone receptor status:
Estrogen receptor positive AND/OR Progesterone receptor positive OR Unknown status allowed
if over 50 years old

PATIENT CHARACTERISTICS: Age: 18 and over Sex: Female Menopausal status: Not specified
Performance status: ECOG 0-1 Life expectancy: At least 24 weeks Hematopoietic: Granulocyte
count at least 1500/mm3 Platelet count at least 100,000/mm3 Hemoglobin at least 9 g/dL,
transfusion independent Hepatic: Bilirubin no greater than 1.5 times normal PT/PTT no
greater than 1.25 times upper limit of normal (ULN) ALT/AST no greater than 2.5 times ULN
Renal: Creatinine less than 1.5 times ULN Calcium no greater than 11 mg/dL No hypercalcemia
Other: Not pregnant or nursing Fertile patients must use approved nonhormonal contraceptive
during and for 3 months after study No known predisposition to thromboembolic disorder At
least 5 years since other primary malignancy except: Adequately treated nonmelanomatous
skin cancer Carcinoma in situ of the cervix No serious concurrent systemic disorders
incompatible with study

PRIOR CONCURRENT THERAPY: Biologic therapy: No concurrent immunotherapy Concurrent
hematopoietic growth factor allowed Chemotherapy: No prior chemotherapy for metastatic
breast cancer No concurrent chemotherapy Endocrine therapy: No prior hormonal therapy for
metastatic breast cancer (except tamoxifen) No concurrent supplemental estrogen or
progesterone At least 3 weeks since prior estrogen replacement therapy No other concurrent
hormone therapy Radiotherapy: At least 2 weeks since prior radiotherapy Surgery: Not
specified Other: At least 4 weeks since prior use of other investigational agents
Concurrent bisphosphonate therapy allowed No other concurrent

investigational agent
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00003443
Intervention Type: Drug
Intervention Name: bryostatin 1
Title: Bryostatin 1 in Treating Patients With Metastatic or Recurrent Head and Neck Cancer
Condition: Head and Neck Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS: Histologically confirmed metastatic or recurrent squamous cell
carcinoma of the oral cavity, lip, hypopharynx, oropharynx, nasopharynx, paranasal sinuses,
nasal cavity, nostril, or larynx that is not curable by surgery or radiation therapy Must
have one or more measurable indicator lesions Bone metastases, brain metastases, elevated
enzyme levels and lesions on radionuclide scans are not acceptable as the sole parameters
of measurable disease

PATIENT CHARACTERISTICS: Age: 18 and over Performance status: Karnofsky 60-100% Life
expectancy: Not specified Hematopoietic: WBC greater than 4,000/mm3 Platelet count greater
than 100,000/mm3 Hepatic: Bilirubin less than 1.5 mg/dL Transaminases (SGOT/SGPT) less than
2.5 times upper limit of normal Renal: Creatinine less than 1.5 mg/dL OR Creatinine
clearance at least 50 mL/min Cardiovascular: No unstable cardiac rhythm Other: No active
infection requiring antibiotics No concurrent medical condition that makes participation in
this study medically unsafe No other prior malignancy in the last 2 years except basal or
squamous cell carcinoma of the skin, carcinoma in situ of the cervix, or
metachronous/synchronous epidermoid/squamous cell cancers of the head and neck Not pregnant
or nursing Effective contraception required of all fertile patients

PRIOR CONCURRENT THERAPY: Biologic therapy: Not specified Chemotherapy: One prior
chemotherapy regimen as part of a locoregional treatment (e.g., induction/concomitant)
allowed, either as primary treatment or as therapy for locoregional relapse, if relapse
occurred more than 6 months later No other prior chemotherapy Prior chemoprevention agents
(e.g., cisretinoic acid or other vitamin analogues) allowed Endocrine therapy: Not
specified Radiotherapy: See Disease Characteristics At least 4 weeks since prior
radiotherapy No prior radiotherapy to more than 50% of bone marrow-bearing bones Surgery:
See Disease Characteristics
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00003441
Intervention Type: Drug
Intervention Name: Irofulven (MGI-114)
Title: Irofulven in Treating Patients With Metastatic Colorectal Cancer
Condition: Colorectal Cancer

Eligibility Criteria: DISEASE CHARACTERISTICS: Histologically confirmed metastatic adenocarcinoma of the colon or rectum Bidimensionally measurable lesions Sentinel lesions outside the field of any prior radiation therapy No confirmed or suspected brain metastases

PATIENT CHARACTERISTICS: Age: 18 and over Performance status: Zubrod 0-1 Life expectancy: At least 12 weeks Hematopoietic: Granulocyte count at least 1,500/mm3 Platelet count at least 100,000/mm3 Hepatic: Bilirubin no greater than 1.5 mg/dL Renal: Creatinine no greater than 1.5 mg/dL Creatinine clearance at least 60 mL/min Cardiovascular: No active congestive heart failure No uncontrolled angina At least 6 months since prior myocardial infarction No uncontrolled hypertension Other: Not pregnant or nursing Negative pregnancy test Fertile patients must use effective contraception No concurrent serious infection No other malignancy within the past 5 years except nonmelanoma skin cancer or carcinoma in situ of the cervix No overt psychosis or mental disability No life threatening illness (unrelated to tumor)

PRIOR CONCURRENT THERAPY: Biologic therapy: No concurrent biologic therapy Chemotherapy: No prior chemotherapy for metastatic disease At least 6 months since prior adjuvant chemotherapy No other concurrent chemotherapy Endocrine therapy: Not specified Radiotherapy: See Disease Characteristics At least 4 weeks since prior radiation therapy and recovered No concurrent radiotherapy Surgery: At least 4 weeks since prior major surgery and recovered No concurrent surgery Other: At least 28 days since prior administration of any investigational drug No other concurrent anticancer therapy
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00003452
Intervention Type: Drug
Intervention Name: Antineoplaston therapy (Atengenal + Astugenal)
Title: Antineoplastons A10 and AS2-1 In Patients With Carcinoma of the Bladder
Condition: Stage IV Bladder Cancer
Eligibility Criteria: Inclusion Criteria:

- Histologically confirmed stage IV bladder carcinoma that is unlikely to respond to existing therapy and for which no curative therapy exists or stage IV newly diagnosed, incurable bladder carcinoma

- Measurable disease by CT scan

- Tumor must be greater than 2 cm at the largest diameter for the lymph nodes located in the head, neck, axillary, inguinal, or femoral areas and at least 0.5 cm in the largest diameter for other localizations

- 18 and over
- Karnofsky 60-100%
- Life expectancy: greater than 2 months
- WBC at least 2,000/mm^3
- Platelet count at least 50,000/mm^3
- Bilirubin no greater than 2.5 mg/dL
- SGOT/SGPT no greater than 5 times upper limit of normal
- No hepatic failure
- Creatinine no greater than 2.5 mg/dL
- No history of renal conditions that contraindicate high dosages of sodium
- No severe heart disease
- No uncontrolled hypertension
- No history of congestive heart failure
- No history of other cardiovascular conditions that contraindicate high dosages of sodium
- No severe lung disease
- Not pregnant or nursing
- Fertile patients must use effective contraception during and for 4 weeks after study participation
- No serious active infections or fever
- No other serious concurrent disease
- At least 4 weeks since prior immunotherapy and recovered
- No concurrent immunomodulating agents
- At least 4 weeks since prior chemotherapy (6 weeks for nitrosoureas) and recovered
- Concurrent corticosteroids allowed
- At least 8 weeks since prior radiotherapy and recovered
- Recovered from any prior operative procedure
- Prior cytodifferentiating agent allowed

Exclusion Criteria:

- Prior antineoplaston therapy

Overall Status: Terminated
Phase: Phase 2

NCTID: NCT00003445
Intervention Type: Drug
Intervention Name: docetaxel
Title: Docetaxel in Treating Patients With Advanced Cancer of the Cervix
Condition: Cervical Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS: Histologically proven stage IIB, IIIA, IIIB, and IVA squamous cell
carcinoma of the cervix Bidimensionally measurable disease No bilateral hydronefrosis

PATIENT CHARACTERISTICS: Age: Any age Performance status: WHO 0-2 Life expectancy: At least
12 weeks Hematopoietic: Hemoglobin at least 10 g/dL Leukocytes at least 4,000/mm3 Platelet
count at least 75,000/mm3 Hepatic: Bilirubin less than 1.25 times upper limit of normal
(ULN) AST less than 1.25 times ULN Renal: BUN less than 30 mg/dL AND Creatinine less than
1.5 mg/dL OR Creatinine clearance at least 60 mL/min Other: No prior or other concurrent
malignancies, other than properly treated basal cell skin cancer

PRIOR CONCURRENT THERAPY: Not specified
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00003454
Intervention Type: Drug
Intervention Name: Antineoplaston therapy (Atengenal + Astugenal)
Title: Antineoplaston Therapy in Treating Women With Stage IV Breast Cancer
Condition: Stage IV Breast Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS:

- Histologically confirmed stage IV breast cancer that is unlikely to respond to
existing therapy and for which no curative therapy exists
  - Must have failed prior standard therapy
- Measurable disease by MRI or CT scan
- Tumor must be at least 2 cm in the lymph nodes in the head, neck, axillary, inguinal,
or femoral areas and at least 0.5 cm in other locations
- Hormone receptor status:
  - Not specified

PATIENT CHARACTERISTICS:

Age:

- 18 and over

Sex:

- Female

Menopausal Status:

- Not specified

Performance status:

- Karnofsky 60-100%

Life expectancy:

- At least 2 months

Hematopoietic:

- WBC at least 2,000/mm^3
- Platelet count at least 50,000/mm^3

Hepatic:

- Bilirubin nor greater than 2.5 mg/dL
- SGOT/SGPT no greater than 5 times upper limit of normal
- No hepatic failure

Renal:

- Creatinine no greater than 2.5 mg/dL
- No history of renal conditions that contraindicate high dosages of sodium

Cardiovascular:

- No chronic heart failure
- No uncontrolled hypertension
- No history of congestive heart failure
- No history of other cardiovascular conditions that contraindicate high dosages of sodium

Pulmonary:

- No severe lung disease, such as chronic obstructive pulmonary disease

Other:

- Not pregnant or nursing
- Fertile patients must use effective contraception during and for 4 weeks after study participation
- No serious medical or psychiatric disorders
- No active infections
- No other serious concurrent disease

PRIOR CONCURRENT THERAPY:

Biologic therapy:

- At least 4 weeks since prior immunotherapy, except in patients with

disease
progression during or after initial therapy

- Recovery from prior immunotherapy

- No concurrent immunomodulating agents

Chemotherapy:

- At least 4 weeks since prior chemotherapy (6 weeks for nitrosoureas), except in
patients with disease progression during or after initial therapy

- Recovery from prior chemotherapy

- No concurrent antineoplastic agents

Endocrine therapy:

- At least 12 weeks since prior hormonal therapy, except in patients with disease
progression during and after initial therapy

- Concurrent corticosteroids allowed

- Recovery from prior hormonal therapy

Radiotherapy:

- At least 8 weeks since prior radiotherapy and recovered (patients with multiple tumors
who have received radiotherapy to some, but not all, tumors may be admitted earlier
than 8 weeks)

Surgery:

- Recovered from any prior surgery

Other:

- No prior antineoplaston therapy

- Prior cytodifferentiating agent allowed
Overall Status: Terminated
Phase: Phase 2

NCTID: NCT00003491
Intervention Type: Drug
Intervention Name: Antineoplaston therapy (Atengenal + Astugenal)
Title: Antineoplaston Therapy in Treating Patients With Stage IV Lung Cancer
Condition: Stage IV Lung Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS:

- Histologically confirmed stage IV adenocarcinoma of the lung that is unlikely to
respond to existing therapy and for which no curative therapy exists

- Measurable disease by MRI or CT scan

PATIENT CHARACTERISTICS:

Age:

- 18 and over

Performance status:

- Karnofsky 60-100%

Life expectancy:

- At least 2 months

Hematopoietic:

- WBC at least 2,000/mm^3
- Platelet count at least 50,000/mm^3

Hepatic:

- No hepatic insufficiency
- Bilirubin no greater than 2.5 mg/dL
- SGOT/SGPT no greater than 5 times upper limit of normal

Renal:

- Creatinine no greater than 2.5 mg/dL
- No renal insufficiency
- No history of renal conditions that contraindicate high dosages of sodium

Cardiovascular:

- No chronic heart disease that would preclude study treatment
- No history of chronic heart failure
- No uncontrolled hypertension
- No history of congestive heart failure
- No history of cardiovascular conditions that contraindicate high dosages of sodium

Pulmonary:

- No lung disease that would preclude study treatment
- No serious lung disease (e.g., severe chronic obstructive pulmonary disease)

Neurologic:

- No neurological disease that would preclude study treatment

Other:

- Not pregnant or nursing
- Fertile patients must use effective contraception during and for 4 weeks after study

participation

- No gastrointestinal or psychiatric disease that would preclude study treatment

- No active infection

PRIOR CONCURRENT THERAPY:

Biologic therapy:

- At least 4 weeks since prior immunotherapy and recovered

- No concurrent immunomodulatory agents

Chemotherapy:

- At least 4 weeks since prior chemotherapy (6 weeks for nitrosoureas) and recovered

- No concurrent antineoplastic agents

Endocrine therapy:

- Concurrent corticosteroids allowed

Radiotherapy:

- At least 8 weeks since prior radiotherapy and recovered

Surgery:

- Not specified

Other:

- Prior cytodifferentiating agents allowed

- No prior antineoplaston therapy

Overall Status: Terminated
Phase: Phase 2

NCTID: NCT00003492
Intervention Type: Drug
Intervention Name: Antineoplaston therapy (Atengenal + Astugenal)
Title: Antineoplaston Therapy in Treating Patients With Stage IV Lung Cancer
Condition: Stage IV Lung Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS:

- Histologically confirmed large cell, undifferentiated, or poorly differentiated stage IV lung cancer unlikely to have a curative response to existing standard regimens

- Measurable disease by MRI or CT scan

  - At least 2 cm in diameter

PATIENT CHARACTERISTICS:

Age:

- 18 and over

Performance status:

- Karnofsky 60-100%

Life expectancy:

- At least 2 months

Hematopoietic:

- WBC at least 2,000/mm^3
- Platelet count at least 50,000/mm^3

Hepatic:

- Bilirubin no greater than 2.5 mg/dL
- SGOT/SGPT no greater than 5 times upper limit of normal
- No hepatic failure

Renal:

- Creatinine no greater than 2.5 mg/dL
- No renal insufficiency
- No history of renal conditions that contraindicate high dosages of sodium

Cardiovascular:

- No severe heart disease
- No uncontrolled hypertension
- No history of congestive heart failure
- No history of other cardiovascular conditions that contraindicate high dosages of sodium

Pulmonary:

- No severe lung disease (e.g., chronic obstructive pulmonary disease)

Other:

- Not pregnant or nursing
- Fertile patients must use effective contraception during and for 4 weeks after study participation
- No serious active infections
- No other concurrent serious disease

PRIOR CONCURRENT THERAPY:

Biologic therapy:

- At least 4 weeks since prior immunotherapy and recovered

- No concurrent immunomodulating agent

Chemotherapy:

- At least 4 weeks since prior chemotherapy (6 weeks for nitrosoureas) and recovered

- No concurrent antineoplastic agent

Endocrine therapy:

- Concurrent corticosteroids allowed

Radiotherapy:

- At least 8 weeks since prior radiotherapy and recovered

Surgery:

- Recovered from prior surgery

Other:

- No prior antineoplaston therapy

- Prior cytodifferentiating agent allowed

Overall Status: Terminated
Phase: Phase 2

NCTID: NCT00003495
Intervention Type: Drug
Intervention Name: Antineoplaston therapy (Atengenal + Astugenal)
Title: Antineoplaston Therapy in Treating Patients With Recurrent or Stage IV Lung Cancer
Condition: Stage IV Lung Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS:

- Histologically confirmed recurrent or stage IV squamous cell lung cancer unlikely to have a curative response to existing standard regimens

- Measurable disease by MRI or CT scan

  - At least 2 cm in diameter

PATIENT CHARACTERISTICS:

Age:

- 18 and over

Performance status:

- Karnofsky 60-100%

Life expectancy:

- At least 2 months

Hematopoietic:

- WBC at least 2,000/mm3

- Platelet count at least 50,000/mm3

Hepatic:

- Bilirubin no greater than 2.5 mg/dL
- SGOT/SGPT no greater than 5 times upper limit of normal
- No hepatic failure

Renal:

- Creatinine no greater than 2.5 mg/dL
- No renal insufficiency
- No history of renal conditions that contraindicate high dosages of sodium

Cardiovascular:

- No severe heart disease
- No uncontrolled hypertension
- No history of congestive heart failure
- No history of other cardiovascular conditions that contraindicate high dosages of sodium

Pulmonary:

- No severe lung disease (e.g., chronic obstructive pulmonary disease)

Other:

- Not pregnant or nursing
- Fertile patients must use effective contraception during and for 4 weeks after study
- No serious active infections
- No other serious concurrent disease

PRIOR CONCURRENT THERAPY:

Biologic therapy:

- At least 4 weeks since prior immunotherapy and recovered
- No concurrent immunomodulating agents

Chemotherapy:

- At least 4 weeks since prior chemotherapy (6 weeks since nitrosoureas) and recovered
- No concurrent antineoplastic agents

Endocrine therapy:

- Concurrent corticosteroids allowed

Radiotherapy:

- At least 8 weeks since prior radiotherapy and recovered

Surgery:

- Recovered from prior surgery

Other:

- No prior antineoplaston therapy

- Prior cytodifferentiating agent allowed

Overall Status: Terminated
Phase: Phase 2

NCTID: NCT00003489
Intervention Type: Drug
Intervention Name: Antineoplaston therapy (Atengenal + Astugenal)
Title: Antineoplaston Therapy in Treating Patients With Advanced Head and Neck Cancer
Condition: Head and Neck Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS:

- Histologically confirmed cancer of the head and neck that is unlikely to respond to existing therapy and for which no curative therapy exists

  - Metastatic disease OR incurable with surgery or radiation

- Measurable disease by CT scan or MRI

  - Tumor must be at least 2 cm for the lymph nodes located in the head, neck, axillary, inguinal or femoral areas and at least 0.5 cm for other areas

PATIENT CHARACTERISTICS:

Age:

- 16 and over

Performance status:

- Karnofsky 60-100%

Life expectancy:

- At least 2 months

Hematopoietic:

- WBC at least 2,000/mm^3

- Platelet count at least 50,000/mm^3

Hepatic:

- No hepatic insufficiency

- Bilirubin no greater than 2.5 mg/dL
- SGOT and SGPT no greater than 2.5 mg/dL

Renal:

- No renal insufficiency
- Creatinine no greater than 2.5 mg/dL
- No renal conditions that contraindicate high dosages of sodium

Cardiovascular:

- No chronic heart failure
- No uncontrolled hypertension
- No history of congestive heart failure
- No other cardiovascular conditions that contraindicate high dosages of sodium

Pulmonary:

- No serious lung disease (e.g., severe chronic obstructive pulmonary disease)

Other:

- Not pregnant or nursing
- Fertile patients must use effective contraception during and for 4 weeks after study participation
- No other serious medical or psychiatric conditions
- No active infection

PRIOR CONCURRENT THERAPY:

Biologic therapy:

- At least 4 weeks since prior immunotherapy and recovered
- No concurrent immunomodulatory agents

Chemotherapy:

- At least 4 weeks since prior chemotherapy (6 weeks for nitrosoureas) and recovered
- No concurrent antineoplastic therapy

Endocrine therapy:

- Concurrent corticosteroids allowed

Radiotherapy:

- See Disease Characteristics
- At least 8 weeks since prior radiotherapy (unless multiple tumors)

and recovered

Surgery:

- See Disease Characteristics

Other:

- Prior cytodifferentiating agents allowed

Overall Status: Terminated
Phase: Phase 2

NCTID: NCT00003497
Intervention Type: Drug
Intervention Name: Antineoplaston therapy (Atengenal + Astugenal)
Title: Antineoplaston Therapy in Treating Patients With Stage IV Non-small Cell Lung Cancer
Condition: Stage IV Non-small Cell Lung Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS:

- Histologically confirmed stage IV non-small cell lung cancer that cannot be cured with existing therapeutic regimens
- Measurable disease by CT scan or MRI
  - Tumor must be at least 2 cm for the lymph nodes located in the head, neck, axillary, inguinal or femoral areas and at least 0.5 cm for other areas

PATIENT CHARACTERISTICS:

Age:

- 18 and over

Performance status

- Karnofsky 60-100%

Life expectancy:

- At least 2 months

Hematopoietic:

- WBC at least 2,000/mm^3
- Platelet count at least 50,000/mm^3

Hepatic:

- No hepatic insufficiency
- Bilirubin no greater than 2.5 mg/dL
- SGOT and SGPT no greater than 5 times upper limit of normal

Renal:

- No renal insufficiency
- Creatinine no greater than 2.5 mg/dL

Cardiovascular:

- No chronic heart failure
- No uncontrolled hypertension

Pulmonary:

- No serious lung disease (e.g., severe chronic obstructive pulmonary disease)

Other:

- Not pregnant or nursing
- Fertile patients must use effective contraception during and for 4 weeks after study participation
- No other serious medical or psychiatric conditions
- No active infection
- No serious malabsorption syndromes

PRIOR CONCURRENT THERAPY:

Biologic therapy:

- At least 4 weeks since prior immunotherapy and recovered

Chemotherapy:

- At least 4 weeks since prior chemotherapy (6 weeks for nitrosoureas) and recovered

Endocrine therapy:

- Concurrent corticosteroids allowed

Radiotherapy:

- At least 8 weeks since prior radiotherapy (less than 8 weeks if multiple tumors are involved) and recovered

Surgery:

- No prior extensive stomach or intestinal surgery
- Recovered from any prior surgery

Other:

- Prior cytodifferentiating agents allowed
- No prior antineoplaston treatment
- No other concurrent treatment for metastatic lung cancer

Overall Status: Terminated
Phase: Phase 2

NCTID: NCT00003516

Intervention Type: Drug
Intervention Name: Antineoplaston therapy (Atengenal + Astugenal)
Title: Antineoplaston Therapy in Treating Patients With Stage III or Stage IV Prostate Cancer
Condition: Prostate Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS:

- Histologically proven stage III or IV adenocarcinoma of the prostate not potentially curable by surgery or radiotherapy
- Measurable tumors or tumor markers
- No response to antiandrogen withdrawal

PATIENT CHARACTERISTICS:

Age:

- 18 and over

Performance status:

- Karnofsky 60-100%

Life expectancy:

- At least 3 months

Hematopoietic:

- WBC at least 3000/mm^3
- Platelet count at least 100,000/mm^3

Hepatic:

- Bilirubin no greater than 2.5 mg/dL
- SGOT no greater than 2 times normal
- No hepatic failure

Renal:

- BUN less than 60 mg/dL
- Creatinine no greater than 2.5 mg/dL OR
- Creatinine clearance greater than 60 mL/min
- Blood ammonia normal
- No chronic renal failure

Cardiovascular:

- No severe heart disease

Pulmonary:

- No severe lung disease

Other:

- Fertile patients must use effective contraception during and for 4 weeks after study participation

- No serious active infection or fever

- No other concurrent serious disease

- No other prior or concurrent malignancy within the past 2 years

PRIOR CONCURRENT THERAPY:

Biologic therapy:

- At least 4 weeks since prior immunotherapy and recovered

Chemotherapy:

- At least 4 weeks since prior chemotherapy and recovered

Endocrine therapy:

- At least 4 weeks since prior hormonal therapy and recovered

- Prior corticosteroids for at least 2 months allowed, but must be on stable or decreasing dose during study participation

Radiotherapy:

- See Disease Characteristics

- At least 4 weeks since prior radiotherapy and recovered

Surgery:

- See Disease Characteristics

- At least 4 weeks since prior surgery and recovered

Other:

- At least 4 weeks since prior experimental clinical trial

- No other concurrent therapy for metastatic disease

Overall Status: Terminated
Phase: Phase 2

NCTID: NCT00003496
Intervention Type: Drug
Intervention Name: Antineoplaston therapy (Atengenal + Astugenal)
Title: Antineoplaston Therapy in Treating Patients With Recurrent or Extensive-Stage Small Cell Lung Cancer
Condition: Small Cell Lung Cancer Extensive Stage
Eligibility Criteria: DISEASE CHARACTERISTICS:

- Histologically confirmed recurrent or extensive stage small cell lung cancer unlikely to have a curative response to existing standard regimens

- Measurable disease by MRI or CT scan

  - At least 2 cm in diameter

PATIENT CHARACTERISTICS:

Age:

- 18 and over

Performance status:

- Karnofsky 60-100%

Life expectancy:

- At least 2 months

Hematopoietic:

- WBC at least 2,000/mm^3
- Platelet count at least 50,000/mm^3

Hepatic:

- Bilirubin no greater than 2.5 mg/dL
- SGOT/SGPT no greater than 5 times upper limit of normal
- No hepatic failure

Renal:

- Creatinine no greater than 2.5 mg/dL
- No renal insufficiency
- No history of renal conditions that contraindicate high dosages of sodium

Cardiovascular:

- No severe heart disease
- No uncontrolled hypertension
- No history of congestive heart failure
- No history of other cardiovascular conditions that contraindicate high dosages of sodium

Pulmonary:

- No severe lung disease (e.g., chronic obstructive pulmonary disease)

Other:

- Not pregnant or nursing
- Fertile patients must use effective contraception during and for 4 weeks after study participation
- No active infections

- No other concurrent serious disease

PRIOR CONCURRENT THERAPY:

Biologic therapy:

- At least 4 weeks since prior immunotherapy and recovered

- No concurrent immunomodulating agents

Chemotherapy:

- At least 4 weeks since prior chemotherapy (6 weeks for nitrosoureas) and recovered

- No concurrent antineoplastic agents

Endocrine therapy:

- Concurrent corticosteroids allowed

Radiotherapy:

- At least 8 weeks since prior radiotherapy and recovered

Surgery:

- Recovered from prior surgery

Other:

- No prior antineoplaston therapy

- Prior cytodifferentiating agent allowed

Overall Status: Terminated
Phase: Phase 2

NCTID: NCT00003485
Intervention Type: Drug
Intervention Name: antineoplaston A10, antineoplaston AS2-1 (ANP)
Title: Antineoplaston Therapy in Treating Patients With Metastatic or Unresectable Colon Cancer
Condition: Colon Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS:

- Histologically confirmed adenocarcinoma of the colon that is unlikely to respond to existing therapy and for which no curative therapy exists

- Metastatic or unresectable disease

- Measurable disease by CT scan or MRI

PATIENT CHARACTERISTICS:

Age:

- 18 and over

Performance status:

- Karnofsky 60-100%

Life expectancy:

- At least 2 months

Hematopoietic:

- WBC at least 2,000/mm^3
- Platelet count at least 50,000/mm^3

Hepatic:

- Bilirubin no greater than 2.5 mg/dL
- SGOT/SGPT no greater than 5 times upper limit of normal
- No hepatic failure

Renal:

- Creatinine no greater than 2.5 mg/dL
- No renal failure
- No history of renal conditions that contraindicate high dosages of sodium

Cardiovascular:

- No chronic heart failure
- No uncontrolled hypertension
- No history of congestive heart failure
- No history of other cardiovascular conditions that contraindicate high dosages of sodium

Pulmonary:

- No serious lung disease, such as chronic obstructive pulmonary disease

Other:

- Not pregnant or nursing
- Fertile patients must use effective contraception during and for 4 weeks after study participation
- No active infection
- No other serious concurrent disease

PRIOR CONCURRENT THERAPY:

Biologic therapy:

- At least 4 weeks since prior immunotherapy and recovered
- No concurrent immunomodulatory agents

Chemotherapy:

- At least 4 weeks since prior chemotherapy (6 weeks for nitrosoureas) and recovered

- No concurrent antineoplastic agents

Endocrine therapy:

- Concurrent corticosteroids allowed

Radiotherapy:

- At least 8 weeks since prior radiotherapy and recovered (patients with multiple tumors may be admitted earlier)

Surgery:

- Recovered from prior surgery

Other:

- Prior cytodifferentiating agent allowed

- No prior antineoplaston therapy

Overall Status: Terminated
Phase: Phase 2

NCTID: NCT00003551
Intervention Type: Drug
Intervention Name: aminocamptothecin colloidal dispersion
Title: Aminocamptothecin in Treating Patients With Advanced or Recurrent Kidney Cancer
Condition: Kidney Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS: Histologically proven stage III, stage IV, or recurrent renal cell carcinoma Measurable disease No brain metastases

PATIENT CHARACTERISTICS: Age: 18 and over Performance status: ECOG 0-2 Life expectancy: At least 3 months Hematopoietic: Platelet count at least 100,000/mm3 Absolute neutrophil count at least 1500/mm3 Hemoglobin at least 9.0 g/dL Hepatic: Bilirubin no greater than 1.5 mg/dL ALT and AST no greater than 2.5 times the institutional normal values Renal: Creatinine no greater than 1.5 mg/dL Other: Not pregnant or nursing Fertile patients must use effective contraception No uncontrolled systemic infection No other prior or concurrent malignancies except nonmelanoma skin cancer, carcinoma in situ of the cervix, or ductal carcinoma in situ of the breast that have been curatively treated No evidence of delirium, confusion, suicidal ideation, or untreated depression

PRIOR CONCURRENT THERAPY: Biologic therapy: At least 30 days since prior cytokines and recovered No more than 1 prior treatment with cytokines (interleukin-2 or interferons) Chemotherapy: No prior cytotoxic chemotherapy No prior aminocamptothecin No other concurrent antineoplastic agents Endocrine therapy: At least 30 days

since prior hormone
therapy and recovered No more than 1 prior hormone therapy (tamoxifen or
medroxyprogesterone) Radiotherapy: Prior radiotherapy allowed if
indicator lesion and
greater than 15% of marrow producing bone have not been irradiated
Surgery: Recovered from
prior surgery Other: At least 30 days since other investigational agents
No concurrent
investigational agents
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00003522
Intervention Type: Drug
Intervention Name: Antineoplaston therapy (Atengenal + Astugenal)
Title: Antineoplaston Therapy in Treating Patients With Cancer of the Small
Intestine
Condition: Small Intestine Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS:

- Histologically proven incurable and/or metastatic carcinoma of the
small intestine
that is unlikely to respond to existing therapy

- Measurable disease by MRI or CT scan

- Tumor must be greater than 2 cm

PATIENT CHARACTERISTICS:

Age:

- 18 and over

Performance status:

- Karnofsky 60-100%

Life expectancy:

- At least 2 months

Hematopoietic:

- WBC at least 2,000/mm^3

- Platelet count at least 50,000/mm^3

Hepatic:

- No hepatic insufficiency

- Bilirubin no greater than 2.5 mg/dL

- SGOT and SGPT no greater than 5 times upper limit of normal

Renal:

- No renal insufficiency

- Creatinine no greater than 2.5 mg/dL

- No history of renal conditions that contraindicate high dosages of
sodium

Cardiovascular:

- No known chronic heart failure
- No uncontrolled hypertension
- No history of congestive heart failure
- No history of other cardiovascular conditions that contraindicate high dosages of sodium

Pulmonary:

- No serious lung disease, such as chronic obstructive pulmonary disease

Other:

- Not pregnant or nursing
- Fertile patients must use effective contraception during and for 4 weeks after study participation
- Not high medical or psychiatric risk
- No concurrent nonmalignant systemic disease
- No active infection

PRIOR CONCURRENT THERAPY:

Biologic therapy:

- At least 4 weeks since prior immunotherapy and recovered
- No concurrent immunomodulating agents

Chemotherapy:

- At least 4 weeks since prior chemotherapy (6 weeks for nitrosoureas) and recovered

Endocrine therapy:

- Concurrent corticosteroids allowed

Radiotherapy:

- At least 8 weeks since prior radiotherapy and recovered

Surgery:

- Recovered from prior surgery

Other:

- Prior cytodifferentiating agents allowed
- No other concurrent antineoplastic agents

Overall Status: Terminated
Phase: Phase 2

NCTID: NCT00003534
Intervention Type: Drug
Intervention Name: Antineoplaston therapy (Atengenal + Astugenal)
Title: Antineoplaston Therapy in Treating Patients With Refractory Stage IV Prostate Cancer
Condition: Stage IV Prostate Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS:

- Histologically confirmed incurable stage IV adenocarcinoma of the prostate that failed to respond to treatment with antineoplaston A10 and AS2-1 capsules and for which no curative therapy exists
  - Evidence of tumor by MRI or CT scan
- No prostate-specific antigen (PSA) response to antiandrogen withdrawal
- If PSA changes used to indicate progressive disease, then PSA must increase more than 50% on two determinations at least 2 weeks apart

PATIENT CHARACTERISTICS:

Age:

- 18 and over

Performance status:

- Karnofsky 60-100%

Life expectancy:

- At least 2 months

Hematopoietic:

- Hemoglobin at least 9 g/dL
- WBC at least 2000/mm^3
- Platelet count at least 50,000/mm^3

Hepatic:

- No hepatic insufficiency
- Bilirubin no greater than 2.5 mg/dL
- SGOT and SGPT no greater than 5 times upper limit of normal

Renal:

- Creatinine no greater than 2.5 mg/dL
- No history of renal conditions that contraindicate high dosages of sodium

Cardiovascular:

- No known chronic heart failure

- No uncontrolled hypertension

- No history of congestive heart failure

- No history of other cardiovascular conditions that contraindicate high dosages of sodium

Pulmonary:

- No serious lung disease, such as severe chronic obstructive pulmonary disease

Other:

- Fertile patients must use effective contraception during and for 4 weeks after study participation

- Not a high medical or psychiatric risk

- No concurrent nonmalignant systemic disease that would preclude therapy

- No active infection

PRIOR CONCURRENT THERAPY:

Biologic therapy:

- At least 4 weeks since prior immunotherapy and recovered

Chemotherapy:

- At least 4 weeks since prior chemotherapy and recovered

Endocrine therapy:

- See Disease Characteristics

- At least 4 weeks since prior hormonal therapy and recovered

- Concurrent corticosteroids allowed if dose is stable or decreasing

Radiotherapy:

- At least 4 weeks since prior radiotherapy and recovered

Surgery:

- Recovered from prior surgery

Other:

- Prior cytodifferentiating agents allowed

Overall Status: Withdrawn
Phase: Phase 2

NCTID: NCT00003520
Intervention Type: Drug
Intervention Name: Antineoplaston therapy (Atengenal + Astugenal)
Title: Antineoplaston Therapy in Treating Patients With Stage IV Kidney Cancer
Condition: Stage IV Kidney Cancer

Eligibility Criteria: DISEASE CHARACTERISTICS:

- Histologically confirmed stage IV adenocarcinoma or transitional cell carcinoma of the kidney that is unlikely to respond to existing therapy
- Measurable disease by MRI or CT scan
- Tumor must be more than 2 cm for lymph nodes in head, neck, axillary, inguinal, or femoral areas and at least 0.5 cm for other locations

PATIENT CHARACTERISTICS:

Age:

- 18 and over

Performance status:

- Karnofsky 60-100%

Life expectancy:

- At least 2 months

Hematopoietic:

- WBC at least 2,000/mm^3
- Platelet count at least 50,000/mm^3

Hepatic:

- No hepatic insufficiency
- Bilirubin no greater than 2.5 mg/dL
- SGOT and SGPT no greater than 5 times upper limit of normal

Renal:

- No renal insufficiency
- Creatinine no greater than 2.5 mg/mL
- No history of renal conditions that contraindicate high dosages of sodium

Cardiovascular:

- No known chronic heart failure
- No uncontrolled hypertension
- No history of congestive heart failure
- No history of other cardiovascular conditions that contraindicate high dosages of sodium

Pulmonary:

- No severe lung disease, such as chronic obstructive pulmonary

disease

Other:

- Not pregnant or nursing

- Fertile patients must use effective contraception during and for 4 weeks after study participation

- Not a high medical or psychiatric risk

- No concurrent nonmalignant systemic disease that would preclude therapy

- No active infection

PRIOR CONCURRENT THERAPY:

Biologic therapy:

- At least 4 weeks since prior immunotherapy

- No concurrent immunomodulatory agents

Chemotherapy:

- At least 4 weeks since prior chemotherapy (6 weeks for nitrosoureas) and recovered

- No concurrent antineoplastic agents

Endocrine therapy:

- Concurrent corticosteroids allowed

Radiotherapy:

- At least 8 weeks since prior radiotherapy and recovered

Surgery:

- Recovered from prior surgery

Other:

- Prior cytodifferentiating agents allowed

- No prior antineoplastons

Overall Status: Terminated
Phase: Phase 2

NCTID: NCT00003540
Intervention Type: Drug
Intervention Name: gemcitabine hydrochloride
Title: Gemcitabine in Treating Women With Metastatic Breast Cancer Previously Treated With Doxorubicin and Paclitaxel
Condition: Breast Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS:

- Histologically confirmed metastatic breast cancer

- Bidimensionally measurable disease

- No bone scan abnormalities alone
- Lytic lesions in conjunction with bone scan abnormalities allowed
- No pure blastic bone metastases
- No pleural or peritoneal effusions
- No previously irradiated lesions

- Must have received 2-4 prior chemotherapy regimens, including paclitaxel and doxorubicin, for breast cancer
- Brain metastases allowed if other measurable disease exists
  - No uncontrolled or life threatening brain lesions
- No carcinomatous meningitis
- Hormone receptor status:
  - Not specified

PATIENT CHARACTERISTICS:

Age:

- 18 and over

Sex:

- Female

Menopausal status:

- Not specified

Performance status:

- Karnofsky 60-100%

Life expectancy:

- Not specified

Hematopoietic:

- Granulocyte count at least 1,500/mm^3
- Platelet count at least 100,000/mm^3

Hepatic:

- AST/ALT no greater than 5 times upper limit of normal

Renal:

- Calcium no greater than 11.0 mg/dL

Other:

- Not pregnant

- Negative pregnancy test

- No history of other malignancy except carcinoma in situ of the cervix or curatively treated nonmelanoma skin cancer

- No other serious medical illnesses, including severe infection and severe malnutrition

PRIOR CONCURRENT THERAPY:

Biologic therapy:

- Not specified

Chemotherapy:

- See Disease Characteristics

- At least 4 weeks since prior chemotherapy (6 weeks for nitrosoureas and mitomycin) and recovered

- No other concurrent chemotherapy

Endocrine therapy:

- Prior hormonal therapies for stage IV disease and/or adjuvant therapy allowed

- At least 3 weeks since prior hormonal therapy

Radiotherapy:

- See Disease Characteristics

- No prior radiotherapy to greater than 30% of the marrow bearing bone

- At least 4 weeks since prior radiotherapy and recovered

- No concurrent radiotherapy to the only measurable lesion

Surgery:

- Recovered from prior surgery

- No concurrent surgery to the only measurable lesion

Other:

- No concurrent nonprotocol treatment

Overall Status: Completed
Phase: Phase 2

NCTID: NCT00003548
Intervention Type: Drug
Intervention Name: aminocamptothecin colloidal dispersion
Title: Aminocamptothecin in Treating Patients With Advanced Cancer of the Peritoneal Cavity
Condition: Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS: Histologically confirmed advanced malignancy involving the

peritoneal cavity, excluding leukemia and lymphoma Patients with ovarian cancer must have
received prior standard therapy Predominantly small tumor metastases less than 1.0 cm in
diameter including: Ovarian cancer with epithelial histology Other gynecological tumors
Breast cancer Gastric cancer Colorectal cancer Appendiceal cancer Pancreatic cancer Unknown
primary cancer Other malignancies with predominantly intraperitoneal manifestation No
extensive intraperitoneal adhesions that cannot be easily lysed laparoscopically or by
laparotomy No symptomatic disease outside the peritoneal cavity Asymptomatic disease
outside the peritoneum considered (e.g., bone lesions)

PATIENT CHARACTERISTICS: Age: 18 and over Performance status: ECOG 0-2 Life expectancy: At
least 3 months Hematopoietic: Neutrophil count at least 1,500/mm3 Platelet count at least
100,000/mm3 Hepatic: Bilirubin no greater than 2.0 mg/dL AST no greater than 2 times upper
limit of normal Renal: Creatinine no greater than 2.0 mg/dL Other: Not pregnant or nursing
Negative pregnancy test Fertile patients must use effective contraception

PRIOR CONCURRENT THERAPY: Biologic therapy: Not specified Chemotherapy: See Disease
Characteristics At least 3 weeks since prior chemotherapy (6 weeks for nitrosoureas and/or
mitomycin) Endocrine therapy: Not specified Radiotherapy: At least 3 weeks since prior
radiotherapy Surgery: See Disease Characteristics
Overall Status: Completed
Phase: Phase 1

NCTID: NCT00003530
Intervention Type: Drug
Intervention Name: Antineoplaston therapy (Atengenal + Astugenal)
Title: Antineoplaston Therapy in Treating Patients With Primary Liver Cancer
Condition: Primary Liver Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS:

- Histologically confirmed primary liver cancer that is unlikely to respond to existing
  therapy and for which no curative therapy exists

- Measurable disease by CT scan or MRI

- Tumor must be at least 2 cm

PATIENT CHARACTERISTICS:

Age:

- 14 and over

Performance status:

- Karnofsky 60-100%

Life expectancy:

- At least 2 months

Hematopoietic:

- WBC at least 2,000/mm3
- Platelet count at least 50,000/mm3

Hepatic:

- Bilirubin less than 3 mg/dL
- SGOT/SGPT no greater than 10 times upper limit of normal
- No hepatic failure

Renal:

- Creatinine no greater than 2.5 mg/dL
- No history of renal conditions that contraindicate high doses of sodium

Cardiovascular:

- No uncontrolled hypertension
- No known chronic heart failure
- No history of congestive heart failure
- No history of other cardiovascular conditions that contraindicate high doses of sodium

Pulmonary:

- No serious lung disease (e.g., chronic obstructive pulmonary disease)

Other:

- Not pregnant or nursing
- Fertile patients must use effective contraception for 4 weeks before study, during study, and for 4 weeks after study
- No serious medical or psychiatric disease
- No active infection

PRIOR CONCURRENT THERAPY:

Biologic therapy:

- At least 4 weeks since prior immunotherapy and recovered
- No concurrent immunomodulating agents

Chemotherapy:

- At least 4 weeks since prior chemotherapy (6 weeks for nitrosoureas) and recovered

- No concurrent antineoplastic agents

Endocrine therapy:

- Concurrent steroids allowed

Radiotherapy:

- At least 8 weeks since prior radiotherapy and recovered

Surgery:

- Recovered from prior surgery

Other:

- No prior antineoplaston therapy

- Prior cytodifferentiating agents allowed

Overall Status: Terminated
Phase: Phase 2

NCTID: NCT00003524
Intervention Type: Drug
Intervention Name: Antineoplaston therapy (Atengenal + Astugenal)
Title: Antineoplaston Therapy in Treating Patients With Stomach Cancer
Condition: Stomach (Gastric) Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS:

- Histologically proven adenocarcinoma of the stomach that is unlikely to respond to existing therapy, including surgery, radiotherapy, and chemotherapy

- Evidence of tumor by MRI, CT scan, chest x-ray, or radionuclide scan

PATIENT CHARACTERISTICS:

Age:

- 18 and over

Performance status:

- Karnofsky 60-100%

Life expectancy:

- At least 2 months

Hematopoietic:

- WBC at least 2,000/mm^3

- Platelet count at least 50,000/mm^3

Hepatic:

- No hepatic insufficiency

- Bilirubin no greater than 2.5 mg/dL

- SGOT and SGPT no greater than 5 times upper limit of normal

Renal:

- No renal insufficiency
- Creatinine no greater than 2.5 mg/dL
- No history of renal conditions that contraindicate high dosages of sodium

Cardiovascular:

- No known chronic heart failure
- No uncontrolled hypertension
- No history of congestive heart failure
- No history of other cardiovascular conditions that contraindicate high dosages of sodium

Pulmonary:

- No serious lung disease, such as chronic obstructive pulmonary disease

Other:

- Not pregnant or nursing
- Fertile patients must use effective contraception during and for 4 weeks after study participation
- Not a high medical or psychiatric risk
- No concurrent nonmalignant systemic disease
- No active infection

PRIOR CONCURRENT THERAPY:

Biologic therapy:

- At least 4 weeks since prior immunotherapy
- No concurrent immunomodulating agents

Chemotherapy:

- At least 4 weeks since prior chemotherapy (6 weeks for nitrosoureas) and recovered

Endocrine therapy:

- Concurrent corticosteroids allowed

Radiotherapy:

- At least 8 weeks since prior radiotherapy and recovered

Surgery:

- Recovered from prior surgery

Other:

- Prior cytodifferentiating agents allowed

- No other concurrent antineoplastic agents

Overall Status: Terminated
Phase: Phase 2

NCTID: NCT00003533
Intervention Type: Drug
Intervention Name: Antineoplaston therapy (Atengenal + Astugenal)
Title: Antineoplaston Therapy in Treating Patients With Metastatic Prostate Cancer
Condition: Metastatic Prostate Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS:

- Histologically proven incurable, metastatic, hormone-refractory adenocarcinoma of the prostate that is unlikely to respond to existing therapy

  - Evidence of tumor by MRI, CT scan, chest x-ray, or radionuclide scan

  - Stage D2

PATIENT CHARACTERISTICS:

Age:

- 18 and over

Performance status:

- Karnofsky 60-100%

Life expectancy:

- At least 2 months

Hematopoietic:

- Hemoglobin at least 9 g/dL

- WBC at least 2,000/mm^3

- Platelet count at least 50,000/mm^3

Hepatic:

- No hepatic insufficiency

- Bilirubin no greater than 2.5 mg/dL

- SGOT and SGPT no greater than 5 times upper limit of normal

Renal:

- Creatinine no greater than 2.5 mg/dL

- No history of renal conditions that contraindicate high dosages of sodium

Cardiovascular:

- No known chronic heart failure

- No uncontrolled hypertension

- No history of congestive heart failure

- No history of other cardiovascular conditions that contraindicate high dosages of sodium

Pulmonary:

- No serious lung disease, such as severe chronic obstructive pulmonary disease

Other:

- Fertile patients must use effective contraception during and for 4 weeks after study participation

- Not a high medical or psychiatric risk

- No concurrent nonmalignant systemic disease

- No active infection

PRIOR CONCURRENT THERAPY:

Biologic therapy:

- At least 4 weeks since prior immunotherapy and recovered

Chemotherapy:

- At least 4 weeks since prior chemotherapy and recovered

Endocrine therapy:

- At least 4 weeks since prior hormonal therapy (unless progression documented upon discontinuation of hormones)

- Concurrent corticosteroids allowed, if stable or decreasing for at least 2 months before study entry

Radiotherapy:

- At least 4 weeks since prior radiotherapy and recovered

Surgery:

- Recovered from prior surgery

Other:

- Prior cytodifferentiating agent allowed

Overall Status: Terminated
Phase: Phase 2

NCTID: NCT00003531
Intervention Type: Drug

Intervention Name: Antineoplaston therapy (Atengenal + Astugenal)
Title: Antineoplaston Therapy in Treating Patients With Stage IV Pancreatic Cancer
Condition: Stage IV Pancreatic Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS:

- Histologically confirmed stage IV adenocarcinoma of the pancreas that is unlikely to respond to existing therapy
- Measurable disease by MRI or CT scan
- Tumor must be at least 2 cm

PATIENT CHARACTERISTICS:

Age:

- 18 and over

Performance status:

- Karnofsky 60-100%

Life expectancy:

- At least 2 months

Hematopoietic:

- WBC at least 2,000/mm^3
- Platelet count at least 50,000/mm^3

Hepatic:

- No hepatic insufficiency
- Bilirubin no greater than 2.5 mg/dL
- SGOT and SGPT no greater than 5 times upper limit of normal

Renal:

- No renal insufficiency
- Creatinine no greater than 2.5 mg/dL
- No history of renal conditions that contraindicate high dosages of sodium

Cardiovascular:

- No uncontrolled hypertension
- No history of congestive heart failure
- No history of other cardiovascular conditions that contraindicate high dosages of sodium

Pulmonary:

- No serious lung disease, such as chronic obstructive pulmonary

disease

Other:

- Not pregnant or nursing

- Fertile patients must use effective contraception during and for 4 weeks after study participation

- No active infection

- No nonmalignant systemic disease

- Not a high medical or psychiatric risk

PRIOR CONCURRENT THERAPY:

Biologic therapy:

- At least 4 weeks since prior immunotherapy

- No concurrent immunomodulating agents

Chemotherapy:

- At least 4 weeks since prior chemotherapy (6 weeks for nitrosoureas)

Endocrine therapy:

- Concurrent corticosteroids allowed

Radiotherapy:

- At least 8 weeks since prior radiotherapy

Surgery:

- Recovered from prior surgery

Other:

- Prior cytodifferentiating agents allowed

- No prior antineoplastons

- No other concurrent antineoplastic agents

Overall Status: Terminated
Phase: Phase 2

NCTID: NCT00003635
Intervention Type: Drug
Intervention Name: nelarabine
Title: 506U78 in Treating Patients With Chronic Lymphocytic Leukemia That Has Not Responded to Fludarabine or Alkylating Agents
Condition: Leukemia
Eligibility Criteria: DISEASE CHARACTERISTICS: Diagnosis of refractory chronic lymphocytic leukemia Evidence of active disease after fludarabine or alkylator therapy Must meet one or more of the following criteria for active disease: Minimum of one of the following disease-related symptoms: Weight loss of 10% or more within the previous 6 months

Extreme fatigue (e.g.,
unable to work or perform usual activities) Fevers greater than 100.5 degrees F for 2 weeks
or more without evidence of infection Night sweats without evidence of infection Evidence
of progressive marrow failure manifested by the development or worsening of autoimmune
anemia and/or thrombocytopenia that is poorly responsive to corticosteroid therapy Massive
(e.g., greater than 6 cm below the left costal margin) or progressive splenomegaly Massive
nodes or clusters (e.g., greater than 10 cm in longest diameter) or progressive
lymphadenopathy Progressive lymphocytosis with an increase of more than 50% over a 2-month
period or an anticipated doubling time of less than 6 months Ineligible if marked
hypogammaglobulinemia or development of monoclonal protein in the absence of the above
criteria for active disease Must have one of the following resulting from prior fludarabine
or alkylator-containing therapy: Disease progression during therapy Failure to respond or
obtained less than a partial response to therapy Disease progression within 6 months of the
last course of therapy after an initial response Failure to respond or disease progression
allowed at any time after the final dose if alkylator agent was not the most recent therapy

PATIENT CHARACTERISTICS: Age: 18 and over Performance status: Karnofsky 60-100% Life
expectancy: At least 12 weeks Hematopoietic: See Disease Characteristics Hepatic: See
Disease Characteristics Bilirubin no greater than 2 times upper limit of normal No liver
dysfunction due to organ infiltration by lymphocytes Renal: Creatinine clearance at least
50 mL/min Other: Not pregnant or nursing Negative pregnancy test Fertile patients must use
effective contraception during and for up to 28 days after study No neurotoxicity of grade
2 or higher No history of significant neurologic toxicity (grade 2 or greater motor or
sensory impairment) due to prior chemotherapy or radiotherapy No history of seizure
disorder No active infection No other malignancy within the past 2 years (except adequately
treated non- melanomatous skin cancer or carcinoma in situ) that would preclude study No
systemic nonmalignant comorbid disease that would preclude study No psychological,
sociological, or geographical condition that would preclude study

PRIOR CONCURRENT THERAPY: Biologic therapy: No prior bone marrow or peripheral blood stem
cell transplantation Recovered from prior immunotherapy At least 4 weeks since prior
biologic therapy and recovered Concurrent growth factors allowed Chemotherapy: See Disease
Characteristics At least 4 weeks since prior chemotherapy (6 weeks for nitrosoureas or
mitomycin) and recovered No prior 506U78 therapy No other concurrent chemotherapy Endocrine

therapy: See Disease Characteristics No concurrent corticosteroid therapy greater than 10
mg/day of prednisone equivalent No concurrent corticosteroids as antiemetics Concurrent
hormone replacement therapy or oral contraceptives allowed Concurrent hydrocortisone as
prophylaxis or treatment of transfusion reactions allowed Radiotherapy: At least 4 weeks
since prior radiotherapy and recovered No concurrent radiotherapy Surgery: Not specified
Other: No other concurrent anticancer agents
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00003626
Intervention Type: Drug
Intervention Name: dolastatin 10
Title: Dolastatin 10 in Treating Patients With Metastatic Prostate Cancer That Has Not Responded to Previous Hormone Therapy
Condition: Prostate Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS: Hormone refractory metastatic prostate cancer (stage D1 or D2)
with no greater than 3 prior endocrine manipulations PSA level increased on 3 consecutive
measurements at least 2 weeks apart PSA at least 10 ng/mL (not required if measurable
disease)

PATIENT CHARACTERISTICS: Age: Not specified Performance status: SWOG 0-2 Life expectancy:
At least 12 weeks Hematopoietic: Granulocyte count at least 1,500/mm3 Hemoglobin at least 8
g/dL Platelet count at least 100,000/mm3 Hepatic: Bilirubin less than 2 mg/dL AST no
greater than 2 times upper limit of normal Renal: Creatinine less than 2.0 mg/dL Other: No
other serious medical illness No serious infection No other prior malignancy within the
past 5 years except nonmelanoma skin cancer or any in situ carcinoma

PRIOR CONCURRENT THERAPY: Biologic therapy: Not specified Chemotherapy: No prior
chemotherapy Endocrine therapy: See Disease Characteristics Concurrent LHRH-agonist therapy
allowed without antiandrogens At least 4 weeks since prior flutamide and nilutamide At
least 6 weeks since prior bicalutamide At least 4 weeks since other prior hormone therapy
including steroids Radiotherapy: At least 4 weeks since prior radiation therapy and
recovered No prior strontium Surgery: Recovered from prior surgery
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00003666
Intervention Type: Drug
Intervention Name: 6-hydroxymethylacylfulvene
Title: Irofulven in Treating Patients With Relapsed or Refractory Non-small Cell Lung Cancer
Condition: Lung Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS: Histologically or cytologically proven recurrent or refractory
non-small cell lung cancer Squamous cell Adenocarcinoma (including bronchoalveolar cell)

Large cell anaplastic (giant and clear cell carcinomas) Measurable disease (not bone
disease only, pleural or pericardial effusions, or irradiated lesions, unless progression
is documented after radiotherapy) No CNS metastases

PATIENT CHARACTERISTICS: Age: 18 and over Performance status: ECOG 0-1 Life expectancy: Not
specified Hematopoietic: Granulocyte count at least 1,500/mm3 Platelet count at least
100,000/mm3 Hepatic: Bilirubin no greater 1.5 mg/dL SGOT no greater than 2 times upper
limit of normal (ULN) Renal: Creatinine no greater than ULN Cardiovascular: No active
cardiac disease No unstable angina No myocardial infarction within 6 months No congestive
heart failure No inability to tolerate hypotension Other: Not pregnant or nursing Fertile
patients must use effective contraception HIV negative No uncontrolled diabetes mellitus No
psychiatric disorders No concurrent secondary malignancies except nonmelanomatous skin
cancer or patients with less than a 30% risk of relapse

PRIOR CONCURRENT THERAPY: Biologic therapy: Not specified Chemotherapy: At least 4 weeks
since prior chemotherapy (6 weeks since mitomycin) At least 1 prior chemotherapy agent or
combination, including adjuvant or neoadjuvant therapy for non-small cell lung cancer No
more than 1 prior chemotherapy agent or combination for metastatic or recurrent disease No
prior HMAF No other concurrent chemotherapy Endocrine therapy: No concurrent hormonal
therapy except for nondisease related conditions Radiotherapy: See Disease Characteristics
At least 4 weeks since prior radiotherapy No concurrent palliative radiotherapy Surgery:
Not specified
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00003669
Intervention Type: Drug
Intervention Name: arzoxifene hydrochloride
Title: Hormone Therapy With Arzoxifene Hydrochloride in Treating Women With Recurrent, Advanced, or Metastatic Endometrial Cancer
Condition: Endometrial Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS: Histologically confirmed recurrent, advanced, or metastatic
endometrial cancer not amenable to curative surgery or radiotherapy Patients should have
previously undergone radical surgery (minimum of total abdominal hysterectomy and
bisalpingoophorectomy), radical radiotherapy, or not be candidate for such procedures
Bidimensionally measurable disease by x-ray, CT scan, MRI, or physical exam No papillary
serous or clear cell carcinomas of the endometrium Hormone receptor status: Estrogen
receptor positive and/or progesterone receptor positive Unknown receptor status patients
allowed provided (1) original tumor was well- or moderately-well differentiated (2) had

endometrioid histology

PATIENT CHARACTERISTICS: Age: 18 and over Performance status: Karnofsky 70-100% Menopausal
status: Not specified Life expectancy: At least 12 weeks Hematopoietic: Granulocyte count
at least 1,500/mm3 Platelet count at least 100,000/mm3 Hemoglobin at least 9 g/dL
(transfusion-independent) Prothrombin time or activated partial thromboplastin time no
greater than 1.25 times upper limit of normal (ULN) Hepatic: Bilirubin no greater than 1.5
times normal ALT or AST no greater than 2.5 times ULN (ALT and AST no greater than 5 times
ULN in the presence of liver metastases) Renal: Creatinine no greater than 1.5 ULN Other:
No other primary malignancy within the past 5 years except adequately treated
nonmelanomatous cancer of the skin or carcinoma in situ of the cervix

PRIOR CONCURRENT THERAPY: Biologic therapy: Not specified Chemotherapy: No prior
chemotherapy for recurrent or metastatic endometrial cancer At least 1 year since prior
adjuvant chemotherapy Endocrine therapy: No prior antiestrogen therapy for any stage of
endometrial cancer At least 12 months from time of diagnosis since prior raloxifene Prior
progesterone treatment allowed Radiotherapy: See Disease Characteristics At least 2 weeks
since prior radiotherapy and recovered Surgery: See Disease Characteristics
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00003677
Intervention Type: Drug
Intervention Name: Dolastatin 10
Title: Dolastatin 10 in Treating Patients With Metastatic Pancreatic Cancer
Condition: Pancreatic Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS: Histologically confirmed metastatic adenocarcinoma of the pancreas
Bidimensionally measurable lesions with sentinel lesions outside field of any prior
radiation therapy No brain metastases

PATIENT CHARACTERISTICS: Age: 18 and over Performance status: Zubrod 0-1 Life expectancy:
At least 12 weeks Hematopoietic: Absolute granulocyte count at least 1500/mm3 Platelet
count at least 100,000/mm3 Hepatic: Bilirubin no greater than 1.5 mg/dL Renal: Creatinine
no greater than 1.5 mg/dL Cardiovascular: No active congestive heart failure No
uncontrolled angina At least 6 months since prior myocardial infarction No uncontrolled
hypertension Other: Not pregnant or nursing Fertile patients must use effective
contraception No concurrent serious infection At least 5 years since prior malignancy
except the following: Nonmelanoma skin cancer Carcinoma in situ of the cervix No overt
psychosis or mental disability

PRIOR CONCURRENT THERAPY: Biologic therapy: No concurrent biologic therapy Chemotherapy: No prior chemotherapy for metastatic disease At least 6 months since prior adjuvant chemotherapy No concurrent chemotherapy Endocrine therapy: Not specified Radiotherapy: See Disease Characteristics At least 6 months since prior adjuvant chemoradiation to disease At least 2 weeks since prior radiotherapy and recovered No concurrent radiotherapy Surgery: At least 4 weeks since prior surgery and recovered No concurrent surgery Other: At least 4 weeks since prior investigational drug (including analgesics or antiemetics) No other concurrent anticancer therapy
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00003735
Intervention Type: Drug
Intervention Name: topotecan hydrochloride
Title: Chemotherapy in Treating Children With Relapsed Acute Leukemia, Acute Myeloid Leukemia, or Blastic Phase Chronic Myelogenous Leukemia
Condition: Leukemia
Eligibility Criteria: DISEASE CHARACTERISTICS: Histologically proven relapsed acute lymphocytic leukemia, acute myeloid leukemia, or blastic phase chronic myelogenous leukemia Refractory to conventional therapy and other therapies of higher priority May have concurrent extramedullary relapse except for testicular relapse or other extramedullary sites that may require concurrent radiotherapy

PATIENT CHARACTERISTICS: Age: 21 and under Performance status: ECOG 0-2 Life expectancy: At least 2 months Hematopoietic: Not specified Hepatic: Bilirubin no greater than 2.0 times normal SGOT or SGPT less than 5 times normal Renal: Creatinine no greater than 1.5 times normal Other: Able to take oral liquid medication No GI neuropathy No other condition that may affect absorption of drug No diabetes mellitus Not pregnant or nursing Fertile patients must use effective contraception

PRIOR CONCURRENT THERAPY: Biologic therapy: Prior bone marrow transplantation (BMT) or peripheral blood stem cell transplantation (PBSCT) allowed and recovered At least 2 weeks since prior cytokine therapy and recovered No concurrent immune modulator therapy No concurrent cytokines including interleukin-11, interleukin-2, and epoetin alfa Chemotherapy: At least 2 weeks since prior chemotherapy (4 weeks for nitrosoureas) and recovered No more than 3 prior chemotherapy regimens No other concurrent chemotherapy Endocrine therapy: No concurrent steroids Radiotherapy: No prior craniospinal radiotherapy Prior total body irradiation allowed as part of BMT or PBSCT and recovered Concurrent radiotherapy for localized painful lesions allowed Surgery: Not specified Other: No

concurrent metoclopramide or cisapride to maintain motility or gastric emptying No
concurrent H2 antagonists No concurrent proton pump inhibitors No concurrent antacids for
gastritis, gastroesophageal reflux, or ulcers (gastric or duodenal) No antacid therapy for
6 hours before and for 90 minutes after topotecan administration
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00003744
Intervention Type: Drug
Intervention Name: gemcitabine
Title: Gemcitabine in Treating Patients With Advanced Salivary Gland Cancer That Cannot Be Removed During Surgery
Condition: Head and Neck Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS:

Inclusion Criteria:

- Histologic diagnosis of any of the following malignancies originating from salivary
tissue: adenoid cystic carcinoma, mucoepidermoid carcinoma, acinic cell carcinoma,
malignant mixed tumor, polymorphous low grade adenocarcinoma, undifferentiated
carcinoma, squamous cell carcinoma, adenocarcinoma.

- Patients must be incurable on the basis of unresectable local or distant disease as
determined by the patient's surgeon and not be potentially curable by radiation
therapy as determined by a radiation oncologist.

- Patients may have received radiation to any site with the following caveat: the sites
used for evaluation for response are either not previously irradiated or they have
shown progression of disease post radiation and there has been a time interval of one
month since these sites were radiated.

- Patients must have an ECOG performance status of less than 3.

- Patients must have at least uni-dimensionally measurable disease documented within one
month of initiation of treatment. Measurement may be by physical exam or
radiologically.

- Patients must be willing and able to go through the process of informed consent.

- Patients must have a life expectancy exceeding 3 months.

- Patients must be at least 18 years old.

- Patients must have adequate organ function as defined by the following tests to be
performed within 14 days of therapy initiation:

  - Absolute neutrophil count > 1999 cells x 10 6/L

  - Platelet count > 99,999 cells x 10 6/L

- Hemoglobin >8.5 gm/dl or HCT > 25%

- Serum creatinine < 1.5 x institutional upper limits of normal (ULN) or creatinine clearance measured by 24 hour urine collection as at least 50% of institutional lower limit of normal.

- Total bilirubin <2 x institutional ULN

- AST (SGOT) <2 x institutional ULN *

---*If from documented liver involvement with cancer, may be up to < 5 x institutional ULN

- Alkaline Phosphatase < 5 x institutional ULN --- If from documented bone or liver involvement with cancer, no upper limit restriction.

Exclusion Criteria

- Patients must have not received cytotoxic chemotherapy for salivary gland cancer.

- Previous immunologic, hormonal, homeopathic, natural, or alternative medicine therapies are acceptable provided treatment ended greater than 28 days prior to protocol therapy. Previous radiotherapy for salivary cancer is acceptable provided treatment ended greater than 28 days prior to protocol therapy.

- Patients must not receive any form (including radiotherapeutic, immunologic, hormonal, homeopathic, natural, or alternative medicine) of anti-neoplastic therapy other than gemcitabine while participating in this study.

- Patients must not have a history of any invasive neoplasm within three years of trial entry, excepting curatively treated non-melanoma skin cancer and cervical cancer.

- Pregnant and breast feeding women are not eligible for this study. No pregnancy test is required. Women of childbearing potential must be counseled on the use of effective birth control prior to participation in this study.

- Patients with significant active illness (e.g. congestive heart failure, COPD, uncontrolled diabetes, AIDS) are not eligible for this study.

Overall Status: Completed
Phase: Phase 2

NCTID: NCT00003752
Intervention Type: Drug
Intervention Name: bexarotene
Title: Bexarotene in Treating Patients With Metastatic Breast Cancer
Condition: Breast Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS: Histologically confirmed metastatic breast cancer No CNS

metastases No rapidly progressing visceral disease Previously irradiated lesions(s) may be designated as measurable indicator tumor(s) only if more than 6 months since radiotherapy, patient has no other measurable disease regrowth, and bidimensionally measurable regrowth is documented within 2 months prior to study Stratum 1 (hormonal): Must be hormone receptor positive (ER or PR) Prior hormonal therapy only allowed for metastatic disease Must have progressed on last hormonal regimen Must have at least one bidimensionally measurable tumor Stratum 2 (chemotherapy): Hormone receptor positive or negative Must have progressed on or after prior chemotherapy (1-2 regimens) for metastatic disease (bone marrow transplant counts as 2 regimens) Prior hormonal therapy allowed Must have at least one bidimensionally measurable tumor Stratum 3 (tamoxifen): Must be hormone receptor positive (ER or PR) and progressing on tamoxifen No symptomatic visceral metastasis if on adjuvant tamoxifen at time of systemic recurrence Must have at least one bidimensionally measurable tumor, or lytic bone lesion which measures at least one cm in diameter Hormone receptor status: See above

PATIENT CHARACTERISTICS: Age: Over 18 Menopausal status: Not specified Performance status: ECOG 0-2 OR Karnofsky 60-100% Life expectancy: At least 3 months Hematopoietic: WBC at least 3,000/mm3 Absolute neutrophil count at least 1,500/mm3 Platelet count at least 100,000/mm3 Fasting triglycerides within normal range Hepatic: Bilirubin no greater than 1.5 times upper limit of normal (ULN) SGOT and/or SGPT no greater than 2.5 times ULN Concurrent medication with drugs that significantly alter hepatic metabolism (e.g., phenobarbital, phenytoin, oral azole antifungals) allowed only if dosage stable Renal: Creatinine less than 2 times ULN OR Creatinine clearance greater than 40 mL/min Concurrent medication with drugs that significantly alter renal metabolism (e.g., probenecid) allowed only if dosage stable Other: At least 5 years since any other prior invasive malignancy except basal cell and squamous cell carcinoma of the skin No serious concurrent illness that would prevent compliance No history of or clinically significant risk factors for developing pancreatitis Fasting triglycerides within normal range Not pregnant or nursing Fertile patients must use effective contraception

PRIOR CONCURRENT THERAPY: Biologic therapy: Prior monoclonal antibody HER2 therapy for metastatic disease allowed only if combined with chemotherapy or hormonal therapy and treatment failed No concurrent immunotherapy Chemotherapy: See Disease Characteristics At least 4 weeks since prior cytotoxic chemotherapy (at least 6 weeks since prior mitomycin or

nitrosourea) No prior retinoid therapy for breast cancer At least 3 months since any other
prior retinoid therapy except topical application for dermatological indications No
concurrent chemotherapy Endocrine therapy: See Disease Characteristics At least 2 weeks
since prior non-FDA approved hormonal therapy No other concurrent hormonal therapy except
chronic low dose hormone replacement therapy or low dose corticosteroids for noncancer
indication Radiotherapy: See Disease Characteristics Prior radiotherapy allowed Concurrent
radiotherapy allowed only to non-indicator tumor(s) that do not represent new disease or
disease progression Surgery: Prior surgery allowed Other: At least one month since prior
investigational therapy (except hormonal) No other concurrent investigational therapy
Concurrent medication with drugs that significantly alter hepatic metabolism (e.g.,
phenobarbital, phenytoin, oral azole antifungals) allowed only if dosage stable No more
than 15,000 IU of vitamin A consumed daily
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00003760
Intervention Type: Drug
Intervention Name: irofulven
Title: Irofulvene in Treating Patients With Stage III or Stage IV Pancreatic Cancer
Condition: Pancreatic Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS: Histologically or cytologically confirmed stage III or IV
unresectable adenocarcinoma of the exocrine pancreas Must have been treated with 1 prior
gemcitabine regimen, and have documented disease progression either during or within 6
months after completion of therapy Measurable or evaluable disease outside of previously
irradiated area No islet cell tumors or lymphoma of the pancreas No significant CNS disease

PATIENT CHARACTERISTICS: Age: 18 and over Performance status: Karnofsky 70-100% Life
expectancy: At least 12 weeks Hematopoietic: WBC at least 3,000/mm3 Absolute neutrophil
count at least 1,500/mm3 Platelet count at least 100,000/mm3 Hemoglobin at least 9 g/dL
Hepatic: Bilirubin no greater than 2 mg/dL AST or ALT no greater than 2 times upper limit
of normal (ULN) (no greater than 5 times ULN if liver metastases) Renal: Creatinine no
greater than 1.5 mg/dL Cardiovascular: No atrial or ventricular arrhythmias requiring
medication No atrial fibrillation (with or without medication) No ischemic event within
past 6 months No history of congestive heart failure Other: Not pregnant or nursing Fertile
patients must use effective contraception No significant psychiatric disorders No active
infection No other prior malignancies within past 5 years, except: Basal or squamous cell
skin cancer Carcinoma in situ of the cervix No concurrent serious

systemic disorder

PRIOR CONCURRENT THERAPY: Biologic therapy: No prior immunotherapy No concurrent immunotherapy Chemotherapy: At least 4 weeks since prior gemcitabine therapy and recovered No other prior chemotherapy (except fluorouracil as a radiation enhancing agent) No other concurrent chemotherapy Endocrine therapy: No prior hormonal therapy No concurrent hormonal therapy (except contraceptives, hormone replacement, or megestrol acetate) Radiotherapy: At least 4 weeks since prior radiotherapy and recovered No concurrent radiotherapy Surgery: Not specified Other: At least 4 weeks since prior investigational agents
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00003773
Intervention Type: Drug
Intervention Name: oglufanide disodium
Title: IM-862 in Treating Patients With Recurrent Ovarian Cancer
Condition: Ovarian Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS: Histologically proven recurrent ovarian cancer Failed or relapsed after cytoreductive surgery followed by a platinum-based chemotherapy regimen Measurable or evaluable disease Recurrent disease manifested by isolated increased levels of CA-125 and no other evaluable disease eligible if CA-125 is at least 100

PATIENT CHARACTERISTICS: Age: 18 and over Performance status: SWOG 0-2 Life expectancy: Not specified Hematopoietic: Absolute granulocyte count at least 1,500/mm3 Platelet count at least 100,000/mm3 Hepatic: Bilirubin no greater than upper limit of normal (ULN) ALT and/or AST no greater than 2.5 times ULN Renal: Creatinine no greater than 2 times ULN Neurological: No evidence of moderate peripheral neuropathy greater than grade 1 Other: Not pregnant Fertile patients must use effective contraception No medical, social, or psychological factors interfering with compliance

PRIOR CONCURRENT THERAPY: Biologic therapy: No prior IM-862 No concurrent biologic therapy (e.g., interleukin-2 and interferons) Chemotherapy: See Disease Characteristics Recovered from prior chemotherapy No concurrent antineoplastic cytotoxic agents Endocrine therapy: Not specified Radiotherapy: Recovered from prior radiotherapy Surgery: See Disease Characteristics Recovered from prior surgery Other: No other concurrent investigational drugs
Overall Status: Completed
Phase: Phase 1

NCTID: NCT00003786
Intervention Type: Drug
Intervention Name: irofulven
Title: Irofulven in Treating Patients With Metastatic or Recurrent Colorectal Cancer

Condition: Colorectal Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS: Histologically confirmed metastatic or locally recurrent
adenocarcinoma of the colon or rectum Bidimensionally measurable disease Lesions seen on
colonoscopic examination or barium studies, bone metastases, CNS lesions, CEA levels and
ascites are not considered measurable No CNS disease only CNS metastases with other sites
of measurable disease allowed provided appropriate therapy for CNS metastases has been
administered and patient is neurologically stable and does not require intravenous steroid
or anticonvulsant therapy

PATIENT CHARACTERISTICS: Age: 18 and over Performance status: ECOG 0-2 OR Zubrod 0-2 Life
expectancy: At least 12 weeks Hematopoietic: WBC at least 3,500/mm3 Absolute neutrophil
count at least 1,500/mm3 Platelet count at least 100,000/mm3 (no platelet transfusion
within 7 days) Hemoglobin at least 9.0 g/dL Hepatic: Bilirubin no greater than 1.5 mg/dL
Transaminases no greater than 2.5 times upper limit of normal Renal: Creatinine no greater
than 1.5 mg/dL OR Creatinine clearance at least 60 mL/min Other: Not pregnant or nursing
Negative pregnancy test Fertile patients must use effective contraception No significant
uncontrolled medical or psychiatric illness No serious active infection No other active
malignancy except nonmelanoma skin cancer or carcinoma in situ of the cervix unless
adequately treated and less than 30% risk of relapse

PRIOR CONCURRENT THERAPY: Biologic therapy: No concurrent prophylactic use of growth
factors except for documented febrile neutropenia or sepsis Chemotherapy: At least 12
months since prior fluorouracil based adjuvant or neoadjuvant chemotherapy No more than 1
prior regimen No prior chemotherapy for advanced metastatic colorectal cancer No other
concurrent chemotherapy No concurrent investigational antineoplastic drugs Endocrine
therapy: See Disease Characteristics Radiotherapy: At least 4 weeks since prior
radiotherapy and recovered No prior radiotherapy to the only site of measurable disease No
concurrent radiotherapy Surgery: Not specified Other: See Disease Characteristics At least
30 days since prior investigational drug
Overall Status: Withdrawn
Phase: Phase 2

NCTID: NCT00003814
Intervention Type: Drug
Intervention Name: eflornithine
Title: Eflornithine in Treating Patients With Bladder Cancer
Condition: Bladder Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS: Histologically confirmed low grade (grade 1 or 2), superficial
(stage Ta or T1) transitional cell carcinoma (TCC) of the bladder Newly diagnosed or

recurrent All visible tumor must have been resected within the past 12 weeks Standard clinical management determined to be expectant observation without further surgery, intravesical therapy, or systemic therapy No prior upper tract TCC No history of grade 3 TCC, carcinoma in situ including severe dysplasia, non-TCC histology, or TCC greater than or equal to T2 No involvement of upper urinary tract prior to or at the time of initial tumor resection Abdominal CT scan, IVP, or retrograde pyelogram within the past 3 months to rule out upper urinary tract tumor

PATIENT CHARACTERISTICS: Age: 18 and over Performance status: Not specified Life expectancy: Not specified Hematopoietic: Not specified Hepatic: Not specified Renal: Not specified Other: Not pregnant or nursing Negative pregnancy test Fertile patients must use effective contraception No prior malignancy within the past 5 years and no concurrent malignancy except nonmelanomatous skin cancer or carcinoma in situ of the cervix No clinically significant hearing loss (i.e., hearing loss effects everyday life and/or wears a hearing aide) No other significant medical or psychiatric condition

PRIOR CONCURRENT THERAPY: Biologic therapy: At least 4 weeks since prior growth factors No concurrent growth factors Chemotherapy: No prior systemic chemotherapy for bladder cancer No concurrent intravesical therapy At least 4 weeks since prior chemotherapy No concurrent chemotherapy Endocrine therapy: At least 4 weeks since prior high dose steroids or prednisone No concurrent high dose steroids No concurrent prednisone or its equivalent in excess of 10 mg/day Radiotherapy: No prior radiotherapy for bladder cancer At least 4 weeks since prior radiotherapy No concurrent radiotherapy Surgery: See Disease Characteristics Other: At least 4 weeks since prior carbamazepine or experimental drugs No concurrent carbamazepine or experimental drugs
Overall Status: Completed
Phase: Phase 3

NCTID: NCT00003808
Intervention Type: Drug
Intervention Name: theophylline
Title: Theophylline in Treating Patients With In Situ, Stage I, or Stage II Chronic Lymphocytic Leukemia
Condition: Leukemia
Eligibility Criteria: DISEASE CHARACTERISTICS: Histologically proven stage 0, I, or II B-cell chronic lymphocytic leukemia Stable disease that would otherwise be observed

PATIENT CHARACTERISTICS: Age: 18 and over Performance status: ECOG 0-2 Life expectancy: At least 1 year Hematopoietic: Absolute lymphocyte count greater than 5,000/mm3 Mature lymphocytes with less than 55% prolymphocytes, atypical lymphocytes, or lymphoblasts Bone

marrow with at least 30% lymphocytes Hepatic: No cirrhosis Renal: Not specified
Cardiovascular: No history of unstable cardiac arrhythmia No active congestive heart
failure Other: No history of uncontrolled seizure disorder Not pregnant or nursing Negative
pregnancy test Fertile patients must use effective contraception No other concurrent
condition that would make life expectancy less than 1 year

PRIOR CONCURRENT THERAPY: Biologic therapy: No concurrent interferon alfa Chemotherapy: No
prior chemotherapy No concurrent chemotherapy Endocrine therapy: At least 3 months since
prior corticosteroids No concurrent corticosteroids Radiotherapy: Not specified Surgery:
Not specified
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00003821
Intervention Type: Drug
Intervention Name: aminopterin
Title: Aminopterin in Treating Patients With Recurrent or Refractory Endometrial Cancer
Condition: Endometrial Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS: Histologically confirmed persistent, recurrent, or refractory
endometrial carcinoma who have failed prior first line chemotherapy Bidimensionally
measurable disease by physical exam or medical imaging techniques (sonography acceptable if
lesion(s) are clearly defined and measurable in two dimensions) Ascites and pleural
effusions are not measurable

PATIENT CHARACTERISTICS: Age: Not specified Performance status: GOG 0-2 Life expectancy: At
least 2 months Hematopoietic: WBC at least 3,000/mm3 Platelet count at least 100,000/mm3
Granulocyte count at least 1,500/mm3 Hemoglobin at least 8 g/dL Hepatic: Bilirubin no
greater than 1.5 times upper limit of normal (ULN) SGOT no greater than 3 times ULN
Alkaline phosphatase no greater than 3 times ULN Renal: Creatinine no greater than 2.0
mg/dL Other: Not pregnant or nursing Negative pregnancy test Fertile patients must use
effective contraception No significant infection

PRIOR CONCURRENT THERAPY: Biologic therapy: Not specified Chemotherapy: See Disease
Characteristics At least 4 weeks since prior chemotherapy and recovered Endocrine therapy:
Not specified Radiotherapy: At least 4 weeks since prior radiotherapy and recovered
Surgery: At least 4 weeks since prior surgery and recovered Other: At least 4 weeks since
any prior therapy directed at malignant endometrial tumor(s) At least 4 weeks since prior
folate-containing vitamins No concurrent folate-containing vitamins No other concurrent
anticancer therapy
Overall Status: Withdrawn

Phase: Phase 2

NCTID: NCT00003796
Intervention Type: Drug
Intervention Name: irofulven
Title: Irofulven in Treating Patients With Metastatic Breast Cancer
Condition: Breast Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS:

- Histologically confirmed metastatic adenocarcinoma of the breast

- Measurable disease outside previously irradiated area or occurred/progressed after completion of radiotherapy

- Must have received 1 or 2 prior chemotherapy regimens for metastatic disease

  - More than 3 prior regimens allowed

- No active brain metastases or meningeal breast cancer involvement

PATIENT CHARACTERISTICS:

Sex:

- Male or female

Performance status:

- SWOG 0-2

Hematopoietic:

- WBC at least 3,000/mm^3

- Platelet count at least 100,000/mm^3

- Absolute neutrophil count at least 1,500/mm^3

Hepatic:

- Bilirubin no greater than 1.5 times upper limit of normal (ULN)

- SGOT or SGPT no greater than 3 times ULN (5 times ULN for liver metastases)

Renal:

- Creatinine no greater than 1.5 mg/dL OR

- Creatinine clearance at least 60 mL/min

Cardiovascular:

- No history of myocardial infarction or unstable angina within the past 6 months

- No uncontrolled congestive heart failure

Other:

- Not pregnant or nursing

- Negative pregnancy test

- Fertile patients must use effective contraception

- Prior diagnosis of cancer allowed (must be off cancer therapy and have no evidence of
disease)

- No history of retinopathy and/or macular degeneration

PRIOR CONCURRENT THERAPY:

Chemotherapy:

- No prior irofulven

Overall Status: Completed
Phase: Phase 2

NCTID: NCT00003856
Intervention Type: Drug
Intervention Name: temoporfin
Title: Photodynamic Therapy in Treating Patients With Recurrent, Refractory, or Second Primary Head and Neck Cancer That Cannot Be Treated With Surgery or Radiation Therapy
Condition: Head and Neck Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS: Histologically confirmed recurrent, refractory, or second primary squamous cell cancer of the head and neck that is incurable with surgery or radiotherapy Any N, Any M, single or multiple tumor(s) Locally accessible, discrete tumor(s) by CT or MRI scan Must be considered incurable with surgery or radiotherapy, for example: Distant disease (e.g., lung and/or liver metastases) OR Cervical disease fixed to surrounding structures (e.g., carotid artery or prevertebral fascia) OR Metastases in the site of prior radiotherapy OR Not suitable for anesthesia or reconstructive surgery OR Multiple cutaneous metastases

PATIENT CHARACTERISTICS: Age: Over 18 Performance status: Karnofsky 60-100% Life expectancy: Not specified Hematopoietic: Not specified Hepatic: Not specified Renal: Not specified Other: No disease exacerbated by light, including systemic lupus erythematosus, psoriasis, porphyria, actinic reticuloid, or xeroderma pigmentosum Not pregnant or nursing Negative pregnancy test Fertile patients must use effective contraception

PRIOR CONCURRENT THERAPY: Biologic therapy: Not specified Chemotherapy: At least 30 days since prior chemotherapy (6 weeks since nitrosoureas) Endocrine therapy: Concurrent steroid therapy allowed Radiotherapy: At least 30 days since prior radiotherapy to the head and neck Surgery: At least 30 days since prior surgery and recovered Other: At least 30 days since prior light activated therapy or medication (e.g.,PUVA or Accutane) No prior photodynamic therapy At least 30 days since prior experimental drugs
Overall Status: Unknown status

Phase: Phase 2

NCTID: NCT00003858
Intervention Type: Drug
Intervention Name: mitoxantrone hydrochloride
Title: Mitoxantrone Following Surgery in Treating Patients With Prostate Cancer at High Risk for Recurrence
Condition: Prostate Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS: Adenocarcinoma of the prostate treated by radical prostatectomy
within the past 3 months Considered to be at high risk for recurrence as defined by at
least 1 of the following characteristics on the radical prostatectomy specimen: Positive
seminal vesicles Gleason 6 and preoperative PSA greater than 18 ng/mL Gleason 7 and
preoperative PSA greater than 14 ng/mL Gleason 8, 9, or 10 and any preoperative PSA
Undetectable PSA (i.e., less than 0.1 ng/mL) within 3 months following radical
prostatectomy and at time of enrollment Negative lymph nodes at time of radical
prostatectomy if lymphadenectomy performed Extracapsular penetration and/or positive
surgical margins allowed

PATIENT CHARACTERISTICS: Age: 18 and over Performance status: Zubrod 0-1 Life expectancy:
Not specified Hematopoietic: Granulocyte count at least 1,500/mm3 Platelet count at least
100,000/mm3 Hepatic: Bilirubin no greater than 1.5 times upper limit of normal (ULN) SGOT
no greater than 2 times ULN Renal: Not specified Cardiovascular: No New York Heart
Association class III or IV cardiac disease or angina pectoris No myocardial infarction
within the past 6 months

PRIOR CONCURRENT THERAPY: Biologic therapy: No concurrent filgrastim or sargramostim except
for febrile neutropenia Chemotherapy: No other concurrent chemotherapy Endocrine therapy:
No prior neoadjuvant or adjuvant hormonal therapy for prostate cancer No concurrent
hormonal therapy except for non-disease related conditions (e.g., insulin for diabetes) No
concurrent systemic corticosteriods unless for adrenal insufficiency No concurrent
prednisone, dexamethasone, or other steroidal antiemetics At least 6 months since prior
finasteride No concurrent finasteride No concurrent antiandrogens (e.g., flutamide,
bicalutamide, nilutamide) or gonadotropin releasing hormone agonists (e.g., leuprolide,
goserelin) Radiotherapy: No prior adjuvant radiotherapy for prostate cancer No prior pelvic
radiotherapy for prostate cancer Surgery: See Disease Characteristics Other: At least 6
months since prior saw palmetto No concurrent compounds with 5 alpha-reductase inhibitor
activity (e.g., saw palmetto)
Overall Status: Withdrawn
Phase: Phase 2

NCTID: NCT00003865
Intervention Type: Drug
Intervention Name: toremifene
Title: Toremifene in Treating Patients With Ovarian Cancer
Condition: Ovarian Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS:

- Histologically confirmed serous papillary carcinoma of the ovary
    - Recurrent or refractory disease following at least one regimen including paclitaxel, cisplatin, or carboplatin
- Measurable disease outside of irradiated field
- No CNS metastases

PATIENT CHARACTERISTICS:

Age:

- 18 and over

Performance status:

- Zubrod 0-2

Life expectancy:

- At least 16 weeks

Hematopoietic:

- Absolute neutrophil count at least 1,800/mm^3
- Platelet count at least 125,000/mm^3
- No history of thrombosis or thromboembolic events

Hepatic:

- Bilirubin no greater than 2.0 mg/dL

Renal:

- Creatinine no greater than 2.0 mg/dL

Other:

- Not pregnant or nursing
- Negative pregnancy test
- Fertile patients must use effective contraception during and for 2 months after study
- No other concurrent second malignancy or prior malignancy within past 5 years, except basal or squamous cell skin cancer or curatively treated stage I carcinoma of the cervix
- No concurrent infection

- At least 3 days since prior fever (unless due to tumor)

- No other concurrent severe medical illness

- No HIV positivity

PRIOR CONCURRENT THERAPY:

Biologic therapy:

- Not specified

Chemotherapy:

- See Disease Characteristics

- No concurrent chemotherapy

Endocrine therapy:

- No prior tamoxifen or antiestrogen therapy

Radiotherapy:

- See Disease Characteristics

- At least 6 months since prior radiotherapy

- No concurrent radiotherapy except to symptomatic or potentially disabling bone lesion
accompanied by other measurable disease

Surgery:

- Not specified

Other:

- No concurrent anticoagulants

- No other concurrent therapeutic trials

Overall Status: Withdrawn
Phase: Phase 2

NCTID: NCT00003850
Intervention Type: Drug
Intervention Name: thalidomide
Title: Thalidomide in Treating Patients With Recurrent or Metastatic Head and Neck Cancer
Condition: Head and Neck Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS:

- Histologically proven squamous cell carcinoma of the head and neck

- Recurrent disease OR metastatic disease at initial diagnosis or at recurrence

- Initial therapy of surgery and/or radiotherapy, induction chemotherapy, or concurrent
chemotherapy and radiotherapy allowed

- No more than one prior regimen of chemotherapy or biologic therapy for metastatic
disease

- Recurrence after adjuvant or induction chemotherapy may have received one additional course of chemotherapy or biologic therapy

PATIENT CHARACTERISTICS:

- Age: 18 and over
- Performance status: Zubrod 0-2
- Life expectancy: At least 3 months
- WBC at least 3000/mm3
- Platelet count at least 100,000/mm3
- Hematocrit at least 30%
- Bilirubin no greater than 1.5 times normal
- SGOT/SGPT no greater than 1.5 times normal
- Creatinine no greater than 1.5 mg/dL
- Not pregnant or nursing
- Negative pregnancy test
- Fertile women must use 2 methods of effective contraception, 1 barrier and 1 hormonal, beginning at least 4 weeks before study and continuing during and for 1 month after study
- Men must use effective barrier contraception during and for 1 month after study
- No grade 2 or greater peripheral neuropathy
- No serious infection or other concurrent illness requiring immediate therapy
- Must be able to take oral medications
- No medical or social factors that would interfere with compliance

PRIOR CONCURRENT THERAPY:

- Any number of courses of one regimen of chemotherapy allowed
- No concurrent cytotoxic chemotherapy
- No concurrent radiotherapy

Overall Status: Completed
Phase: Phase 2

NCTID: NCT00003892
Intervention Type: Drug
Intervention Name: ISIS 5132
Title: ISIS 5132 in Treating Patients With Metastatic or Recurrent Ovarian Cancer
Condition: Ovarian Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS: Histologically documented ovarian

epithelial cancer Metastatic
and/or locally recurrent disease that is incurable with standard therapy Must have received
1 or 2 prior regimens of chemotherapy At least 1 regimen must have contained cisplatin or
carboplatin Bidimensionally measurable disease Indicator lesion size must be as follows: At
least 4-50 cm2 by CT scan At least 1 cm2 by chest xray At least 1 cm2 (e.g., nodules) by
physical exam No abdominal adenocarcinoma of unknown origin No borderline ovarian tumor No
tumor known to be of primary fallopian tube or peritoneal origin

PATIENT CHARACTERISTICS: Age: 18 and over Performance status: ECOG 0-1 Life expectancy: At
least 12 weeks Hematopoietic: Platelet count at least 100,000/mm3 Absolute granulocyte
count at least 1,500/mm3 No known bleeding disorder Hepatic: Bilirubin no greater than 2
times upper limit of normal (ULN) AST less than 5 times ULN PT/PTT normal (except when
elevated due to therapeutic coumadin) Renal: Creatinine no greater than 2 times ULN
Cardiovascular: No significant cardiac dysfunction Neurologic No history of significant
neurologic disorder No significant psychiatric disorder Other: Not pregnant or nursing
Fertile patients must use effective contraception At least 5 years since prior malignancy
and no evidence of recurrence No other serious illness or medical condition No active
uncontrolled infection No complete bowel obstruction

PRIOR CONCURRENT THERAPY: Biologic therapy: Not specified Chemotherapy: See Disease
Characteristics At least 4 weeks since prior chemotherapy No other concurrent cytotoxic
therapy Endocrine therapy: Not specified Radiotherapy: Recovered from prior radiotherapy At
least 4 weeks since radiotherapy to at least 20% of bone marrow Surgery: Not specified
Other: As least 28 days since prior investigational agent or new anticancer therapy No
concurrent therapeutic heparin No other concurrent investigational therapy
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00003938
Intervention Type: Drug
Intervention Name: liposomal amphotericin B
Title: Liposomal Amphotericin B in Treating Granulocytopenia and Persistent Unexplained Fever in Cancer Patients
Condition: Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS:

- Hematologic malignancy or solid tumor

- Must be undergoing remission induction and/or consolidation therapy for hematologic
malignancy only OR

- Must be undergoing allogeneic or autologous bone marrow transplantation

- Granulocyte count less than 500/mm^3 and profound granulocytopenia expected to last
  for greater than 5 days

- Fever (greater than 38.5 degrees C) refractory for greater than 72 hours and less than
  84 hours to broad spectrum antimicrobials, after exclusion of current bacterial,
  fungal, viral, parasitic, and mycobacterial infections

- Peripheral blood cultures and central venous catheter cultures negative for infections

- No microbiological documentation of a bacterial infection (e.g., abscess at catheter
  site)

- No invasive fungal infection

- No probable noninfectious cause of fever

PATIENT CHARACTERISTICS:

Age:

- Not specified

Performance status:

- Karnofsky 40-100% OR

- WHO 0-2

Life expectancy:

- Not specified

Hematopoietic:

- See Disease Characteristics

Hepatic:

- Not specified

Renal:

- Not specified

Other:

- No prior anaphylactic reaction to amphotericin B

- No psychological, familial, sociological, or geographical conditions that would
  prevent compliance

- Not pregnant or nursing

- Normal chest X-ray or normal high resolution CT scan of the lungs

PRIOR CONCURRENT THERAPY:

Biologic therapy:

- See Disease Characteristics

Chemotherapy:

- See Disease Characteristics

Endocrine therapy:

- Not specified

Radiotherapy:

- Not specified

Surgery:

- Not specified

Other:

- No concurrent active systemic antifungal agents or antifungal prophylaxis (e.g., azoles or polyenes)

- No prior IV amphotericin B during same neutropenic episode

- No change in antibacterial regimen within 48 hours prior to study

Overall Status: Completed
Phase: Phase 3

NCTID: NCT00003917
Intervention Type: Drug
Intervention Name: topotecan hydrochloride
Title: Topotecan in Treating Patients With Relapsed Small Cell Lung Cancer
Condition: Lung Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS: Histologically or cytologically confirmed limited or extensive stage small cell lung cancer (SCLC) Disease recurring at least 90 days following completion of first line chemotherapy Partial or complete response to first line therapy Must have at least one bidimensionally measurable non CNS lesion May be within a prior radiation port if at least 6 weeks since prior radiotherapy and progressing Brain and/or leptomeningeal metastases allowed if asymptomatic and not requiring corticosteroids

PATIENT CHARACTERISTICS: Age: 18 and over Performance status: ECOG 0-2 Life expectancy: At least 2 months Hematopoietic: WBC at least 3,500/mm3 Neutrophil count at least 1,500/mm3 Platelet count at least 100,000/mm3 Hemoglobin at least 9.0 g/dL (after transfusion, if needed) Hepatic: Bilirubin no greater than 2.0 mg/dL SGOT and SGPT no greater than 2 times upper limit of normal (ULN) (no greater than 5 times ULN if liver metastases present) Alkaline phosphatase no greater than 2 times ULN (no greater than 5 times ULN if liver metastases present) Renal: Creatinine no greater than 1.5 mg/dL OR Creatinine clearance at least 60 mL/min Other: No active uncontrolled infection No other

malignancies within the
past 5 years except curatively treated basal or squamous cell skin cancer, carcinoma in
situ of the cervix, or stage I low grade prostate cancer No other severe medical conditions
that would preclude study or cause exposure to extreme risk or decreased life expectancy No
uncontrolled emesis No active peptic ulcer, diabetes mellitus, chronic gastritis,
significant ascites, or other gastrointestinal (GI) conditions (e.g., removal of a portion
of the stomach or recent GI obstruction) that would alter absorption or GI motility No
history of allergic reactions to compounds chemically related to topotecan Not pregnant or
nursing Negative pregnancy test Fertile patients must use effective contraception for 3
months prior to, during, and at least 4 weeks after the study

PRIOR CONCURRENT THERAPY: Biologic therapy: At least 3 months since prior immunotherapy No
concurrent immunotherapy for SCLC Chemotherapy: See Disease Characteristics No prior
topotecan Only one prior chemotherapy regimen allowed No other concurrent chemotherapy for
SCLC Endocrine therapy: See Disease Characteristics Radiotherapy: See Disease
Characteristics At least 24 hours since prior radiotherapy No concurrent radiotherapy for
SCLC Surgery: At least 4 weeks since prior surgery Other: At least 30 days or five half
lives since other prior investigational drugs No prior drugs (e.g., cisapride) that would
alter absorption or GI motility No other concurrent investigational therapy for SCLC
Overall Status: Completed
Phase: Phase 3

NCTID: NCT00003946
Intervention Type: Drug
Intervention Name: danazol
Title: Danazol in Treating Patients With Advanced or Recurrent Endometrial Cancer
Condition: Endometrial Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS: Histologically proven advanced or recurrent endometrial cancer
that is not amenable to curative surgery or radiotherapy Measurable disease Tumor at least
1.0 cm by 1.0 cm per x-ray or physical exam OR Tumor at least 2.0 cm by 2.0 cm per CT scan,
MRI, or ultrasound

PATIENT CHARACTERISTICS: Age: Not specified Performance status: GOG 0-2 Life expectancy:
Not specified Hematopoietic: WBC at least 3000/mm3 Platelet count at least 100,000/mm3 No
history of porphyria Hepatic: Bilirubin no greater than 1.5 times normal SGOT no greater
than 3 times normal Alkaline phosphatase no greater than 3 times normal Renal: Creatinine
no greater than 2 mg/dL Other: No concurrent or prior malignancy within past 5 years
(except nonmelanoma skin cancer) or for which patient received chemotherapy Not pregnant or

nursing Fertile patients must use effective contraception Must have tissue available for
estrogen receptor/ progesterone receptor analysis

PRIOR CONCURRENT THERAPY: Biologic therapy: Not specified Chemotherapy: No prior
chemotherapy Endocrine therapy: Not specified Radiotherapy: At least 3 weeks since prior
radiotherapy and recovered Surgery: At least 3 weeks since prior surgery and recovered
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00003914
Intervention Type: Drug
Intervention Name: dolastatin 10
Title: Dolastatin 10 in Treating Patients With Advanced Kidney Cancer
Condition: Kidney Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS: Histologically confirmed renal cell carcinoma considered incurable
by surgery and not amenable to radiation therapy with curative intent Locally advanced
disease OR Locally recurrent disease OR Metastatic disease No transitional cell carcinoma
Measurable disease No CNS metastases or carcinomatous meningitis

PATIENT CHARACTERISTICS: Age: 18 and over Performance status: ECOG 0-2 Life expectancy: At
least 12 weeks Hematopoietic: WBC at least 3,500/mm3 Absolute neutrophil count at least
1,500/mm3 Platelet count at least 100,000/mm3 Hepatic: AST less than 3 times upper limit of
normal (ULN) Bilirubin normal Renal: Creatinine less than 1.5 times ULN Cardiovascular: No
New York Heart Association class III or IV heart disease Metabolic: Oral intake at least
1,200 calories per day Other: Not pregnant or nursing Negative pregnancy test Fertile
patients must use effective contraception No uncontrolled infection No known seizure
disorder No other malignancy within the past 5 years except nonmelanoma skin cancer or
carcinoma in situ of the cervix No other medical or psychiatric condition that would
interfere with compliance

PRIOR CONCURRENT THERAPY: Biologic therapy: At least 4 weeks since prior biologic therapy
No concurrent immunomodulating agents Chemotherapy: No prior chemotherapy for renal cell
carcinoma No other concurrent cytostatic or cytotoxic therapy Endocrine therapy: At least 4
weeks since prior hormonal therapy No concurrent hormonal agents Radiotherapy: See Disease
Characteristics At least 3 weeks since prior radiotherapy No prior radiotherapy to greater
than 15% of bone marrow No concurrent radiotherapy Surgery: See Disease Characteristics
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00003968
Intervention Type: Drug
Intervention Name: bryostatin 1

Title: Bryostatin 1 in Treating Patients With Metastatic Kidney Cancer
Condition: Kidney Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS:

- Histologically confirmed metastatic renal cell carcinoma

- Bidimensionally measurable disease

- Clear evidence of progression if only site of measurable disease is within previous radiation port

- Previously irradiated brain metastases allowed, if not life threatening, symptoms controlled for 3 months, and not requiring corticosteroids

PATIENT CHARACTERISTICS:

- Age: 18 and over

- Performance status: ECOG 0-1

- Life expectancy: Greater than 3 months

- WBC at least 3,000/mm3

- Platelet count at least 100,00/mm3

- Bilirubin no greater than 1.5 mg/dL

- Creatinine no greater than 2.0 mg/dL OR creatinine clearance greater than 50 mL/min

- Not pregnant or nursing

- Negative pregnancy test

- Fertile patients must use effective contraception for 1 month before, during, and for 3 months after study

- No active bacterial or viral infection

- No serious underlying medical condition that would interfere with compliance

- No other malignancy within the past 5 years except basal cell carcinoma of the skin

- No dementia or altered mental status that would prevent informed consent

PRIOR CONCURRENT THERAPY:

- No more than 1 prior therapy with biologic response modifiers

- No prior chemotherapy for advanced disease

- No other concurrent chemotherapy

- No concurrent steriods (except topical use)

- At least 4 weeks since prior radiotherapy

- No concurrent radiotherapy

- At least 4 weeks since major surgery (including nephrectomy)

- No other concurrent experimental agents

Overall Status: Completed
Phase: Phase 2

NCTID: NCT00003951
Intervention Type: Drug
Intervention Name: exatecan mesylate
Title: DX-8951f in Treating Patients With Metastatic Cancer of the Pancreas
Condition: Pancreatic Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS: Histologically or cytologically confirmed epithelial cancer of the exocrine pancreas Metastatic disease Previously untreated disease or progressive disease after first-line chemotherapy Bidimensionally measurable disease Indicator lesion must be outside of any prior radiation port No brain metastases No islet cell tumors, lymphoma, or sarcoma of the pancreas

PATIENT CHARACTERISTICS: Age: 18 and over Performance status: ECOG 0-2 Life expectancy: At least 12 weeks Hematopoietic: Absolute neutrophil count at least 1,500/mm3 Platelet count at least 100,000/mm3 Hepatic: Bilirubin no greater than 1.5 mg/dL SGOT/SGPT no greater than 2 times upper limit of normal (ULN) (5 times ULN if liver metastases present) Renal: Creatinine no greater than 1.5 mg/dL Cardiovascular: No active congestive heart failure No uncontrolled angina No myocardial infarction within the past 6 months Other: Not pregnant or nursing Negative pregnancy test Fertile patients must use effective contraception No concurrent serious infection No history of other malignancy within the past 5 years except nonmelanoma skin cancer or carcinoma in situ of the cervix No overt psychosis, mental disability, or incompetence No other life threatening illness

PRIOR CONCURRENT THERAPY: Biologic therapy: No concurrent biologic therapy No prophylactic colony stimulating factors to prevent neutropenia Chemotherapy: See Disease Characteristics At least 4 weeks since prior chemotherapy and recovered No other concurrent cytotoxic chemotherapy Endocrine therapy: Not specified Radiotherapy: See Disease Characteristics At least 4 weeks since prior radiotherapy and recovered No concurrent radiotherapy Surgery: At least 4 weeks since prior major surgery and recovered No concurrent surgery Other: No other concurrent anticancer treatment At least 28 days since other prior investigational drugs, including analgesics or antiemetics No other investigational drugs during and for 28 days after study No concurrent drugs that induce or inhibit CYP3A enzyme
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00004009

Intervention Type: Drug
Intervention Name: tipifarnib
Title: R115777 in Treating Patients With Refractory or Recurrent Acute Leukemia or Chronic Myelogenous Leukemia
Condition: Leukemia
Eligibility Criteria: DISEASE CHARACTERISTICS: Histologically or cytologically proven leukemia of any of the
following types: Acute myelogenous leukemia (AML) Newly diagnosed de novo AML in patients
over 60 years with poor risk features Antecedent hematologic disorder Complex karyotypes or
other adverse cytogenetics Stem cell immunophenotype AML arising from myelodysplastic
syndrome Secondary AML Recurrent or refractory AML, including primary induction failure
Acute lymphoblastic leukemia (ALL) Newly diagnosed de novo ALL in patients over 60 years
with poor risk disease features Complex karyotype or other adverse cytogenetics Mixed
lineage immunophenotype Recurrent or refractory ALL, including primary induction failure
Chronic myelogenous leukemia in accelerated phase or blast crisis No more than 2 prior
induction/reinduction therapy courses if failed primary induction therapy or relapsed
following complete remission Not eligible for or refused allogeneic bone marrow
transplantation Acute progranulocytic leukemia (M3) must meet following criteria: Prior
treatment with tretinoin required No coagulopathy Low risk for developing coagulopathy No
disseminated intravascular coagulation No CNS leukemia

PATIENT CHARACTERISTICS: Age: 18 and over Performance status: ECOG 0-2 Life expectancy: Not
specified Hematopoietic: No hyperleukocytosis (at least 50,000 leukemic blasts/mm3)
Hepatic: Bilirubin normal SGOT and SGPT no greater than 2 times normal Renal: Creatinine no
greater than 2 times normal Cardiovascular: LVEF at least 45% by MUGA or echocardiogram No
myocardial infarction within the past 3 months No severe coronary artery disease No
cardiomyopathy No congestive heart failure No prior coagulation related sequelae: Deep vein
thrombosis Pulmonary embolus CNS thrombosis or bleed Other: No pregnant or nursing Negative
pregnancy test Fertile patients must use effective contraception

PRIOR CONCURRENT THERAPY: Biologic therapy: At least 1 week since prior growth factors
(epoetin alfa, filgrastim, sargramostim, interleukin-3, interleukin-11) and recovered No
prior allogeneic bone marrow transplantation No concurrent immunotherapy Chemotherapy: See
Disease Characteristics At least 3 weeks since prior chemotherapy and recovered No other
concurrent chemotherapy Endocrine therapy: At least 3 weeks since prior endocrine therapy
and recovered Radiotherapy: At least 3 weeks since prior radiotherapy and recovered No
prior extensive radiotherapy to greater than 25% bone marrow No concurrent radiotherapy
Surgery: Not specified

Overall Status: Completed
Phase: Phase 1

NCTID: NCT00004008
Intervention Type: Drug
Intervention Name: bryostatin 1
Title: Bryostatin 1 in Treating Patients With Ovarian Epithelial Cancer
Condition: Ovarian Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS:

- Histologically proven ovarian epithelial cancer

  - Progressive disease during or after completion of at least one platinum based chemotherapy regimen

- Bidimensionally measurable disease

  - At least 2 cm by x-ray, CT scan, or ultrasound

- No active, symptomatic brain metastases (e.g., cerebral edema and/or progressive tumor growth)

PATIENT CHARACTERISTICS:

Age:

- 18 and over

Performance status:

- WHO 0-2

Life expectancy:

- At least 12 weeks

Hematopoietic:

- Hemoglobin at least 10 g/dL

- WBC at least 4,000/mm3

- Platelet count at least 100,000/mm3

Hepatic:

- Bilirubin no greater than 1.7 mg/dL

- AST/ALT no greater than 2.5 times upper limit of normal (ULN) (no greater than 5 times ULN if liver metastases present)

Renal:

- Creatinine no greater than 1.4 mg/dL

Other:

- No active, uncontrolled infection

- No nonmalignant systemic disease which would increase risk to patient

- No other malignancies within the past 5 years except curatively treated basal or
squamous cell skin cancer or carcinoma in situ of the cervix

- Not pregnant or nursing

- Negative pregnancy test

- Fertile patients must use effective contraception during and for 2 months after study

PRIOR CONCURRENT THERAPY:

Biologic therapy:

- At least 4 weeks since prior immunotherapy and recovered

Chemotherapy:

- See Disease Characteristics

- At least 4 weeks since prior chemotherapy (6 weeks since nitrosoureas or mitomycin)
and recovered

- No more than 2 prior multidrug chemotherapy regimens

- No more than 1 prior single agent chemotherapy regimen

Endocrine therapy:

- At least 4 weeks since prior endocrine therapy and recovered

- No concurrent steroids

- Concurrent hormone replacement therapy allowed

Radiotherapy:

- At least 4 weeks since prior radiotherapy (excluding palliative therapy) and recovered

- No concurrent radiotherapy

Surgery:

- At least 4 weeks since prior major thoracic or abdominal surgery

Other:

- No other concurrent anticancer therapy or investigational drugs
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00004014
Intervention Type: Drug
Intervention Name: pegylated liposomal doxorubicin hydrochloride
Title: Liposomal Doxorubicin in Treating Patients With Prostate Cancer
Condition: Prostate Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS: Histologically confirmed hormone refractory prostate cancer
Castrate serum testosterone levels less than 30 mg/dL occurring at least 4 weeks since

prior flutamide or at least 6 weeks since prior bicalutamide Measurable or evaluable
progressive disease Rising PSA involving two determinations (one at least 20 ng/mL if PSA
is sole criterion) at least two weeks apart OR Increasing measurable or evaluable disease
OR New metastasis

PATIENT CHARACTERISTICS: Age: Not specified Performance status: ECOG 0-2 Life expectancy:
At least 3 months Hematopoietic: Absolute neutrophil count at least 1,500/mm3 Platelet
count at least 100,000/mm3 Hepatic: Bilirubin no greater than 2.0 mg/dL No hepatic
insufficiency Renal: Creatinine no greater than 2.0 mg/dL No renal failure Cardiovascular:
Cardiac ejection fraction at least 50% by radionuclide ventriculogram No myocardial
infarction within the past year No active angina No congestive heart failure No arrhythmias
requiring medication Other: No active peptic ulcers No uncontrolled infection or other
serious medical condition that would prevent compliance with chemotherapy No uncontrolled
diabetes No spinal cord compression or carcinomatous meningitis

PRIOR CONCURRENT THERAPY: Biologic therapy: Not specified Chemotherapy: No prior
chemotherapy No other concurrent chemotherapy Endocrine therapy: No concurrent
corticosteroid therapy Concurrent gonadotropin-releasing hormone analogue allowed
Radiotherapy: At least 2 months since prior radiotherapy (not to a measurable lesion)
Concurrent palliative radiotherapy allowed Surgery: Not specified
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00004045
Intervention Type: Drug
Intervention Name: exatecan mesylate
Title: Chemotherapy in Treating Patients With Prostate Cancer
Condition: Prostate Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS: Histologically or cytologically confirmed prostate carcinoma
Metastatic disease Documented progression of prostate cancer while receiving androgen
ablative therapy (i.e., surgical or chemical castration and a serum testosterone level in
the castrate range) Documented hormone therapy resistance defined as: PSA rise on 3
occasions not less than 4 weeks apart Any evidence of progressive measurable disease PSA
must be above 20 ng/mL prior to study entry No brain metastases

PATIENT CHARACTERISTICS: Age: 18 and over Performance status: ECOG 0-2 Life expectancy: At
least 12 weeks Hematopoietic: Absolute neutrophil count at least 1,500/mm3 Hemoglobin at
least 9.0 g/dL Platelet count at least 100,000/mm3 Hepatic: Bilirubin no greater than 1.5
mg/dL SGOT/SGPT no greater than 2 times upper limit of normal (ULN) (5 times ULN if liver
metastases present) Renal: Creatinine no greater than 1.5 mg/dL

Cardiovascular: No active
congestive heart failure No uncontrolled angina No myocardial infarction within the past 6
months Other: Fertile patients must use effective contraception No uncontrolled pain
requiring irradiation No concurrent serious infection No other malignancy within the past 5
years except nonmelanoma skin cancer No overt psychosis, mental disability, or incompetence

PRIOR CONCURRENT THERAPY: Biologic therapy: No prophylactic colony stimulating factors to
prevent neutropenia No concurrent biologic therapy Chemotherapy: No more than 1 prior
cytotoxic chemotherapy regimen No concurrent cytotoxic chemotherapy Endocrine therapy: See
Disease Characteristics At least 6 weeks since prior peripheral antiandrogens (e.g.,
flutamide) No concurrent steroid therapy initiated within past 2 months Current LHRH
agonist therapy should continue through study Radiotherapy: At least 4 weeks since prior
radiotherapy (except low dose, non myelosuppressive) and recovered No prior irradiation to
greater than 25% of bone marrow No prior strontium chloride Sr 89 or samarium Sm 153
lexidronam pentasodium No concurrent radiotherapy Surgery: See Disease Characteristics At
least 4 weeks since prior major surgery and recovered No concurrent surgery Other: No other
concurrent anticancer treatment At least 28 days since investigational drugs, including
analgesics or antiemetics No other investigational drugs during and for 28 days after study
No concurrent drugs that induce or inhibit CYP3A enzyme No concurrent herbal preparations
(e.g., PC-SPES)
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00004046
Intervention Type: Drug
Intervention Name: exatecan mesylate
Title: Chemotherapy in Treating Women With Metastatic Breast Cancer
Condition: Breast Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS: Histologically confirmed metastatic adenocarcinoma of the breast
Prior treatment with an anthracycline (e.g., doxorubicin or epirubicin) and a taxane (e.g.,
paclitaxel or docetaxel) either as adjuvant therapy or for advanced disease Bidimensionally
measurable disease Sentinel lesions must be outside of any prior radiation port No resected
disease or stage IV with no evaluable disease No brain metastases or leptomeningeal disease
No symptomatic lymphangitic pulmonary metastases Hormone receptor status: Not specified

PATIENT CHARACTERISTICS: Age: 18 and over Sex: Female Menopausal status: Not specified
Performance status: ECOG 0-2 Life expectancy: At least 12 weeks Hematopoietic: Hemoglobin
at least 9.0 g/dL Absolute neutrophil count at least 1,500/mm3 Platelet count at least

100,000/mm3 Hepatic: Bilirubin no greater than 1.5 mg/dL SGOT or SGPT no greater than 2
times upper limit of normal (ULN) (5 times ULN if liver metastases present) Renal:
Creatinine no greater than 2.0 mg/dL Cardiovascular: No active congestive heart failure No
uncontrolled angina No myocardial infarction within past 6 months Neurologic: No history of
an existing grade 3-4 peripheral neuropathy of any etiology Other: Not pregnant or nursing
Negative pregnancy test Fertile patients must use effective contraception No allergy to
camptothecin or its derivatives No concurrent serious infection No other malignancy within
the past 5 years except nonmelanoma skin cancer or carcinoma in situ of the cervix No overt
psychosis, mental disability, or incompetence No other life threatening disease

PRIOR CONCURRENT THERAPY: Biologic therapy: No concurrent biologic therapy No prophylactic
colony stimulating factors to prevent neutropenia (except when neutropenia fever occurs
despite dose reduction) Chemotherapy: See Disease Characteristics No greater than 3 prior
chemotherapy regimens for metastatic breast cancer or as either adjuvant or neoadjuvant
therapy At least 4 weeks since prior chemotherapy (6 weeks for nitrosoureas and mitomycin)
and recovered No other concurrent cytotoxic chemotherapy Endocrine therapy: Exogenous
hormonal therapy for stage IV disease and/or as adjuvant therapy allowed At least 3 weeks
since prior hormonal therapy except for: Patients who are highly unlikely to have a
withdrawal response to cessation of hormonal therapy (e.g., patients with disease that is
primarily resistant to hormonal therapy, patients without prior partial response, or
stabilization of disease lasting less than 6 months) Patients with new or extensive
visceral metastases Patients with rapidly progressive or symptomatic metastases during
hormonal therapy Radiotherapy: See Disease Characteristics At least 4 weeks since prior
radiotherapy and recovered No prior radiotherapy to greater than 50% of bone marrow No
concurrent radiotherapy Surgery: See Disease Characteristics At least 4 weeks since prior
major surgery and recovered No concurrent surgery Other: No other concurrent anticancer
treatment At least 28 days since other prior investigational drugs, including analgesics or
antiemetics No other investigational drugs during and for 28 days after the study No drugs
that induce or inhibit CYP3A enzyme
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00004083
Intervention Type: Drug
Intervention Name: cisplatin liposomal
Title: Liposomal Cisplatin in Treating Patients With Recurrent Ovarian Cancer
Condition: Ovarian Cancer

Eligibility Criteria: DISEASE CHARACTERISTICS: Histologically or cytologically proven recurrent ovarian
epithelial cancer Metastatic disease allowed Must have received prior platinum containing
chemotherapy Must be considered platinum sensitive and have had the following: Response to
a prior platinum containing regimen No disease progression during prior platinum containing
regimen Disease free interval of greater than 6 months following platinum containing
regimen At least 1 bidimensionally measurable lesion No CNS metastases

PATIENT CHARACTERISTICS: Age: 18 and over Performance status: Karnofsky 70-100% Life
expectancy: At least 3 months Hematopoietic: Absolute neutrophil count at least 1,500/mm3
Platelet count at least 100,000/mm3 Hemoglobin at least 9.0 g/dL Hepatic: Bilirubin no
greater than 2.0 mg/dL AST no greater than 2 times upper limit of normal Albumin at least
2.5 g/dL Renal: Creatinine clearance at least 50 mL/min Cardiovascular: No uncontrolled
heart disease or abnormal symptomatic cardiac function Other: Must have had a baseline
hearing evaluation including an audiogram Not pregnant or nursing Negative pregnancy test
Fertile patients must use effective contraception No acute infection requiring systemic
therapy No signs of confusion or disorientation or prior major psychiatric illness that may
preclude informed consent No grade 3 or 4 neurotoxicity from prior anticancer treatment or
grade 2 or higher neuropathy from other causes No requirement for total parental nutrition
with lipids No prior allergic reaction to cisplatin or platinum containing products

PRIOR CONCURRENT THERAPY: Biologic therapy: Not specified Chemotherapy: See Disease
Characteristics No prior SPI-77 At least 3 weeks since other prior chemotherapy (6 weeks
for nitrosoureas, mitomycin, or suramin) No concurrent antineoplastic agents Endocrine
therapy: No concurrent hormonal anticancer therapy Radiotherapy: At least 2 weeks since
prior radiotherapy No concurrent radiotherapy Surgery: At least 2 weeks since prior major
surgery for cancer Other: At least 30 days since other prior investigational agent No other
concurrent investigational agents
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00004108
Intervention Type: Drug
Intervention Name: exatecan mesylate
Title: DX-8951f in Treating Patients With Liver Cancer
Condition: Liver Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS: Histologically confirmed hepatocellular carcinoma with or without
evidence of unresectable extrahepatic metastasis Previously untreated disease OR
Progressive disease after first line chemotherapy Bidimensionally measurable disease by CT

scan, chest x-ray, or MRI of the abdomen No brain metastases

PATIENT CHARACTERISTICS: Age: 16 and over Performance status: ECOG 0-2 Life expectancy: At least 12 weeks Hematopoietic: Absolute neutrophil count at least 1,500/mm3 Platelet count at least 80,000/mm3 Hemoglobin at least 9.0 g/dL Hepatic: Bilirubin no greater than 2.0 mg/dL Albumin at least 2.8 g/dL SGOT/SGPT no greater than 5 times upper limit of normal (ULN) PT/INR no greater than 1.5 times ULN if not on coumadin therapy Renal: Creatinine no greater than 1.5 mg/dL Cardiovascular: No active congestive heart failure No uncontrolled angina No myocardial infarction within the past 6 months Other: No concurrent serious infection No other life threatening illness No overt psychosis or mental disability that would preclude informed consent No other malignancy within the past 5 years except curatively treated nonmelanomatous skin cancer or carcinoma in situ of the cervix Not pregnant or nursing Negative pregnancy test Fertile patients must use effective contraception 1 month prior to and during the study

PRIOR CONCURRENT THERAPY: Biologic therapy: No concurrent biologic therapy Chemotherapy: See Disease Characteristics At least 4 weeks since prior chemotherapy and recovered No prior camptothecin analogues No other concurrent chemotherapy Endocrine therapy: Not specified Radiotherapy: At least 4 weeks since prior radiotherapy and recovered No concurrent radiotherapy Surgery: At least 4 weeks since prior major surgery and recovered No concurrent surgery Other: No other concurrent anticancer therapy At least 4 weeks since prior investigational drugs (including analgesics or antiemetics) No other investigational drugs during or within 28 days after final dose of study drug
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00004149
Intervention Type: Drug
Intervention Name: arsenic trioxide
Title: Arsenic Trioxide in Treating Patients With Stage IV Prostate Cancer That Has Not Responded to Previous Hormone Therapy
Condition: Prostate Cancer
Eligibility Criteria: Eligibility Criteria:

- Diagnosis of stage IVA or IVB hormone-refractory prostate cancer

- Obstructive uropathy and/or hydronephrosis allowed if adequate renal function and urinary drainage

- WBC at least 2,500/mm^3

- Absolute neutrophil count at least 1,500/mm^3

- Platelet count at least 100,000/mm^3

- Hemoglobin at least 9.0 g/dL

- Bilirubin less than 2 mg/dL

Exclusion Criteria:

- No significant active infectious disease

- No grade 2 or greater peripheral neuropathy

- No other debilitating acute or chronic co-morbid medical, neurological, or psychiatric condition that would preclude study compliance

- No concurrent amphotericin B or other agent that prevents restoration of potassium or magnesium to normal levels and/or correction of QT interval to under 500 milliseconds

Overall Status: Completed
Phase: Phase 2

NCTID: NCT00004151
Intervention Type: Drug
Intervention Name: acridine carboxamide
Title: Acridine Carboxamide in Treating Patients With Advanced Non-small Cell Lung Cancer
Condition: Lung Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS: Histologically proven unresectable, locally advanced, progressive or metastatic non-small cell lung cancer Not amenable to curative surgery or radiotherapy No prior first line chemotherapy for metastatic or advanced disease At least 1 bidimensionally measurable target lesion by CT scan No symptomatic brain metastases

PATIENT CHARACTERISTICS: Age: 18 and over Performance status: ECOG 0-2 Life expectancy: At least 3 months Hematopoietic: WBC greater than 3,000/mm3 Platelet count greater than 100,000/mm3 Hepatic: Bilirubin less than 1.5 times upper limit of normal (ULN) SGOT, SGPT, and alkaline phosphatase no greater than 2 times ULN (5 times ULN if liver metastases present) Renal: Creatinine no greater than 1.7 mg/dL Cardiovascular: No ischemic heart disease within the past 6 months Normal 12 lead ECG Other: Not pregnant or nursing Negative pregnancy test Fertile patients must use effective contraception No other prior or concurrent malignancy except cone biopsied carcinoma of the cervix or adequately treated basal or squamous cell skin cancer No unstable systemic disease or active uncontrolled infection No psychological, familial, sociological, or geographical condition that could preclude compliance

PRIOR CONCURRENT THERAPY: Biologic therapy: Not specified Chemotherapy: See Disease Characteristics No prior chemotherapy Endocrine therapy: Not specified Radiotherapy: At least 4 weeks since prior radiotherapy Surgery: At least 2 weeks since prior major surgery

Other: No other concurrent anticancer agents No other concurrent investigational therapy
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00004163
Intervention Type: Drug
Intervention Name: Trastuzumab
Title: Trastuzumab in Treating Patients With Advanced Salivary Gland Cancer
Condition: Head and Neck Cancer
Eligibility Criteria: Inclusion Criteria

- Histologic diagnosis of any of the following malignancies originating from salivary tissue: adenoid cystic carcinoma, mucoepidermoid carcinoma, acinic cell carcinoma, malignant mixed tumor, polymorphous low grade adenocarcinoma, undifferentiated carcinoma, squamous cell carcinoma, adenocarcinoma.

- Her2/neu determination: Patients must have overexpression of the Her2/neu protein in the tumor documented by the Dako polyclonal rabbit anti-Her2 antisera assay.

Overexpression may be documented by staining of the original paraffin embedded tumor from the time of diagnosis or from material obtained at the time of locoregional or distant recurrence.

Overexpression of HER2/neu will be per the Dako Herceptest guidelines. A Score of 2+ or 3+ will be defined as overexpression. All slides will be reviewed by members of the departments of pathology at either the Brigham and Women's Hospital or the Beth Israel Hospital in Boston.

- Patients must be incurable on the basis of unresectable local or distant disease as determined by the patient's surgeon.

- Patients must have an ECOG performance status of 0 to 1.

- Patients must have at least uni-dimensionally measurable disease documented within one month of initiation of treatment. Measurement may be by physical exam or radiologically. Attempts should be made to photo document all tumor sites assessed by physical examination with a metric ruler within the photo for measurement confirmation.

- Patients must be willing and able to go through the process of informed consent.

- Patients must have a life expectancy exceeding 3 months.

- Patients must be at least 18 years old.

- Patients must have adequate organ function as defined by the following tests to be

performed within 14 days of therapy initiation:

- Absolute neutrophil count > 1999 cells x 10 61L

- Platelet count > 99,999 cells x 106/L

- Hemoglobin >8.5 gm/di or HCT > 25%

- Serum creatinine < 1.5 x institutional upper limits of normal (ULN) or creatinine clearance measured by 24 hour urine collection as at least 50% of institutional lower limit of normal.

- Total bilirubin <2 x institutional ULN

- AST (SGOT) < 2 x institutional ULN *

- If from documented liver involvement with cancer, may be up to < 5 x institutional ULN
Alkaline Phosphatase < 5 x institutional ULN *

- If from documented bone or liver involvement with cancer, no upper limit restriction.

- Baseline determination of normal left ventricular ejection fraction as evidenced MUGA or echocardiogram.

Exclusion Criteria:

- Patients must not have received more than two regimens of cytotoxic chemotherapy for salivary gland cancer. Previous immunologic, hormonal, homeopathic, natural, or alternative medicine therapies are acceptable provided treatment ended greater than 28 days prior to protocol therapy.

- Patients must not receive any form (including radiotherapeutic, immunologic, hormonal, homeopathic, natural, or alternative medicine) of anti-neoplastic therapy other than Herceptin while participating in this study.

- Patients must not have a history of any non-salivary invasive neoplasm within three years of trial entry, excepting curatively treated non-melanoma skin cancer and cervical cancer.

- Pregnant and breast feeding women are not eligible for this study. No pregnancy test is required. Women of childbearing potential must be counseled on the use of effective birth control prior to participation in this study.

- Patients with significant active illness (e.g. congestive heart failure, COPD, uncontrolled diabetes, AIDS, previous MI, cardiomyopathies, history of uncontrolled arrhythmias) are not eligible for this study.

- Patients who have received anthracyclines (e.g. doxorubicin,

daunorubicin, epirubicin)
            are eligible but must have a baseline MUGA scan documenting normal cardiac
            contractility (at or above the normal institutional limit) within one month of trial
            enrollment. The upper limit of doxorubicin exposure should be no more than 360mg1m2
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00004193
Intervention Type: Drug
Intervention Name: ISIS 2503
Title: ISIS 2503 in Treating Patients With Metastatic and/or Locally Recurrent Colorectal Cancer
Condition: Colorectal Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS: Histologically proven metastatic and/or locally recurrent
        adenocarcinoma of the colon or rectum that is not expected to be cured with standard
        therapy Patients who previously underwent definitive surgical resection and subsequently
        develop metastatic disease should have diagnosis reconfirmed with new histologic or
        cytologic specimen if: More than 5 years have elapsed since primary surgery OR Primary
        tumor was stage I or II At least 1 measurable lesion (2 cm or more in widest diameter) by
        CT or MRI scan No CNS metastases

        PATIENT CHARACTERISTICS: Age: 18 and over Performance status: ECOG 0 or 1 Life expectancy:
        Not specified Hematopoietic: Absolute neutrophil count greater than 1,500/mm3 Platelet
        count greater than 100,000/mm3 Hepatic: Bilirubin no greater than 1.5 mg/dL Renal:
        Creatinine no greater than 1.5 mg/dl Other: Not pregnant or nursing Negative pregnancy test
        Fertile patients must use effective contraception during and for 6 months after study No
        underlying disease state associated with active bleeding No active infection requiring
        therapy No second malignancy within the past 5 years except curatively treated
        nonmelanomatous skin cancer

        PRIOR CONCURRENT THERAPY: Biologic therapy: Not specified Chemotherapy: No prior
        chemotherapy for metastatic disease At least 6 months since prior adjuvant chemotherapy
        with or without radiotherapy Endocrine therapy: Not specified Radiotherapy: Prior
        radiotherapy to nonindicator lesion allowed and recovered See Chemotherapy Surgery: See
        Disease Characteristics Other: No concurrent approved cancer therapy or other experimental
        therapy
Overall Status: Terminated
Phase: Phase 2

NCTID: NCT00004182
Intervention Type: Drug
Intervention Name: irinotecan hydrochloride
Title: Irinotecan in Treating Patients With Metastatic or Recurrent Breast

Cancer
Condition: Breast Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS: Histologically proven advanced breast cancer Must have received
anthracycline and taxane based chemotherapy for metastatic disease Measurable disease No
CNS metastases or carcinomatous meningitis Hormone receptor status: Not specified

PATIENT CHARACTERISTICS: Age: 18 and over Menopausal status: Not specified Performance
status: ECOG 0-2 Life expectancy: At least 12 weeks Hematopoietic: Granulocyte count
greater than 1500/mm3 Hemoglobin at least 9.0 g/dL Platelet count greater than 100,000/mm3
Hepatic: Bilirubin no greater than 1.3 mg/dL SGOT no greater than 3 times upper limit of
normal (no greater than 5 times ULN if liver involvement) No Gilbert's disease Renal:
Creatinine no greater than 2.0 mg/dL Calcium at least 12.0 mg/dL Cardiovascular: No
myocardial infarction in the past 6 months No congestive heart failure requiring therapy
Other: No active or uncontrolled infection HIV negative No psychiatric disorder that would
preclude study No prior malignancy within the past 5 years except adequately treated basal
cell or squamous cell skin cancer or carcinoma in situ of the cervix No history of seizures
No uncontrolled diabetes mellitus (random blood sugar at least 200 mg) No other severe
disease that would preclude study Not pregnant or nursing Fertile patients must use
effective contraception

PRIOR CONCURRENT THERAPY: Biologic therapy: Not specified Chemotherapy: See Disease
Characteristics Greater than 4 weeks since prior chemotherapy No prior irinotecan or
topotecan Endocrine therapy: Not specified Radiotherapy: Greater than 4 weeks since prior
radiotherapy No radiotherapy to greater than 30% of bone marrow Surgery: Not specified
Other: No concurrent phenytoin, phenobarbitol, or other antiepileptic prophylaxis
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00004207
Intervention Type: Drug
Intervention Name: liposomal daunorubicin citrate
Title: Liposomal Daunorubicin in Treating Patients With Metastatic Breast Cancer
Condition: Breast Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS: Histologically or cytologically proven metastatic breast cancer
Measurable disease No bone metastases only No CNS involvement or leptomeningeal disease
Hormone receptor status: Not specified

PATIENT CHARACTERISTICS: Age: 18 and over Menopausal status: Not specified Performance
status: ECOG 0-2 Life expectancy: At least 3 months Hematopoietic: Absolute neutrophil
count at least 1,500/mm3 Platelet count at least 100,000/mm3 Hemoglobin

at least 9 g/dL
Hepatic: Bilirubin less than 1.5 times upper limit of normal (ULN) AST or ALT less than 2
times ULN (less than 5 times ULN if liver metastases present) Renal: Creatinine normal
Cardiovascular: Left ventricular ejection fraction at least 50% or normal by echocardiogram
or MUGA scan No active ischemic heart disease No uncontrolled hypertension No poorly
controlled atrial arrhythmias, symptomatic angina pectoris, or myocardial infarction within
the past 6 months No symptomatic congestive heart failure, percutaneous transluminal
coronary angioplasty, or coronary artery bypass graft surgery within the past 12 months
Other: No other primary cancer within the past 5 years except curatively treated
nonmelanomatous skin cancer or carcinoma in situ of the cervix Not pregnant or nursing
Negative pregnancy test Fertile patients must use effective contraception No condition that
would preclude informed consent or compliance

PRIOR CONCURRENT THERAPY: Biologic therapy: At least 3 weeks since prior immunotherapy No
prior bone marrow transplantation Chemotherapy: Prior nonanthracycline based chemotherapy
for breast cancer allowed No prior anthracycline based chemotherapy for metastatic disease
Prior anthracycline based adjuvant chemotherapy allowed if: At least 6 months have elapsed
from completion of adjuvant therapy until the detection of metastatic disease Cumulative
dose no greater than 300 mg/m2 Endocrine therapy: At least 3 weeks since prior hormonal
therapy No concurrent hormonal or corticosteroid therapy for breast cancer Radiotherapy: At
least 2 weeks since prior radiotherapy and recovered No concurrent radiotherapy Surgery:
Not specified
Overall Status: Unknown status
Phase: Phase 1

NCTID: NCT00004238
Intervention Type: Drug
Intervention Name: pralatrexate
Title: 10-Propargyl-10-Deazaaminopterin in Treating Patients With Stage IIIB or Stage IV Non-small Cell Lung Cancer
Condition: Lung Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS: Histologically confirmed stage IIIB (pleural or pericardial
disease) or stage IV non-small cell lung cancer Measurable or evaluable indicator lesion
that has not been irradiated Pleural effusions, bone metastases, brain metastases, elevated
serum enzymes, and abnormal radionucliotide scans are unacceptable as sole indicator
lesions No clinically significant pleural effusions or ascites No grade III or IV edema No
prior pneumonectomy No symptomatic or uncontrolled brain or leptomeningeal involvement

PATIENT CHARACTERISTICS: Age: 18 and over Performance status: Karnofsky 70-100% Life

expectancy: Not specified Hematopoietic: WBC at least 4,000/mm3 Hemoglobin at least 10 g/dL
Platelet count at least 160,000/mm3 Hepatic: Bilirubin no greater than 1.0 mg/dL AST no
greater than 1.5 times upper limit of normal (ULN) Alkaline phosphatase no greater than 5
times ULN Renal: Creatinine no greater than 1.5 mg/dL OR Creatinine clearance at least 50
mL/min Cardiovascular: No unstable cardiac disease requiring treatment Other: Not pregnant
or nursing Negative pregnancy test Fertile patients must use effective contraception No
other concurrent active cancer No history of significant neurologic or psychiatric
disorders, including psychotic disorders, dementia, or seizures No active uncontrolled
infection No other serious illness or medical condition

PRIOR CONCURRENT THERAPY: Biologic therapy: Not specified Chemotherapy: No prior
chemotherapy OR Progression after stable disease or initial response to 1 prior
chemotherapy regimen, including 1 preoperative or adjuvant chemotherapy regimen Endocrine
therapy: Concurrent steroids allowed if dose is stable Radiotherapy: See Disease
Characteristics At least 3 weeks since prior radiotherapy Surgery: See Disease
Characteristics Other: No prior antifolates At least 7 days since prior folic acid
supplements
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00004251
Intervention Type: Drug
Intervention Name: letrozole
Title: Letrozole in Treating Women With Recurrent or Metastatic Endometrial Cancer
Condition: Endometrial Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS: Histologically proven, recurrent or metastatic, adenocarcinoma or
adenosquamous carcinoma of the endometrium not curable by surgery and/or radiotherapy
Failed one prior progestin therapy for advanced/metastatic disease OR Considered for
letrozole as first line therapy of advanced/metastatic disease No clear cell or papillary
serous histology, uterine sarcomas, mixed muellerian tumors, and/or adenosarcomas At least
one site of measurable disease by clinical exam, CT, or MRI scan Bone lesion(s) are not
considered measurable No CNS metastases

PATIENT CHARACTERISTICS: Age: 18 and over Performance status: ECOG 0-2 Menopausal status:
Postmenopausal (surgical or natural) Life expectancy: At least 12 weeks Hematopoietic:
Absolute granulocyte count at least 1,500/mm3 Platelet count at least 100,000/mm3 Hepatic:
Bilirubin less than upper limit of normal (ULN) AST or ALT no greater than 2 times ULN
Alkaline phosphatase less than 2 times ULN Renal: Creatinine no greater than 2 times ULN

Other: No other malignancy within the past 5 years, except: Adequately treated basal or squamous cell skin cancer Carcinoma in situ of the cervix No other concurrent medical illness that would preclude compliance

PRIOR CONCURRENT THERAPY: Biologic therapy: Not specified Chemotherapy: No prior chemotherapy for advanced/metastatic disease At least 4 weeks since prior adjuvant chemotherapy Endocrine therapy: See Disease Characteristics No more than one prior progestational hormone therapy regimen for advanced/metastatic disease At least 1 week since prior hormonal therapy No prior tamoxifen or other aromatase inhibitor therapy Radiotherapy: See Disease Characteristics At least 4 weeks since prior radiotherapy Concurrent radiotherapy for symptomatic metastatic lesions allowed Surgery: See Disease Characteristics Other: No other concurrent anticancer therapy No other concurrent investigational therapy
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00004265
Intervention Type: Drug
Intervention Name: paclitaxel
Title: Paclitaxel in Treating Patients With Recurrent or Refractory Non-small Cell Lung Cancer
Condition: Lung Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS: Histologically confirmed non-small cell lung cancer with documented recurrent or refractory disease Progressive disease at more than 3 months from completion of first line chemotherapy OR Progressive disease during first line chemotherapy Clinically stable CNS metastases allowed

PATIENT CHARACTERISTICS: Age: Over 18 Performance status: ECOG 0-1 Life expectancy: Not specified Hematopoietic: WBC at least 3,500/mm3 Absolute neutrophil count at least 1,500/mm3 Platelet count at least 100,000/mm3 Hemoglobin at least 9.0 g/dL Hepatic: Bilirubin no greater than 2.0 mg/dL AST no greater than 5 times upper limit of normal Renal: Creatinine no greater than 1.5 mg/dL OR Creatinine clearance at least 60 mL/min Cardiovascular: No clinically significant bradyarrhythmias Other: Neuropathy less than grade 2 Fertile patients must use effective contraception

PRIOR CONCURRENT THERAPY: Biologic therapy: At least 4 weeks since prior immunotherapy Chemotherapy: See Disease Characteristics Must have had at least 1 prior first line chemotherapy regimen for metastatic or locally advanced disease One prior paclitaxel regimen (every 3 week schedule) allowed if no progressive disease at less than 3 months from completion of therapy At least 4 weeks since prior chemotherapy Endocrine therapy: Not

specified Radiotherapy: At least 2 weeks since prior radiotherapy (indicator lesions within
the radiation port must have progressed since completion of therapy)
Surgery: Not specified
Overall Status: Unknown status
Phase: Phase 2

NCTID: NCT00002063
Intervention Type: Drug
Intervention Name: Zidovudine
Title: Treatment of AIDS and AIDS Related Complex. Part-1- Treatment of Patients With ARC (AZT Vs. Placebo)
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Patient must have AIDS related complex (ARC) as defined by Walter Reed stages, be
ambulatory, and be able to give informed consent.

Exclusion Criteria

Co-existing Condition:

Patients with unstable disease characterized by the following are excluded:

- Hospitalization within the past 14 days.

- Major opportunistic infection, current or past.

- An active infection of onset during the past 30 days, as evidenced by symptoms, signs,
or laboratory abnormalities such as:

- Temperature = or > 100.5 degrees F.

- Night sweats.

- Weight loss = or > 10 percent of body weight.

- Diarrhea (3 or more bowel movements/day).

- Persistent cough, shortness of breath, or dyspnea on exercise.

- Abnormal chest x-ray suggesting pneumonia or increased arterial-alveolar (A-a)
gradient.

- Altered mental status, seizures, or focal neurologic signs.

- Abnormal computerized tomography (CT) scan or magnetic resonance imaging (MRI)
suggestive of toxoplasmosis, peripheral mononuclear leukocytes, lymphoma, or other
focal abnormality of the central nervous system (CNS).

- Abnormal cerebrospinal fluid (CSF) suggestive of cryptococcal, mycobacterial, or other
meningitis. (The decision to perform invasive tests, such as lumbar puncture,
specialized microbiological tests such as bone marrow culture for Mycobacteria or
Histoplasma capsulatum, or specialized radiological tests such as CT scan or MRI

should be based on clinical assessment of the patient.)

- Kaposi's sarcoma.
- Lymphoma; malignancy requiring chemotherapy.
- Dementia.
- Requiring hemodialysis or renal insufficiency or failure.
- Leukopenia.
- Thrombocytopenia.

Patients with the following are excluded:

- Unstable disease.
- Kaposi's sarcoma.
- Lymphoma; malignancy requiring chemotherapy.
- Dementia.
- Major opportunistic infection, current or past.
- Anemia (hemoglobin less than 9.5 g/dl).

Prior Medication:

Excluded within 1 month of study entry:

- Ribavirin or zidovudine (AZT) or other antivirals.
- Immunomodulating agents.

Overall Status: Completed
Phase: nan

NCTID: NCT00002066
Intervention Type: Drug
Intervention Name: Thymopentin
Title: Double Blind Study of Thymopentin Effects on Patients With HIV-1 Infection
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Concurrent Medication:

Allowed:

- Aerosolized pentamidine.

Prior Medication:

Allowed:

- Aerosolized pentamidine.

Exclusion Criteria

Co-existing Condition:

Patients with an abnormal chest x-ray indicative of active disease (opportunistic

infection) within 30 days prior to entry are excluded.

Concurrent Medication:

Excluded within 90 days of study entry:

- Zidovudine (AZT).

Prior Medication:

Excluded within 30 days of study entry:

- Immunomodulatory or experimental therapy.

- Excluded within 90 days of study entry:

- Zidovudine (AZT).

Patients must not have:

- Hemophilia A or B or other hematologic disorders requiring current or previous administration of blood products.

- AIDS as defined by the CDC (except for those with HIV "wasting syndrome").

- Significant hepatic disease.

- Thrombocytopenia (< 75000 platelets/mm3).

Patient must voluntarily sign consent and be seropositive for HIV-1 (ELISA assay) confirmed by Western blot.

- HIV-1 p24 antigen must be detected in supernatant fluids from co-cultures of patient's peripheral blood monocytes (PBMC) on two separate occasions.

- Patients with HIV "wasting syndrome" are included.

Intravenous drug abuse.
Overall Status: Completed
Phase: nan

NCTID: NCT00002092
Intervention Type: Drug
Intervention Name: Cimetidine
Title: A Study to Evaluate the Effect of Cimetidine on CD4 Lymphocyte Counts in HIV Infection
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria:

Concurrent Medication:

Allowed:

- All FDA-approved medications, antiretrovirals, and PCP prophylaxis drugs, with the exception of warfarin (Coumadin).

- Other self-prescribed medications available either over the counter or through buyer's clubs.

Patients must have:

HIV positivity.

NOTE:

- Patients on an antiviral or immunomodulating drug must have received it for at least 2 months and have no intention to make clinical or therapeutic changes in the first 8 weeks (such as adding a new agent or discontinuing effective viral suppressive therapy) that may interfere with the study.

NOTE:

- Patients who become pregnant after enrollment will be permitted to continue on study drug but must sign an additional informed consent indicating their awareness of the issues in taking a drug with limited safety data during pregnancy.

Prior Medication:

Allowed:

- Antiviral and immunomodulating drugs, provided patient has been on such therapy for at least 2 months prior to study entry.

Exclusion Criteria:

Co-existing Condition:

Patients with the following symptoms or conditions are excluded:

- Known intolerance or hypersensitivity to cimetidine.

- Evidence of active opportunistic infection or malignancy requiring high-dose systemic chemotherapy.

- Any symptoms suggestive of concurrent illness that are not attributable to overall impairment by HIV or are not diagnosable based on the available evidence.

- Inability to swallow tablets (gastric feeding tubes are allowed).

- Not willing to comply with visit schedule and study procedures.

Concurrent Medication:

Excluded:

- Warfarin (Coumadin).

Prior Medication:

Excluded within 4 weeks prior to study entry:

- cimetidine (Tagamet), ranitidine (Zantac), famotidine (Pepcid), and nizatidine (Axid).

Overall Status: Completed
Phase: nan

NCTID: NCT00002087
Intervention Type: Drug
Intervention Name: Alvircept sudotox
Title: Safety, Tolerance, Efficacy and Pharmacokinetics of Multiple Doses of sCD4-PE40 in the Treatment of HIV-Infected Individuals
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Patients must have:

- HIV positivity confirmed by Western blot.

- CD4 count of 100 - 500 cells/mm3 on a morning draw within 3 weeks prior to study entry.

Exclusion Criteria

Co-existing Condition:

Patients with the following symptoms and conditions are excluded:

- Concurrent neoplasms other than basal cell carcinoma of the skin, in situ carcinoma of the cervix, or nondisseminated Kaposi's sarcoma.

- Hemophilia or other clotting disorders.

- Major organ allograft.

- Significant cardiac, hepatic, renal, or CNS disease.

Prior Medication:

Excluded:

- Antiretroviral agents within 2 months prior to study entry.

- Known anti-HIV medication within 60 days prior to study entry.

- Prior immunomodulators (e.g., systemic steroids, interferons, or interleukins) or other chemotherapy.

Prior Treatment:

Excluded:

- Prior radiation therapy. Active substance abuse.
Overall Status: Completed
Phase: Phase 1

NCTID: NCT00002091
Intervention Type: Drug
Intervention Name: Pentoxifylline
Title: An Evaluation of Pentoxifylline in HIV-Positive Persons With Symptomatic HIV Infection and a Karnofsky Score > 40 Percent and < 100 Percent
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Concurrent Medication:

Allowed:

- Stable antiretroviral therapy.

- Maintenance medication for opportunistic infection.

Patients must have:

HIV positivity.

NOTE:

- Patients on an antiretroviral must have received it for at least 2 months and have no currently perceived need to change or add to the regimen for the next 3 months.

Prior Medication:

Allowed:

- Antiviral therapy (provided patient has been on such therapy for at least 2 months at study entry and dose is stable).

Exclusion Criteria

Co-existing Condition:

Patients with the following symptoms and conditions are excluded:

- Evidence of active opportunistic infection or malignancy requiring high-dose systemic chemotherapy (only patients who are 30 days from a diagnosis of an opportunistic infection and on appropriate maintenance medication are allowed).

- Known significant intolerance or hypersensitivity to theophylline, theobromine (chocolate), or caffeine, for reasons other than dyspepsia.

- Inability to swallow tablets (gastric feeding tubes are allowed).

- Active bleeding disorder or major bleeding source, including peptic ulcer or gastritis.

- Any symptoms suggestive of concurrent illness that are not attributable to overall impairment by HIV or are not diagnosable based on the available evidence.

- Not willing to comply with visit schedule and study procedures.

Concurrent Medication:

Excluded:

- Concurrent use of the anticoagulant warfarin (Coumadin) and heparin.

Prior Medication:

Excluded:

- Treatment with biologic response modifiers (e.g., interferon, interleukin) within 14 days prior to study entry.

Prior Treatment:

Excluded:

- Major surgery within 30 days of study entry.

Overall Status: Completed
Phase: nan

NCTID: NCT00002094
Intervention Type: Drug
Intervention Name: Atevirdine mesylate
Title: Prospective Open-Label Study of the Emergence of Drug Resistance in Patients Infected With HIV-1 Who Are Taking Oral U-87201E
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Patients must have:

- Enrollment on protocol RV-43 (AZT resistance study).

- Development of a primary RV-43 study endpoint-opportunistic infection.

- HIV isolate with an AZT IC50 > 50 times that of the sensitive type strain.

- Able to swallow tablets without difficulty.

- Normal QTc interval on EKG.

Exclusion Criteria

Co-existing Condition:

Patients with the following symptoms or conditions are excluded:

- Clinically significant hypersensitivity to piperazine type drugs (Antepar, Stelazine).

- Severe uncontrollable diarrhea or vomiting or known malabsorption.

- Symptomatic hyperlipidemia.

Concurrent Medication:

Excluded:

- Other experimental drugs.

- AZT, ddI, ddC, foscarnet, immunomodulators or other agents with primary antiretroviral activity (exemptions by principal investigator permitted).

Patients with the following prior conditions are excluded:

History of clinically significant cardiovascular disease or nervous system or muscle disease, including seizures, peripheral neuropathy, dementia, or motor

dysfunction.

Prior Medication:

Excluded:

- Experimental drugs within 4 weeks prior to study entry.

Overall Status: Completed
Phase: nan

NCTID: NCT00002069
Intervention Type: Drug
Intervention Name: Ditiocarb sodium
Title: A Study of DTC in Patients With AIDS and AIDS Related Complex
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Concurrent Medication:

Allowed:

- Zidovudine (AZT).

Exclusion Criteria

Co-existing Condition:

Patients with the following are excluded:

- Active opportunistic infection or progressive Kaposi's sarcoma (KS).

- Dementia.

- Lymphoma.

Concurrent Medication:

Excluded within 3 weeks of study entry:

- Other experimental AIDS therapy.

Patients with the following are excluded:

- Active opportunistic infection or progressive Kaposi's sarcoma (KS).

Patients must be either HIV seropositive or have AIDS or AIDS related complex (ARC) and
have life expectancy of at least 6 months.

Overall Status: Completed
Phase: nan

NCTID: NCT00002078
Intervention Type: Drug
Intervention Name: Interferon alfa-n3
Title: Phase I Study of Alferon N Injection in Persons With Asymptomatic Human Immunodeficiency Virus (HIV) Infection
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Patients must have:

- HIV-1 seropositivity.

- CD4 count > 400/mm3.

- Eligibility for care in the military medical system.

Prior Medication:

Allowed:

- Acyclovir.

Exclusion Criteria

Co-existing Condition:

Patients with the following symptoms or conditions are excluded:

- AIDS- or ARC-defining condition (unexplained weight loss, fever, diarrhea, night sweats).

- Evidence of AIDS dementia.

- Chronic hepatitis with severe liver dysfunction.

- Active gastrointestinal, renal, respiratory, endocrine, hematologic, cardiovascular, or psychiatric disorder that would limit ability to complete the study.

- Hemophilia.

- Co-existent disease likely to result in death within the next 2 years.

- Known hypersensitivity to human interferon alpha.

- Known anaphylactic hypersensitivity to mouse immunoglobulin (IgG), egg protein, or neomycin.

Concurrent Medication:

Excluded:

- Any other concurrent experimental medications.

Patients with the following prior conditions are excluded:

- History of AIDS- or ARC-defining condition (unexplained weight loss, fever, diarrhea, night sweats).

- Evidence of chronic hepatitis with severe liver dysfunction.

Prior Medication:

Excluded within 5 days prior to study entry:

- Immunosuppressive agents.

- Chemotherapy.

- Steroids.

Excluded within 45 days prior to study entry:

- BCG vaccine.

- Isoprinosine.

- Other immune modulators.

Excluded within 3 months prior to study entry:

- Any form of interferon.

- Antiviral therapy.

- Immunoregulatory therapy (other than acyclovir).

1. Active drug abuse (narcotic or alcohol abuse documented within the past 6 months).

- Unlikely or unable to comply with the requirements of the protocol.

Overall Status: Completed
Phase: Phase 1

NCTID: NCT00002065
Intervention Type: Drug
Intervention Name: Disulfiram
Title: Depot Disulfiram for AIDS and ARC
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Patients must have a positive diagnosis of AIDS or AIDS related complex (ARC) according to
the CDC criteria.

- Also patient must be:

- Able to understand the study.

- Strongly motivated to participate in the study, and willing to comply with all the
conditions specified in the informed consent forms.

- Ambulatory and able to maintain an independent life outside the hospital.

- Free of clinically significant organic disease affecting neurologic, hepatic, renal,
and clinical status.

Patients must be free of clinically significant organic disease affecting neurologic,
hepatic, renal, and clinical status.

Patients must be free of clinically significant organic disease affecting neurologic,
hepatic, renal, and clinical status.

History of alcohol abuse.

Overall Status: Completed
Phase: nan

NCTID: NCT00002128
Intervention Type: Drug

Intervention Name: Adefovir dipivoxil
Title: Phase I Study of the Safety, Tolerance, and Pharmacokinetics of 9-[2-(Bispivaloyloxymethyl)Phosphonylmethoxyethyl]Adenine (Bis-POM PMEA; Adefovir Dipivoxil) in HIV-Infected Patients
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Concurrent Medication:

Allowed:

- AZT, ddI, or ddC (provided patient has been on a stable regimen for at least 4 weeks prior to study entry).

- Prophylactic aerosolized pentamidine, fluconazole, ketoconazole, trimethoprim/sulfamethoxazole, or dapsone (provided patient has been on a stable regimen for at least 4 weeks prior to study entry).

Patients must have:

- Documented HIV infection or diagnosis of AIDS.

- Life expectancy of at least 3 months.

Prior Medication:

Allowed:

- Prior AZT, ddI, or ddC.

- Prophylactic aerosolized pentamidine, fluconazole, ketoconazole, trimethoprim/sulfamethoxazole, or dapsone.

Exclusion Criteria

Co-existing Condition:

Patients with the following symptoms or conditions are excluded:

- Active, serious infections (other than HIV infections) that require parenteral antibiotic therapy.

- Clinically significant cardiac disease, including symptoms of ischemia, congestive heart failure, or arrhythmia.

- Gastrointestinal malabsorption syndrome or inability to receive oral medication.

Concurrent Medication:

Excluded:

- Diuretics.

- Amphotericin B.

- Aminoglycoside antibiotics.

- Parenteral antibiotics.

- Other nephrotoxic agents.

- Other investigational agents.

- Non-steroidal anti-inflammatory drugs.

- Aspirin.

Prior Medication:

Excluded within 2 weeks prior to study entry:

- Diuretics.

- Amphotericin B.

- Aminoglycoside antibiotics.

- Parenteral antibiotics.

- Other nephrotoxic agents.

- Other investigational agents.

Excluded within 3 days prior to study entry:

- Non-steroidal anti-inflammatory drugs.

- Aspirin. Active substance abuse (including alcohol or drug abuse).

Overall Status: Completed
Phase: Phase 1

NCTID: NCT00002107
Intervention Type: Drug
Intervention Name: Aldesleukin
Title: A Phase I Study of Subcutaneously Administered Proleukin (Aldesleukin) in HIV-Infected Patients
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Patients must have:

- Documented HIV infection by ELISA and Western blot.

- CD4 count > 200 cells/mm3.

Required:

- FDA-approved antiretroviral therapy for at least 2 months prior to study entry.

Overall Status: Completed
Phase: Phase 1

NCTID: NCT00002114
Intervention Type: Drug
Intervention Name: Procysteine
Title: A Double-Blind, Randomized Parallel Group Study Comparing Procysteine to Placebo in HIV-Infected Patients Who Are Taking Antiretroviral Nucleosides
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Concurrent Medication:

Required:

Antiretroviral nucleosides (AZT alone, ddI alone, AZT plus ddI, or AZT plus ddC). Regimen may be altered on or after Week 16.

Allowed:

- Appropriate topical treatment or local radiotherapy for KS.

- Treatment or prophylaxis for opportunistic infections, including pentamidine, cotrimoxazole, acyclovir, fluconazole, etc., at the discretion of the investigator.

Patients must have:

- Documented serologic evidence confirming HIV infection.

- Ability to participate in an outpatient study for at least 26 weeks.

- Either:

- (a) diagnosis of AIDS or AIDS-Related Complex (ARC) with CD4 count of 50 - 300 cells/mm3, or (b) CD4 count of 50 - 200 cells/mm3 and no symptoms of AIDS (asymptomatic). (Note:

- Patients whose AIDS-defining condition is Kaposi's sarcoma alone must have CD4 count of 50 - 200 cells/mm3.)

Exclusion Criteria

Co-existing Condition:

Patients with the following symptoms or conditions are excluded:

- Evidence of organ involvement with CMV and/or positive blood cultures for Mycobacterium avium.

- Life expectancy less than 26 weeks.

- Malignancy or advancing Kaposi's sarcoma (KS) with advancing or unstable skin lesion, or known or suspected visceral disease which requires systemic cytotoxic, myelosuppressive chemotherapy.

- Stage 2 or greater AIDS-dementia complex (ADC), defined as ability to perform basic activities of self-care but inability to work or maintain more demanding aspects of daily life as a result of an acquired decrease in cognitive CNS-related motor function characteristic of ADC.

- Psychological or emotional problems that prevent adequate compliance with study therapy.

Concurrent Medication:

Excluded:

- Daily Vitamin C dosage greater than 1,000 mg or daily Vitamin E dosage greater than 100 units.

- N-acetylcysteine, cysteine, or glutathione.

- Any investigational drug.

- Systemic chemotherapy.

Patients with the following prior conditions are excluded:

- History of organ involvement with cytomegalovirus (CMV) and/or positive blood cultures for Mycobacterium avium.

- Intractable diarrhea, defined as greater than 4 bowel movements per day for at least 2 weeks.

- History of seizures which have not been controlled with appropriate anticonvulsant medications within the previous 6 months.

Prior Medication:

Excluded:

- Any investigational agent or biological response modifier (including interferon or corticosteroids) within 1 month of study entry.

- Use of erythropoietin (EPO), G-CSF, or GM-CSF within 28 days of randomization.

Risk Behavior:

Excluded:

Active alcohol or drug abuse.

Required:

Antiretroviral nucleosides (AZT alone, ddI alone, AZT plus ddI, or AZT plus ddC) for at least 3 months prior to study entry.
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00002097
Intervention Type: Drug
Intervention Name: Nystatin
Title: A Phase I/II Clinical Study of Nystatin I.V. (Intravenous) in Patients With HIV Infection.
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Concurrent Medication:

Required:

- Aerosolized pentamidine (300 mg once a month) for PCP prophylaxis in patients with CD4 count <= 200 cells/mm3. (Patients with CD4 count > 200 cells/mm3 who are already on aerosolized pentamidine may continue such therapy at the discretion of the investigator.)

Allowed:

- Prophylaxis against Mycobacterium avium Complex in patients with CD4 count <= 100 cells/mm3.

Concurrent Treatment:

Allowed:

- Local treatment for Kaposi's sarcoma lesions with less than 25 percent increase in measurable disease.

Patients must have:

- HIV antibody positivity.

- Absolute CD4 count < 500 cells/mm3 on two determinations within 15 days prior to study entry.

- At least 6 months of prior zidovudine (AZT) therapy.

- No active opportunistic infection requiring ongoing therapy.

- Normal neurologic status by standard assessment.

- Life expectancy of at least 6 months.

Exclusion Criteria

Co-existing Condition:

Patients with the following symptoms and conditions are excluded:

- Neoplasm other than basal cell carcinoma of the skin or stable untreated HIV-related Kaposi's sarcoma (provided there is no progression in the Kaposi's sarcoma beyond 25 percent of measurable disease).

- Clinically significant cardiac disease.

- Known hypersensitivity to polyene antibiotics.

Patients with the following prior conditions are excluded:

- History of myocardial infarction or arrhythmias.

Prior Medication:

Excluded within 2 weeks prior to study entry:

- Antiretroviral agents or interferons.

- Biological response modifiers.

- Corticosteroids.

- Cytotoxic chemotherapeutic agents.

- Drugs that can cause neutropenia or significant nephrotoxicity.

- Rifampin or rifampin derivatives.

- Systemic anti-infectives.

Prior Treatment:

Excluded within 2 weeks prior to study entry:

- Radiation therapy. Active drug or alcohol abuse.

Overall Status: Completed
Phase: Phase 1

NCTID: NCT00002118
Intervention Type: Drug
Intervention Name: Zalcitabine
Title: An Open-Label Safety Program for the Use of Zalcitabine (Dideoxycytidine; ddC) in Pediatric Patients With Symptomatic HIV Infection Who Have Failed or Are Intolerant to AZT Monotherapy, or Who Have Completed Other ddC Protocols, or Are Ineligible for Other Ongoing Clinical Studies
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Patients must have:

- Symptomatic HIV infection.

- Failure on or intolerance to AZT monotherapy OR completed other ddC protocols OR been ineligible for other ongoing clinical trials.

- Consent of parent or guardian required.

Note:

- Patients who do not meet the eligibility requirements may discuss their cases with the medical monitor.

Overall Status: Completed
Phase: nan

NCTID: NCT00002106
Intervention Type: Drug
Intervention Name: Ranitidine hydrochloride
Title: A Pilot Randomized, Double-Blind, Placebo-Controlled, Parallel Design, Multicenter Trial to Evaluate the Effect of Ranitidine on Immunologic Indicators in Asymptomatic HIV-1 Infected Subjects With a CD4 Cell Count Between 400-700 Cells/mm3
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Patients must have:

- Asymptomatic HIV-1 infection.

- CD4 count of 400-700 cells/mm3.

Exclusion Criteria

Co-existing Condition:

Patients with the following symptoms or conditions are excluded:

- Significant illness.
- Acute illness at randomization.
- Hemodialysis.

Prior Medication:

Excluded:

- Antiretroviral use within 60 days prior to study entry.

Overall Status: Completed
Phase: Phase 2

NCTID: NCT00002119
Intervention Type: Drug
Intervention Name: WF10
Title: A Phase I/II Clinical Study of WF 10 IV Solution (TCDO) in Patients With HIV Infection
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Concurrent Medication:

Required:

- Aerosolized pentamidine (300 mg monthly) as prophylaxis for PCP only in patients with CD4 count <= 200 cells/mm3.

Allowed:

- PCP prophylaxis with aerosolized pentamidine in patients with CD4 count > 200 cells/mm3, only at the discretion of the treating physician.

Patients must have:

- HIV positivity.
- Absolute CD4 count of 150 - 500 cells/mm3.
- At least 6 months of prior zidovudine therapy.
- No active opportunistic infection requiring ongoing therapy.
- Life expectancy of at least 6 months.

Exclusion Criteria

Co-existing Condition:

Patients with the following symptoms or conditions are excluded:

- Neoplasm other than basal cell carcinoma of the skin.
- Clinically significant cardiac disease.

- Abnormal neurological status by a standardized assessment including strength, reflex testing, and sensory testing.

- Unwilling to comply with protocol requirements.

Patients with the following prior conditions are excluded:

History of myocardial infarction or arrhythmias.

Prior Medication:

Excluded within 2 weeks prior to study entry:

- Antiretroviral agent or interferon.

- Systemic biologic response modifiers, corticosteroids, cytotoxic chemotherapeutic agents, or other drugs that can cause neutropenia or significant nephrotoxicity.

- Rifampin or rifampin derivatives.

- Systemic anti-infectives.

Required:

- At least 6 months of prior zidovudine. Active drug or alcohol abuse.

Overall Status: Completed
Phase: Phase 1

NCTID: NCT00002129
Intervention Type: Drug
Intervention Name: Vesnarinone
Title: A Phase I Study of Three Doses of OPC-8212 (Vesnarinone) in HIV-Infected Persons With CD4+ Cell Number > 300 Cells/mm3
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Concurrent Medication:

Allowed:

- Chemoprophylaxis for Pneumocystis carinii, candida, mycobacteria, and herpes simplex.

Patients must have:

- Asymptomatic HIV infection.

- CD4 count > 300 cells/mm3.

- No prior AIDS-defining illness or current constitutional symptoms of HIV disease.

Exclusion Criteria

Co-existing Condition:

Patients with the following symptoms or conditions are excluded:

- Current history of cardiac disease, including patients who exhibit long QT syndrome on

EKG screening.

- Active malignancy other than cutaneous basal cell carcinoma or in situ carcinoma of the cervix.

Concurrent Medication:

Excluded:

- Antiretroviral agents, including ddI, ddC, and AZT.
- Immunosuppressive agents.
- Investigational HIV drugs/therapies including vaccines.
- Interferon.
- Steroids (other than topical).
- Hematopoietins.
- Megestrol acetate.
- Trimethoprim/sulfamethoxazole in excess of 160 mg trimethoprim and 800 mg sulfamethoxazole thrice weekly.
- Cytotoxic chemotherapy.

Concurrent Treatment:

Excluded:

- Radiation therapy.

Patients with the following prior conditions are excluded:

- Prior history of cardiac disease.
- History of agranulocytosis or severe (grade 3) drug-induced neutropenia or documented abnormalities in granulocyte number or function.

Prior Medication:

Excluded:

- AZT, ddI, and ddC within 14 days prior to study entry.
- Prior cytotoxic chemotherapy.

Prior Treatment:

Excluded:

- Radiation therapy (including electron beam irradiation) within 30 days prior to study entry.

Active illicit drug abuse.

Overall Status: Completed
Phase: Phase 1

NCTID: NCT00002115
Intervention Type: Drug
Intervention Name: Adefovir
Title: A Phase I/II Study of the Safety, Tolerance, and Pharmacokinetics of 9-(2-Phosphonylmethoxyethyl)Adenine (PMEA; Adefovir) in Patients With Advanced HIV Disease.
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Concurrent Medication:

Allowed:

- Other antiretroviral therapy IF on a stable dose for at least 4 weeks prior to study entry.

- Prophylactic therapy with aerosolized pentamidine, oral trimethoprim/sulfamethoxazole (Bactrim, Septra) or dapsone, and fluconazole or ketoconazole IF on a stable prophylactic regimen for at least 4 weeks prior to study entry.

Patients must have:

- HIV seropositivity.

- Elevated p24 antigen (> 40 pg/ml).

- Mean CD4 count <= 100 cells/mm3.

- Life expectancy of at least 3 months.

Prior Medication:

Allowed:

- Other prior antiretroviral therapy.

- Prophylactic therapy with aerosolized pentamidine, oral trimethoprim/sulfamethoxazole (Bactrim, Septra) or dapsone, and fluconazole or ketoconazole.

Exclusion Criteria

Co-existing Condition:

Patients with the following symptoms or conditions are excluded:

- Inadequate venous access.

- Active serious infection (other than HIV infection) requiring parenteral antibiotic therapy.

- Clinically significant cardiac disease, including symptoms of ischemia, congestive heart failure, or arrhythmia.

- Psychiatric disturbance or illness that may affect compliance.

- Malignancy other than Kaposi's sarcoma.

Concurrent Medication:

Excluded:

- Investigational agents other than stavudine (d4T).
- Interferon-alpha.
- Ganciclovir.
- Foscarnet.
- Diuretics.
- Amphotericin B.
- Aminoglycoside antibiotics.
- Other nephrotoxic agents.
- Acyclovir at doses >= 2 g/day.

Prior Medication:

Excluded within 2 weeks prior to study entry:

- Investigational agents other than stavudine (d4T).
- Interferon-alpha.
- Ganciclovir.
- Foscarnet.
- Diuretics.
- Amphotericin B.
- Aminoglycoside antibiotics.
- Other nephrotoxic agents.

Excluded within 4 weeks prior to study entry:

- Systemic therapy for Kaposi's sarcoma. Substance abuse.

Overall Status: Completed
Phase: Phase 1

NCTID: NCT00002100
Intervention Type: Drug
Intervention Name: Curdlan sulfate
Title: Phase I/II Study of Curdlan Sulfate
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Patients must have:

- HIV seropositivity.
- No current AIDS-defining opportunistic infection, lymphoma, Kaposi's sarcoma, or other malignancy.
- CD4 count < 500 cells/mm3.

- No critical illness that would shorten life expectancy to < 16 weeks.

Exclusion Criteria

Concurrent Medication:

Excluded:

- Antiretroviral or other experimental therapies.
- Anticoagulants.
- Steroids.
- Cytotoxic or immunosuppressive agents.

Concurrent Treatment:

Excluded:

- Radiotherapy.

Patients with the following prior condition are excluded:

History of heparin sensitivity.

Prior Medication:

Excluded within 1 month prior to study entry:

- Antiretroviral or other experimental therapies.
- Anticoagulants.
- Steroids.
- Cytotoxic or immunosuppressive agents.

Prior Treatment:

Excluded:

- Radiotherapy within 1 month prior to study entry. Active IV drug abuse.

Overall Status: Completed
Phase: Phase 1

NCTID: NCT00002111
Intervention Type: Drug
Intervention Name: Saquinavir
Title: A Dose-Escalating Study of Ro 31-8959 (HIV Protease Inhibitor) in Patients With HIV Disease.
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Patients must have:

- Documented HIV infection.
- CD4 count 200 - 500 cells/mm3.
- No evidence of viral resistance.

- HIV RNA quantifiable by PCR.

- Negativity for HBsAg, HBeAg, and anti-HBc.

NOTE:

- Fifty percent of patients must have measurable p24 antigen levels (> 31 pg/ml).

Exclusion Criteria

Co-existing Condition:

Patients with the following symptoms or conditions are excluded:

- Active opportunistic infection requiring immediate treatment, such as tuberculosis, cytomegalovirus, cerebral toxoplasmosis, and Pneumocystis carinii pneumonia.

- Unable to maintain adequate oral intake.

- Clinically significant vomiting and/or diarrhea.

- Malignancy, visceral Kaposi's sarcoma, or lymphoma that will require systemic chemotherapy within the next 12 months.

- Unable to comply with protocol requirements, in the judgment of the investigator.

- Any grade 3 or worse laboratory or clinical abnormality.

Concurrent Medication:

Excluded:

- Antineoplastic agents.

- Concomitant or maintenance treatment with excluded experimental drugs and drugs with known nephrotoxic or hepatotoxic potential.

Concurrent Treatment:

Excluded:

- Radiation therapy other than local skin radiation therapy.

Patients with the following prior conditions are excluded:

- Unexplained temperature >= 38.5 C (101.5 F) persisting for 14 days or more within a 30-day period.

- Unexplained, chronic diarrhea persisting for 14 days or more within a 30-day period.

Prior Medication:

Excluded:

- Prior treatment with an HIV proteinase inhibitor.

- AZT within 30 days prior to study entry OR lasting more than 1 year.

- Other antiretroviral therapy (besides AZT) within 30 days prior to study entry OR lasting more than 14 days.

- Acute therapy for an opportunistic infection within 14 days prior to study entry.

Overall Status: Completed
Phase: Phase 1

NCTID: NCT00002152
Intervention Type: Drug
Intervention Name: WF10
Title: A Study of WF 10 IV Solution in Patients With Advanced HIV Disease
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Concurrent Medication:

Allowed:

- Approved drugs at a stabilized dose except those specifically excluded.

- Aerosolized pentamidine (300 mg) once a month for PCP prophylaxis.

Patients must have:

- HIV positivity.

- Absolute CD4 count < 200 cells/mm3.

- Intolerance to or refusal to take AZT, ddI, ddC, or d4T.

- No active opportunistic infection requiring ongoing therapy.

- Life expectancy at least 3 months.

Exclusion Criteria

Co-existing Condition:

Patients with the following symptoms or conditions are excluded:

- Neoplasm other than basal cell carcinoma of the skin.

- Clinically significant cardiac disease.

- Anemia.

Concurrent Medication:

Excluded:

- Cytotoxic chemotherapy.

- Corticosteroids.

Patients with the following prior conditions are excluded:

History of myocardial infarction or arrhythmias.

Prior Medication:

Excluded within 2 weeks prior to study entry:

- Any antiretroviral agent.
- Interferon.
- Systemic therapy with biologic response modifiers, corticosteroids, cytotoxic chemotherapy, or neutropenic or nephrotoxic drugs.

Excluded within 30 days prior to study entry:

- Investigational drugs.

Prior Treatment:

Excluded within 2 weeks prior to study entry:

- Radiation therapy. Active drug or alcohol abuse.

Overall Status: Completed
Phase: Phase 2

NCTID: NCT00002151
Intervention Type: Drug
Intervention Name: Celgosivir hydrochloride
Title: A Randomized, Double-Blind Active-Controlled, Dose-Ranging Study of the Safety and Efficacy of Chronically Administered MDL 28,574A in the Treatment of HIV-Infected Patients
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Concurrent Medication:

Allowed:

- Prior antiretroviral agents for up to 6 months per agent.

Patients must have:

- HIV infection.
- Asymptomatic or mildly symptomatic.
- CD4 count 301 - 500 cells/mm3.

Exclusion Criteria

Co-existing Condition:

Patients with the following condition are excluded:

Unable or unwilling to comply with study procedures.

Concurrent Medication:

Excluded:

- Chemoprophylactic therapy for mycobacterial infection.
- Any nonstudy prescription medications without approval of investigator.

Patients with the following prior conditions are excluded:

- History of grade 3 or 4 toxicity to <= 600 mg/day AZT.

- History of intolerance to lactose.

- Chronic diarrhea within 6 months prior to study entry.

- Unexplained intermittent or chronic fever, defined as temperature >= 38.5 C for any 7 days within the 30 days prior to study entry.

Prior Medication:

Excluded:

- Antiretroviral therapy within 2 weeks prior to study entry.

- Prior HIV vaccines.

- Biological response modifiers within 30 days prior to study entry.

- Prior foscarnet.

- Any investigational drug with a washout < 5 half-lives prior to study entry.

- Any medications known to alter renal, hepatic, or hematologic / immunologic function (such as barbiturates, phenothiazines, cimetidine, immunomodulators, etc.) within 14 days prior to study entry.

Recent history of alcohol and/or drug abuse.
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00002150
Intervention Type: Drug
Intervention Name: Celgosivir hydrochloride
Title: A Study of the Safety and Efficacy of Chronically Administered MDL 28,574A in the Treatment of HIV-Infected Patients
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Patients must have:

- HIV infection.

- Asymptomatic or mildly symptomatic.

- CD4 count 100 - 300 cells/mm3.

Prior Medication:

Allowed:

- Prior antiretroviral agents for up to 6 months per agent.

Exclusion Criteria

Co-existing Condition:

Patients with the following condition are excluded:

Unable or unwilling to comply with study procedures.

Concurrent Medication:

Excluded:

- Chemoprophylactic therapy for mycobacterial infection.

- Any nonstudy prescription medications without approval of investigator.

Patients with the following prior conditions are excluded:

- History of grade 3 or 4 toxicity to <= 600 mg/day AZT.

- History of intolerance to lactose.

- Chronic diarrhea within 6 months prior to study entry.

- Unexplained intermittent or chronic fever, defined as temperature >= 38.5 C for any 7 days within the 30 days prior to study entry.

Prior Medication:

Excluded:

- Antiretroviral therapy within 2 weeks prior to study entry.

- Prior HIV vaccines.

- Biological response modifiers within 30 days prior to study entry.

- Prior foscarnet.

- Any investigational drug with a washout < 5 half-lives prior to study entry.

- Any medications known to alter renal, hepatic, or hematologic / immunologic function (such as barbiturates, phenothiazines, cimetidine, immunomodulators, etc.) within 14 days prior to study entry.

Recent history of alcohol and/or drug abuse.
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00002141
Intervention Type: Drug
Intervention Name: Abacavir sulfate
Title: A Phase I Trial to Evaluate the Safety and Pharmacokinetics of 1592U89
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Patients must have:

- HIV infection, as documented by ELISA/Western blot detection of HIV antibody, positive p24 antigen assay, positive viral culture, or other accepted technique.

- Written informed consent of parent or legal guardian if under age

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Exclusion Criteria

Co-existing Condition:

Excluded:

- Debilitating disease, as a result of HIV or associated therapies, that, in the opinion of the investigator, might prevent the patient from completing 6-week dosing period.

- Malabsorption syndrome or other gastrointestinal dysfunction that might interfere with drug absorption.

Concurrent Medication:

Excluded:

- Prescription or over-the-counter medication that cannot be withheld for 48 hours prior to dosing and during the 6 dosing periods. (Note:

- Antiretrovirals must be withheld for 24 hours prior to dosing and during the day of dosing.)

- Other investigational treatments (treatments available through a Treatment IND or other expanded access mechanism is evaluated individually in consultation with the sponsor).

- Alcoholic beverages within 48 hours before dosing and during the day of dosing.

- Coffee, tea, and other xanthine-containing beverages and foods on the day of dosing.

Patients with the following symptoms or conditions are excluded:

History of hepatitis, pancreatitis, or cardiomyopathy within the last 5 years.

Risk Behavior:

Excluded:

Current alcohol or illicit drug use that might interfere with the patient's ability to comply with the dosing schedule and protocol evaluations, as determined by the investigator.

Overall Status: Completed
Phase: Phase 1

NCTID: NCT00002130
Intervention Type: Drug
Intervention Name: Vesnarinone
Title: A Long-Term, Follow-On Safety Study of Four Doses of OPC-8212 (Vesnarinone) in HIV-Infected Persons
Condition: HIV Infections

Eligibility Criteria: Inclusion Criteria

Concurrent Medication:

Allowed:

- Chemoprophylaxis for Pneumocystis carinii, candida, and mycobacteria.

- Acyclovir for acute treatment of herpes.

Exclusion Criteria

Concurrent Medication:

Excluded:

- Antiretroviral agents, including ddI, ddC, AZT, and d4T.

- Immunosuppressive agents.

- Investigational HIV drugs/therapies including vaccines.

- Interferon or other immunomodulating agents.

- Corticosteroids (other than topical).

- Megestrol acetate.

- Agents known to cause neutropenia.

- Ganciclovir.

- Cytotoxic chemotherapy.

Concurrent Treatment:

Excluded:

- Radiation therapy.

Patients with the following prior conditions are excluded:

- Poor compliance (less than 80 percent of drug taken) on the Phase I protocol (FDA 234A
or FDA 234B).

- Missed more than one clinic visit on the Phase I protocol.

Prior Medication:

Excluded:

- Acyclovir as prophylaxis for herpes within 48 hours prior to study entry.

Patients meet the following criteria:

Successful completion of short-term therapy with vesnarinone on FDA 234A or FDA 234B.

Active illicit drug abuse.
Overall Status: Completed
Phase: nan

NCTID: NCT00002174
Intervention Type: Drug
Intervention Name: Thalidomide
Title: Further Evaluation of Thalidomide's Ability to Potentiate the Immune Response to HIV-Infected Patients
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Patients must have:

- HIV infection.

- CD4+ cell count >= 200/microliter or > 14% CD4+ cells in peripheral blood.

- Willingness to commit to the study duration and agree to abide to the time table for entry into the study, ingestion of thalidomide and follow-up.

Exclusion Criteria

Co-existing Condition:

Patients with any of the following conditions or symptoms are excluded:

- Fertile females.

- Patients who participated in a clinical study involving a new drug or device within the last 2 months or the period of time equivalent to seven times the half life of the study drug, whichever is longer.

Patients with any of the following prior conditions are excluded:

HIV related pre-existing peripheral neuropathy.

Prior Medication:

Excluded:

Patients using systemic steroidal anti inflammatory drugs or pentoxifylline within 10 days of dosing with thalidomide.

Required:

10 of the 20 patients must be on antiretroviral therapy and the other 10 will be subjects who have decided not to be on any antiretroviral drug prior to enrollment into this study and do not plan to start such treatment during the study period.
Overall Status: Completed
Phase: nan

NCTID: NCT00002171
Intervention Type: Drug
Intervention Name: Nelfinavir mesylate
Title: A Study of Viracept in HIV-Positive Women
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Patients must have:

- HIV infection.

- CD4 T cell count <= 400 cells/mm3.

Exclusion Criteria

Prior Medication:

Excluded:

- Prior therapy or less than 1 month of therapy with d4T and/or 3TC.

- Prior protease inhibitor therapy.

Overall Status: Completed
Phase: Phase 2

NCTID: NCT00002164
Intervention Type: Drug
Intervention Name: Nelfinavir mesylate
Title: Phase I Study of Safety, Tolerability, and Pharmacokinetics of Viracept in HIV-1 Infected Children and Exposed Infants
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Concurrent Medication:

Allowed:

Administration of Pneumocystis carinii pneumonia prophylaxis according to CDC guidelines
will be permitted.

Patients must have:

- For children >= 3 months to 13 years of age:

- HIV infection. For children <3 months of age:

- HIV infection or exposure.

- Newborns must have birth weight >= 2500 gm.

- Absence at screen of any serious or unstable medical conditions.

- Parent or guardian able to give written informed consent and willing to comply with
study requirements.

Exclusion Criteria

Co-existing Condition:

Patients with any of the following symptoms or conditions are excluded:

- Children with HIV associated malignancy requiring chemotherapy.

- Children with clinical or laboratory assessments greater than Grade 1 in the Toxicity
Table at the time of the screening.

Concurrent Medication:

Excluded:

Chemotherapy.

Prior Medication:

Excluded:

- Protease inhibitors.

NOTE:

- Patients who have taken investigational agents, immunomodulators, HIV-1 vaccines, glucocorticoids or unconventional therapies within one month prior to the day 0 of the study must be evaluated to determine the impact of these treatments on the study. Patients may be included or excluded on a case to case basis.

Overall Status: Completed
Phase: Phase 1

NCTID: NCT00002161
Intervention Type: Drug
Intervention Name: Adefovir dipivoxil
Title: A Multi-Center, Randomized, Double-Blind, Placebo-Controlled Study of the Efficacy and Safety of Adefovir Dipivoxil When Added to Standard Antiretroviral Therapy for the Treatment of HIV-Infected Patients With CD4 Cell Counts >= 200/mm3
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Patients must have:

- HIV infection with HIV RNA titer >= 2500 copies/ml (2.5 KEq/ml) plasma.

- CD4 count >= 200 cells/mm3.

- No new AIDS-defining event within the past 2 months.

- Life expectancy at least 1 year.

- Consent of parent or guardian if less than 18 years old.

- Tolerated antiretroviral therapy for the past 2 months.

NOTE:

- Kaposi's sarcoma is permitted provided patient has not received systemic therapy within the past month.

Exclusion Criteria

Co-existing Condition:

Patients with the following symptoms or conditions are excluded:

- Active, serious infections other than HIV that require parenteral antibiotic or antiviral therapy.

- Gastrointestinal malabsorption syndrome or chronic nausea or vomiting that would

preclude oral medication.

- Malignancy other than Kaposi's sarcoma or basal cell carcinoma.

Concurrent Medication:

Excluded:

- Immunomodulating agents such as systemic corticosteroids, IL-2, or interferons.

- Isoniazid.

- Rifampin.

- Investigational agents (unless approved by sponsor).

- Systemic chemotherapeutic agents.

Prior Medication:

Excluded:

- Parenteral antibiotic or antiviral therapy for another active, serious infection within the past 2 weeks.

- Immunomodulating agents such as systemic corticosteroids, IL-2, or interferons within the past month.

- Systemic therapy for KS within the past month.

Required:

- Antiretroviral regimen other than study drug.

Required:

- Antiretroviral therapy for at least the past 2 months. Current alcohol or substance abuse that would interfere with compliance.

Overall Status: Completed
Phase: nan

NCTID: NCT00002175
Intervention Type: Drug
Intervention Name: Dinitrochlorobenzene
Title: Epicutaneous 1-Chloro-2, 4-Dinitrobenzene (DNCB) Patch in HIV Infection.
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Patients must have:

- EITHER HIV negative or documented HIV+ by both the ELISA and Western blot tests.

For HIV+ patients:

- Patients must fail to meet the AIDS-defining criteria.

- CD4 lymphocyte count between 200 - 500 cells/mm3.

Exclusion Criteria

Co-existing Condition:

Excluded:

Patients with obvious ultra violet(UV)-irradiated skin damage in the treatment sites.

Concurrent Medication:

Excluded:

- Patients who are likely to commence antiretrovirals within the 6-month study period.

- Patients using other immunomodulator therapies or other alternative therapies.

- Patients likely to require chemotherapy during the course of the study.

Concurrent Treatment:

Excluded:

- Patients who are likely to require significant UV light exposure during the study period.

- Patients who are likely to require radiation therapy during the course of the study.

Prior Medication:

Excluded:

- Prior exposure to DNCB.

- Patients who have used antiretroviral medications within the previous 3 months.

Overall Status: Completed
Phase: Phase 1

NCTID: NCT00002182
Intervention Type: Drug
Intervention Name: Megestrol acetate
Title: A Study of Megestrol Acetate in HIV-Infected Children
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Patients must have:

- Documented HIV infection.

- Failure to thrive as defined by:

- crossing 2 percentile lines on standard weight for age curves over time or less than 5% percentile weight for age and falling from the curve or loss of 10% of baseline body weight.

- Resistant to oral nutritional supplementation (i.e., FTT despite a minimum 1-month

trial of high-calorie oral supplements).

- Free of significant acute illness (mild upper respiratory tract infections allowed).

- Patients with chronic diarrhea allowed provided malabsorption and gastrointestinal infection ruled out.

Exclusion Criteria

Co-existing Condition:

Patients with the following symptoms are excluded:

- Gastrointestinal infection or malabsorption.

- Significant acute illness.

- Any identified, untreated cause for failure to thrive other than underlying HIV infection.

- Medical contraindications to megestrol acetate.

Patients with any of the following prior conditions or symptoms are excluded:

Medical contraindications to megestrol acetate including a history of poorly-controlled hypertension, deep venous thrombosis, or heart failure.

History of prior megestrol acetate therapy in the past six months.
Overall Status: Completed
Phase: nan

NCTID: NCT00002165
Intervention Type: Drug
Intervention Name: Nelfinavir mesylate
Title: Viracept Expanded Access Program
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Patients must have:

- HIV infection.

- CD4 T cell count <= 100 cells/mm3.

- Failed, been intolerant of or had a contraindication to all three commercially available protease inhibitors (saquinavir, indinavir and ritonavir).

(PER AMENDMENT 1/8/97:

- People now qualify for the Viracept Program if they are unable to take indinavir and/or ritonavir due to intolerance, contraindication or prior failure.)

Exclusion Criteria

Prior Medication:

Excluded:

Prior therapy with Viracept.

Required:

- Indinavir.

- Saquinavir.

- Ritonavir.

Overall Status: Completed
Phase: nan

NCTID: NCT00002180
Intervention Type: Drug
Intervention Name: Tenofovir
Title: A Study of PMPA in HIV-Infected Patients
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Patients must have:

- Laboratory diagnosis of HIV infection.

- CD4 cell count >= 200 cells/mm3 within 28 days prior to entry.

- Plasma HIV RNA >= 10,000 copies/ml within 28 days of entry.

- Minimum life expectancy of 12 months.

Exclusion Criteria

Co-existing Condition:

Patients with any of the following symptoms or conditions are excluded:

- Active, serious infections (other than HIV) that require parental antibiotic therapy.
  Patients may be considered recovered if at least 2 weeks have elapsed following
  cessation of parental therapy before enrollment.

- Active clinically significant medical problems that include cardiac disease (e.g.,
  symptoms of ischemia, congestive heart failure, or arrhythmia).

- Positive test for Hepatitis B surface antigen or Hepatitis C antibody in serum.

Patients with any of the following prior conditions are excluded:

History of malignancy other than basal cell carcinoma or cutaneous Kaposi's sarcoma.

Patients who are receiving:

- Antiretroviral therapy, including nucleoside analogs, non-nucleoside reverse
  transcriptase inhibitors, protease inhibitors or investigational antiretroviral
  agents.

- Interferon or interleukin therapy, aminoglycoside antibiotics, amphotericin B, cidofovir, diuretics, foscarnet, ganciclovir, itraconazole, fluconazole, ketoconazole (topical allowed), isoniazid, rifampin, rifabutin, clarithromycin, azithromycin, systemic chemotherapeutic agents, systemic corticosteroids, other agents with significant nephrotoxic potential, other agents that may inhibit or compete for elimination via active renal tubular secretion (probenecid) and other investigational agents.

Within 2 weeks prior to entry:

- Antiretroviral therapy, including nucleoside analogs, non-nucleoside reverse transcriptase inhibitors, protease inhibitors or investigational antiretroviral agents.

- Interferon or interleukin therapy, aminoglycoside antibiotics, amphotericin B, cidofovir, diuretics, foscarnet, ganciclovir, itraconazole, fluconazole, ketoconazole (topical allowed), isoniazid, rifampin, rifabutin, clarithromycin, azithromycin, systemic chemotherapeutic agents, systemic corticosteroids, other agents with significant nephrotoxic potential, other agents that may inhibit or compete for elimination via active renal tubular secretion (probenecid) and other investigational agents.

Active drug or alcohol abuse as demonstrated by a positive screening test for drugs of abuse (except marijuana or drugs used for medical indications), or substance abuse considered sufficient to hinder patient compliance.
Overall Status: Completed
Phase: Phase 1

NCTID: NCT00002166
Intervention Type: Drug
Intervention Name: Nevirapine
Title: An Open-Label, Non-Randomized Trial to Evaluate the Tolerability and Safety of Viramune (Nevirapine) in Adult and Pediatric Patients With Progressive HIV Disease
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Patients must have:

- Patients > 18 months of age with history of positive serology for HIV-1 infection or patients <= 18 months of age with history of positive viral culture, detectable p24 antigen, or positive peripheral blood mononuclear cell macro culture.

- Patients >= 13 years of age with a CD4+ cell count <= 200 cells/mm3. Patients < 13

years of age with a CD4% <= 14% or a 50% decrease in CD4% in the past 6 months if the
previous CD4% was >=20%.

- Patient has failed or is intolerant to currently approved treatments for HIV-1
infection and is unable to participate in a controlled viramune clinical trial.

- Written and informed consent from a parent or guardian for patients < 18 years of age.

- Patient or guardian is willing and able to follow protocol requirements. (PER
AMENDMENT 1/29/97:

- Enrollment is closed to adults, as of Jan. 29th only pediatric patients will be
enrolled.)

Exclusion Criteria

Co-existing Condition:

Patients with the following symptoms and conditions are excluded:

Patient qualifies for participation in an actively accruing Viramune controlled clinical
trial.

Concurrent Medication:

Excluded:

- Dicumarol, Warfarin, and other anticoagulant medications.

- Tolbutamide.

- Investigational drugs, all protease inhibitors, and all other non-nucleoside
transcriptase inhibitors.

- Neurotoxic drugs.

- Cimetidine.

- Erythromycin.

Required:

Patient has failed or is intolerant to currently approved treatments for HIV-1 infection.
Overall Status: Completed
Phase: Phase 3

NCTID: NCT00002206
Intervention Type: Drug
Intervention Name: Adefovir dipivoxil
Title: A Study of Adefovir Dipivoxil in HIV-Infected Patients Who Have Not Been Treated With Anti-HIV Drugs
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Patients must have:

- HIV infection, as indicated by a history of seropositivity for HIV-1 infection (ELISA confirmed with Western blot).

- Peripheral blood CD4 cell count greater than or equal to 150 cells/mm3 on at least 1 measurement within 28 days prior to enrollment.

- Plasma HIV-1 RNA greater than or equal to 5,000 copies/ml within 28 days of study entry.

- A minimum life expectancy of 12 months.

Exclusion Criteria

Co-existing Condition:

Patients with any of the following symptoms or conditions are excluded:

- Active, serious infections (other than HIV infection) requiring parenteral antibiotic therapy. Patients should be considered recovered from such infectious episodes when at least 2 weeks have elapsed following the cessation of parenteral antibiotic therapy.

- Evidence of a gastrointestinal malabsorption syndrome or inability to receive an orally-administered medication.

- A malignancy other than cutaneous Kaposi's sarcoma (KS). (NOTE:

- Patients with biopsy-confirmed KS are eligible, but must not have received any systemic therapy (including chemotherapy) for KS within 4 weeks prior to study entry.

1. Antiretroviral therapy, including nucleoside analogues, nonnucleoside reverse transcriptase inhibitors, protease inhibitors, or investigational antiretroviral agents (antiretroviral therapy may be started after completion of the Day 35 follow-up visit).

- Interferon (alpha, beta, or gamma) or interleukin (e.g., IL-2).

- Aminoglycoside antibiotics, amphotericin B, cidofovir, diuretics, foscarnet, ganciclovir, itraconazole, fluconazole, ketoconazole (topical allowed), isoniazid, rifampin, rifabutin, clarithromycin, azithromycin, chemotherapeutic agents (systemic), systemic corticosteroids, other agents with significant nephrotoxic potential, other agents that inhibit or compete for elimination via active renal tubular secretion (e.g., probenecid), and other investigational agents.

1. Treatment with any HIV protease inhibitor.

- Treatment for more than a total of 2 weeks with any nucleoside or

nonnucleoside
reverse transcriptase inhibitor antiretroviral agent.

- Ongoing treatment with interferon (alpha, beta, or gamma), interleukins or other
immunomodulatory agents, systemic corticosteroids, or any investigational agents
except on sponsor's approval within 1 month prior to study entry.

Evidence of active substance abuse (including alcohol), as determined by the investigator,
that would preclude adequate compliance with the protocol.
Overall Status: Completed
Phase: Phase 1

NCTID: NCT00002196
Intervention Type: Drug
Intervention Name: CI-1012
Title: A Study of CI-1012 in HIV-Infected Patients
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Patients must have:

- Serologic evidence of infection with HIV-1.

- CD4+ cell count >= 200 cells/mm3.

- HIV-1 RNA >= 10,000 copies/ml.

Exclusion Criteria

Co-existing Condition:

Patients with the following conditions are excluded:

Viral, fungal, or bacterial infection requiring therapy other than topical medications.

Concurrent Medication:

Excluded:

- Prophylactic systematic antibacterial, antifungal or antiviral agents.

- Antiretroviral therapy. NOTE:

- Patient must be willing to remain off antiretroviral therapy for 1 week after
completing study medication.

Prior Medication:

Excluded:

- Experimental therapy for >= 4 weeks prior to initiation of study medication.

- Antiretroviral treatment for 3 weeks prior to initiation of study medication.

- Systemic steroids or anticancer agents for 4 weeks prior to initiation of study

medication.
Overall Status: Completed
Phase: Phase 1

NCTID: NCT00002197
Intervention Type: Drug
Intervention Name: Abacavir sulfate
Title: A Study of 1592U89 in HIV-Infected Children
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Concurrent Medication:

Allowed:

- Intravenous immunoglobulin G.

- Erythropoietin, granulocyte colony stimulating factor and granulocyte macrophage colony stimulating factor, for the management of hematologic toxicity.

Patients must have:

- Documented HIV infection.

- High risk for disease progression or mortality as defined by either of the following:

- Viral load > 100,000 copies/ml and CD4 cells < 15% of total lymphocyte count despite at least 4 weeks of therapy with commercially available antiretrovirals or as a result of no therapy due to treatment-limiting toxicity of ZDV, 3TC, and ddI; or HIV-associated encephalopathy refractory to ZDV-containing regimen.

- No access to any 1592U89 pediatric study where the patient could qualify for inclusion.

- Parent or legal guardian with the ability to understand and provide written consent for the patient to participate in the trial. Study patients over 13 years should also give written informed consent whenever possible.

Exclusion Criteria

Co-existing Condition:

Patients with any of the following symptoms or conditions are excluded:

- In the investigator's opinion, the patient is unlikely to comply with the requirements of the study.

- Renal failure requiring dialysis.

- Hepatic failure evident by Grade 3 or 4 hyperbilirubinemia and AST > 10 X upper limits of normal.

- Life-threatening infection or other chronic disease that may

interfere with taking
1592U89 or compromise the patient's safety.

Patients with the following prior conditions are excluded:

Documented hypersensitivity to 1592U89 or any other nucleoside analogue.

See Inclusion - General Criteria.
Overall Status: Completed
Phase: nan

NCTID: NCT00002210
Intervention Type: Drug
Intervention Name: Delavirdine mesylate
Title: A Study of Delavirdine Mesylate in Combination With Other Anti-HIV Drugs in HIV-Infected Children and Babies
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Patients must have:

- HIV infection.

- Plasma HIV-1 levels greater than 10,000 copies/ml.
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00002198
Intervention Type: Drug
Intervention Name: Abacavir sulfate
Title: A Study of 1592U89 and Ethanol When Given Together to HIV-Infected Patients
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Concurrent Medication:

Allowed:

- Local treatment for Kaposi's sarcoma.

- Prophylactic treatment for opportunistic infections.

Patients must have:

- HIV-1 infection.

- CD4+ lymphocyte count >= 200 cells/microliter within 14 days prior to study drug
administration.

- No active diagnosis of AIDS (other than visceral Kaposi's sarcoma) according to the
1993 Centers for Disease Control and Prevention (CDC) AIDS surveillance definition.

Prior Medication:

Allowed:

Local treatment for Kaposi's sarcoma.

Exclusion Criteria

Co-existing Condition:

Patients with the following symptoms and conditions are excluded:

Malabsorption syndrome or other GI dysfunction which may interfere with drug absorption.

Concurrent Medication:

Excluded:

- Medications that cannot be withheld for 48 hours (24 hours for antiretrovirals) prior to study drug administration and until 12 hours after study drug administration on each dosing day.

- Immunomodulators, such as systemic corticosteroids, interleukins and interferons.

- Cytotoxic chemotherapeutic agents.

- Acute treatment for opportunistic infections.

Concurrent Treatment:

Excluded:

Radiation therapy.

Patients with the following prior conditions are excluded:

- Documented history of alcoholism.

- History of clinically relevant hepatitis or pancreatitis within 6 months prior to study drug administration.

- History of hypersensitivity, anaphylactic, or idiosyncratic reaction to nucleoside analogs.

- Participation in another research study within the past month.

Prior Medication:

Excluded:

- Cytotoxic chemotherapeutic agents within six weeks prior to study drug administration.

- Immunomodulating agents within six weeks prior to study drug administration.

- Treatment with the following within 2 weeks prior to study drug administration:

- acyclovir, carbamazepine, chloramphenicol, ganciclovir, phenytoin, rifampin, sodium valproate, or valacyclovir.

Prior Treatment:

Excluded:

Radiation therapy within 6 weeks prior to study drug administration.

1. Regular weekly alcohol intake of more than 21 units (a unit is equal to 1/2 pint beer or
1 glass of wine or 1 oz of liquor).

- Recent change in normal pattern of alcohol usage (e.g., prolonged use followed by >
one month abstinence).

- Total abstinence from alcohol use.

- Positive breath alcohol test upon arrival at the study center prior to any dosing day.
Overall Status: Completed
Phase: Phase 1

NCTID: NCT00002193
Intervention Type: Drug
Intervention Name: Amprenavir
Title: Safety and Effectiveness of Giving Two Nucleoside Reverse Transcriptase Inhibitors Alone or in Combination With 141W94 to HIV-Infected Children Who Have Never Received Protease Inhibitors
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Your child may be eligible for this study if he/she:

- Is 6 months - 18 years of age.

- Is HIV-positive.

- Has a viral load (level of HIV in the body) greater than 10,000 copies/ml.

- Is able to take medications by mouth.

- Has consent of parent or legal guardian if under 18.

- Has a negative pregnancy test within 7 days of study entry.

- Agrees to practice abstinence or use effective methods of birth control for 1 month
before and throughout the study.

Exclusion Criteria

Your child will not be eligible for this study if he/she:

- Has a serious illness, including any life-threatening infection or other chronic
serious medical condition.

- Has an opportunistic (AIDS-related) infection or a serious bacterial infection.

- Is allergic to NRTIs.

- Is breast-feeding.

- Is unlikely to complete the study.

- Has received certain medications.

- Has received radiation therapy within the past 4 months, or will need to receive it during the study.

Overall Status: Completed
Phase: Phase 3

NCTID: NCT00002200
Intervention Type: Drug
Intervention Name: Abacavir sulfate
Title: A Study of 1592U89 in HIV-Infected Adults
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Concurrent Medication:

Allowed:

Erythropoietin, G-CSF and GM-CSF.

Patients must have:

- CD4+ cell count < 100 cells/mm3.

- HIV-1 RNA > 30,000 copies/ml.

- Signed, informed consent from parent or legal guardian for patient under 18 years of age.

Exclusion Criteria

Co-existing Condition:

Patients with the following conditions or symptoms are excluded:

- Renal failure requiring dialysis.

- Hepatic failure evident by grade 3/4 hyperbilirubinemia and AST 5 times the upper limit of normal.

- Documented hypersensitivity to 1592U89.

- Serious medical conditions, such as diabetes, congestive heart failure, cardiomyopathy, or other cardiac dysfunction, that would compromise the safety of the patient.

- Participation in or ability to participate in an enrolling study of 1592U89.

Required:

At least 2 nucleoside reverse transcriptase inhibitors (NRTI) and one protease inhibitor (or intolerance to one protease inhibitor and one NRTI due to trying at least 2 different regimens with at least one protease inhibitor).

Alcohol or illicit drug use that may interfere with the patient's compliance.

Overall Status: Completed

Phase: nan

NCTID: NCT00002244
Intervention Type: Drug
Intervention Name: WF10
Title: A Study to Evaluate the Safety and Effectiveness of WF10 Given to Patients With Late-Stage HIV Disease
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Patients may be eligible for this study if they:

- Are HIV-positive.

- Have a CD4 cell count of less than 50 cells/mm3 within 14 days prior to study entry.

- Are at least 18 years old.

- Have received anti-HIV drugs at some time in the past.

- Agree to practice abstinence or use effective methods of birth control, including the pill, during the study.

Exclusion Criteria

Patients will not be eligible for this study if they:

- Are being treated for any form of cancer within 30 days of study entry.

- Have ever received an HIV vaccine.

- Have received steroids within 30 days prior to study entry. (Note: Testosterone is allowed.)

- Have received certain medications, including anti-HIV treatments that are not approved by the FDA.

- Have participated in another WF10 study.

- Have an illness or any condition that might exclude them from this study.

- Are pregnant or breast-feeding.

- Abuse drugs or medications.

- Received a blood transfusion within 45 days prior to study entry.
Overall Status: Completed
Phase: Phase 3

NCTID: NCT00002214
Intervention Type: Drug
Intervention Name: Capravirine
Title: Phase I Trial of S-1153 in Patients With HIV Infection
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Concurrent Medication:

1. Required for patients with CD4 cell count lower than 200:

- PCP prophylaxis with aerosolized pentamidine, trimethoprim/sulfamethoxazole, mepron, or dapsone.

- Allowed:

- Continuation on an approved antiretroviral agent other than non-nucleoside reverse transcriptase inhibitors (e.g., Nevirapine) or other specifically excluded prior medications, if received without complications for at least 4 weeks prior to study entry.

Patients must have:

- Serologically documented HIV infection.

- Single-dose patients:

- CD4 cell count greater than 50 (no upper limit for single-dose cohorts). Repeated-dose patients:

- CD4 count from 50 to 500 within 35 days prior to entrance on study.

- No active opportunistic infection.

Prior Medication:

Allowed for entry onto multiple-dose study:

- Single-dose portion of S-1153 study, provided all study visits and evaluations are completed, all eligibility criteria are met, and a minimum of 30 days has elapsed before Day 1 of the repeated-dose administration.

Exclusion Criteria

Co-existing Condition:

Patients with the following symptoms or conditions are excluded:

Active opportunistic infection.

Concurrent Medication:

Excluded:

Concomitant use (within 5 half-lives prior to administration and for at least 24 hours following cessation of treatment with S-1153) of highly plasma-bound drugs with narrow therapeutic indices, including but not limited to coumadin and dilantin.

Prior Medication:

1. Investigational new drugs.

- Excluded within 30 days prior to study entry:

- Chronic (greater than 7 days) use of drugs known to affect or be extensively metabolized by cytochromes P450, including but not limited to ketoconazole, fluconazole, itraconazole, isoniazid, rifampin, rifabutin, astemizole, terfenadine, or protease inhibitors.

Prior Treatment:

Excluded within 3 weeks prior to study entry:

- Cytotoxic chemotherapy.

- Interferon treatment.

- Radiation therapy.

Overall Status: Completed
Phase: Phase 1

NCTID: NCT00002229
Intervention Type: Drug
Intervention Name: Saquinavir
Title: Safety and Effectiveness of Adding Saquinavir (FORTOVASE) in Soft Gel Capsule Form to an Anti-HIV Drug Combination in HIV-Infected Patients
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

You may be eligible for this study if you:

- Are HIV-positive.

- Have an HIV count of 5,000 copies/ml or more.

- Have a CD4 count of 100 cells/mm3 or more.

- Meet specific requirements if you have ever taken NRTIs.

- Are 16 - 64 years old (need consent if under 18).

- Agree to use effective methods of birth control during the study.

Exclusion Criteria

You will not be eligible for this study if you:

- Have taken non-nucleoside reverse transcriptase inhibitors (NNRTIs) or protease inhibitors (PIs) for more than 2 weeks.

- Have taken all the available NRTIs.

- Have certain serious medical conditions, including severe liver disease or active opportunistic (AIDS-related) infection.

- Have a history of weight loss, muscle pain, and loss of appetite.

- Have taken certain medications, including anti-HIV drugs other than those required by this study.

- Are pregnant or breast-feeding.

- Abuse alcohol or drugs.

- Are unable to complete the study for any reason.

Overall Status: Completed
Phase: Phase 4

NCTID: NCT00002237
Intervention Type: Drug
Intervention Name: Peldesine
Title: A Study of Peldesine (BCX-34) in HIV-Infected Patients
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Patients must have:

- Documented HIV infection.

- CD4 cell count greater than or equal to 300 cells/mm3 on 3 occasions prior to protocol treatment.

- Plasma viral load by Roche Amplicor HIV Monitor assay greater than or equal to 2,000 RNA copies/ml and less than or equal to 50,000 RNA copies/ml on at least 2 occasions prior to protocol treatment.

- Normal or non-diagnostic electrocardiogram.

Exclusion Criteria

Co-existing Condition:

Patients with the following symptoms or conditions are excluded:

- Severe opportunistic infection or any other medical condition which in the opinion of the investigators is a contraindication to enrolling in this trial.

- Severe lactose intolerance.

Concurrent Medication:

Excluded:

Concomitant therapy with other medications having primary renal excretion (other than 3TC, ddC, and d4T).

Prior Medication:

Excluded:

- Ongoing dideoxyinosine or other antiretroviral therapy except ZDV, 3TC, ddC, d4T, saquinavir, ritonavir, indinavir, and nelfinavir within 2 weeks of study.

- Participation in a study of any systemic experimental drug within the last 2 months.

Required:

- Ongoing (at least 4 weeks) stable dosage of zidovudine (ZDV) and

lamivudine (3TC), ZDV
and stavudine (d4T), ZDV and zalcitabine (ddC), d4T and 3TC, ZDV alone, or ddC alone, or in
combination with saquinavir, ritonavir, indinavir, or nelfinavir.
Overall Status: Completed
Phase: Phase 1

NCTID: NCT00002243
Intervention Type: Drug
Intervention Name: Calanolide A
Title: A Study to Evaluate the Safety and Effectiveness of a New Non-Nucleoside Reverse Transcriptase Inhibitor (NNRTI), (+)-Calanolide A, in HIV-Positive Patients Who Have Never Received Anti-HIV Treatment
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

You may be eligible for this study if you:

- Are HIV-positive.

- Have a CD4 count of at least 250 cells/mm3.

- Have an HIV count (viral load) of at least 5,000 copies/ml.

- Are at least 18 years old.

Exclusion Criteria

You will not be eligible for this study if you:

- Have received prescription or nonprescription medications within 14 days of study
entry, or if you will need to take any of these medications during the study.

- Have ever received anti-HIV medications.

- Test positive for hepatitis B.

- Have received a blood (or red blood cell) transfusion within 3 months prior to study
entry.

- Have severe diarrhea.

- Have severe heart, liver, kidney, or neurological (brain and spinal cord) disease.

- Have hemophilia or another blood disorder.

- Have received certain medications or vaccines within 30 days prior to study entry.

- Have received chemotherapy or radiation within 16 days prior to study entry, or if you
will need either of these during the study.
Overall Status: Completed
Phase: Phase 1

NCTID: NCT00002218
Intervention Type: Drug
Intervention Name: CI-1012
Title: A Phase I Maximum Tolerated Dose Study of CI-1012 in Late-Stage HIV+ Patients

Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Patients must have:

- Serological evidence of late-stage HIV-1 infection (ELISA and Western Blot).

- CD4 T cell count less than or equal to 200 mm3.

- HIV-1 RNA greater than or equal to 5,000 copies/mL.

Exclusion Criteria

Prior Medication:

Excluded:

- Anti-HIV treatment within 8 weeks prior to entry.

- Systemic steroids within 4 weeks prior to entry.

Prior Treatment:

Excluded:

Treatment with anticancer agents within 4 weeks prior to study.
Overall Status: Completed
Phase: Phase 1

NCTID: NCT00002228
Intervention Type: Drug
Intervention Name: Enfuvirtide
Title: A Study of T-20 in HIV-Positive Adults
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Concurrent Medication:

Allowed:

- Any antiretroviral agent, provided the regimen has not changed within 6 weeks of the screening visit.

- Antibiotics for bacterial infections.

- Prophylactic medications for P. carinii pneumonia and for M. avium, including azithromycin.

- Medications for symptomatic treatment such as antipyretics, analgesics, and antiemetics.

Patients must have:

HIV-1 seropositive status.

Exclusion Criteria

Co-existing Condition:

Patients with the following symptoms or conditions are excluded:

Concurrent neoplasm (except for basal cell carcinoma of the skin, in situ carcinoma of the cervix, and non-disseminated stable Kaposi's sarcoma).

Concurrent Medication:

Excluded:

- Patients must not be taking any concurrent antiretroviral therapy (for at least 2 weeks prior to baseline) or the patient is to be on a stable antiretroviral regimen which has not changed for at least 6 weeks prior to baseline.

- Treatment with any of the following:

- immunomodulators, biological response modifiers, chemotherapy that cannot be discontinued for the duration of the study, astemizole, terfenadine, cisapride, triazolam, midazolam, rifampin, clarithromycin, or an investigational drug within 30 days prior to the initial visit.

Patients with the following prior conditions are excluded:

- Evidence of active opportunistic infections, or unexplained temperature greater than or equal to 38.5 Celsius for 7 consecutive days within 30 days prior to screening visit.

- Chronic diarrhea (defined as greater than 3 liquid stools per day which persists for 15 days) within 30 days prior to screening visit.

- Diagnosis of hemophilia or other clotting disorders.

Prior Medication:

Excluded:

- Prior treatment with an HIV vaccine.

Prior Treatment:

Excluded:

Major organ allograft.

Risk Behavior:

Excluded:

Evidence of substance abuse or addiction that, in the opinion of the investigator, may interfere with the patient's ability to comply with the dosing schedule and protocol evaluations.

Overall Status: Completed
Phase: Phase 2

NCTID: NCT00002271

Intervention Type: Drug
Intervention Name: Alovudine
Title: An Ascending, Single Oral Dose Pharmacokinetic Study of 3'-Deoxy-3'-Fluorothymidine (FLT) in Asymptomatic Human Immunodeficiency Virus (HIV)-Infected Subjects
Condition: HIV Infections
Eligibility Criteria: Exclusion Criteria

Co-existing Condition:

Patients with the following conditions or symptoms are excluded:

- Oral candida infection documented by morphology or by response to antifungal therapy within 2 months prior to study entry.

- Temperature > 37.8 degrees Centigrade.

- Malignancy other than cutaneous basal cell carcinoma or cervical carcinoma in situ.

- Significant chronic underlying medical illnesses which would prevent continuous participation in this clinical trial.

Concurrent Medication:

Excluded:

-

Patients with the following are excluded:

- Significant chronic underlying medical illnesses which would prevent continuous participation in this clinical trial.

- Unwilling to sign informed consent.

- Intolerant to zidovudine (AZT).

- Oral hairy leukoplakia at any time prior to study entry.

Prior Medication:

Excluded within 7 days of study entry:

- Antiretroviral drugs.

- Immunomodulators.

- Excluded within 30 days of study entry:

- Any investigational drugs.

Patients have the following:

- HIV seropositivity by licensed ELISA test, confirmed by Western Blot analysis.

- No symptoms as defined by:

1. Normal neurological exam.

2. Absence of the following:

- Unintentional weight loss of greater than 10 pounds or more than 10 percent of usual body weight within 2 months prior to study entry.

- Unexplained temperature > 37.8 C on more than 5 consecutive days or on more than 10 days in any 30 day period in the one month prior to expected study entry.

- Unexplained diarrhea defined by = or > 3 liquid stools per day persisting > 7 days within 2 months prior to expected study entry.

Overall Status: Completed
Phase: nan

NCTID: NCT00002280
Intervention Type: Drug
Intervention Name: Didanosine
Title: A Study of ddI in Children With AIDS Who Have Not Had Success With Zidovudine
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Concurrent Medication:

Allowed:

- Concomitant medications for the treatment of complications of AIDS.

- CAUTION:

- Concomitant use of ddI with the following drugs must be done with extreme caution:

- Other nucleosides (e.g., ganciclovir).

- Drugs with toxicities similar to those observed with ddI (e.g., phenytoin).

- Drugs with significant pancreatic toxicities, including many drugs used for treatment of major opportunistic infections.

- Use of Sulfonamides or intravenous pentamidine for treatment of acute Pneumocystis carinii pneumonia (PCP) requires discontinuation of ddI for a week following treatment of PCP.

- Caution should also be exercised with patients having intractable diarrhea or patients following a low sodium diet.

Patients must have the following:

- Diagnosis of AIDS. Demonstrated either significant deterioration despite parenteral dosing with zidovudine (AZT) or significant intolerance to AZT.

Signed informed consent by parent or legal guardian. Evaluations every 7-14 days while taking ddI for the first 4 months. Monthly follow-up is required

thereafter.

Exclusion Criteria

Co-existing Condition:

Patients with the following conditions or symptoms are excluded:

- Acute pancreatitis or any history of pancreatitis.
- Seizures or a history of seizure disorder.
- Grade I or greater peripheral neuropathy.
- Preexisting cardiomyopathy.

Concurrent Medication:

Excluded:

- Zidovudine (AZT).
- Chemotherapy with cytotoxic agents.
- AVOID:
- Those agents that may cause pancreatitis such as:
- Pentamidine.
- Sulfonamides.
- Antituberculosis drugs.
- Cimetidine.
- Ranitidine.
- Corticosteroids.
- NOTE the cautionary statement in Patient Inclusion Concurrent Medication.

Patients with the following are excluded:

- Acute pancreatitis or any history of pancreatitis.
- Seizures or a history of seizure disorder.
- Grade I or greater peripheral neuropathy.
- Preexisting cardiomyopathy.

Prior Medication:

Excluded within 15 days of study entry:

- Any anti-retroviral except zidovudine (AZT).

Required:

- Zidovudine (AZT).

Overall Status: Completed
Phase: nan

NCTID: NCT00002260
Intervention Type: Drug
Intervention Name: Alovudine
Title: An Open-Label, Crossover Study to Assess the Effect of Food on the Oral Bioavailability and Pharmacokinetic Profile of 3'-Deoxy-3'-Fluorothymidine (FLT) in Asymptomatic Human Immunodeficiency Virus (HIV)-Infected Subjects
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Patients must have:

- Positive ELISA test confirmed by Western blot analysis.

- Asymptomatic.

- Willing to sign an informed consent.

Exclusion Criteria

Co-existing Condition:

Patients with the following conditions or symptoms are excluded:

- Oral candida infection documented by morphology or by a response to antifungal therapy within two months prior to study entry.

- Oral hairy leukoplakia at any time prior to entry.

- Temperature > 37.8 C.

- Any malignancy other than cutaneous basal cell carcinoma or cervical carcinoma in situ.

- Significant chronic underlying medical illness which would prevent continuous participation in this clinical trial.

- Unwilling to sign an informed consent.

- Zidovudine induced hematological toxicity.

Prior Medication:

Excluded:

- Therapy with antiretroviral drugs or immunomodulators within seven days before entry.

- Therapy with any investigational drug during the preceding 30 days.

Patients may not have:

- Oral candida infection documented by morphology or by a response to antifungal therapy within two months prior to study entry.

- Oral hairy leukoplakia at any time prior to entry.

- Temperature > 37.8 C.

- Any malignancy other than cutaneous basal cell carcinoma or

cervical carcinoma in
situ.

- Significant chronic underlying medical illness which would prevent continuous
participation in this clinical trial.

- Unwilling to sign an informed consent.

- Zidovudine induced hematological toxicity.
Overall Status: Completed
Phase: nan

NCTID: NCT00002256
Intervention Type: Drug
Intervention Name: Zalcitabine
Title: Dideoxycytidine (Ro 24-2027). A Treatment Protocol for the Use of Dideoxycytidine (ddC) in Patients With AIDS or Advanced ARC Who Cannot Be Maintained on Zidovudine (AZT) Therapy.
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Concurrent Medication:

Allowed:

- Aerosolized Pentamidine or Trimethoprim/sulfamethoxazole prophylaxis against
Pneumocystis carinii pneumonia is recommended.

- Dapsone is permitted but discouraged.

- Drugs that could cause other serious toxicity when coadministered with study
medication is allowed for treatment of an acute intercurrent illness or opportunistic
infection at the investigator's discretion.

- Any medication that has the potential to cause peripheral neuropathy should be
avoided; patients should consult their physicians for specific drugs.

- Isoniazid is permitted if there is no evidence of peripheral neuropathy at entry and
the patient is taking pyridoxine = or > 50 mg/day.

- Metronidazole is permitted only with a study drug interruption.

- Patients on amphotericin, pyrimethamine, sulfadiazine, trimethoprim/sulfamethoxazole,
ganciclovir, intravenous pentamidine, intravenous acyclovir = or > 1000 mg/day orally
or other bone marrow or renal toxic drugs may not tolerate concomitant ddC. If these
drugs are given concomitantly with ddC, patients should have frequent (weekly)
laboratory assessments, as appropriate.

- Drugs that are nephrotoxic or have the potential to cause peripheral neuropathy might
be expected to cause increased toxicity when co-administered with ddC.

- The following experimental medications are allowed if, in the judgement of the investigator, no serious additive toxicities are anticipated and the experimental drug is necessary for optimal patient management:

- Ampligen, azithromycin, BW 566C80, bovine colostrum, clarithromycin, diclazuril, foscarnet, oral ganciclovir, GM-CSF, G-CSF, hypericin, IL-2, interferon-beta, interferon-gamma, itraconazole, liposomal amphotericin, liposomal gentamicin, nimodipine, PEG-IL2 (polyethylene glycosylated IL-2), roxithromycin, spiramycin, trimetrexate.

Patients must have the following:

- AIDS or Advanced ARC.

- Patients eligible to enter this protocol must fall into one of the following three categories:

- AZT treatment failure or AZT intolerance or AZT ineligibility or Rollover Patients Under 18 years of age must have the consent of a parent or guardian.

Exclusion Criteria

Patients with the following are excluded:

- Any history of peripheral neuropathy due to any cause, even if peripheral neuropathy was not the reason for discontinuation of other anti-HIV therapy.

- Any finding suggestive of peripheral neuropathy found at baseline neurological exam. If a patient has an isolated finding of an absent achilles reflex he may be entered if no signs or symptoms and no other findings are suggestive of peripheral neuropathy.

- Concomitant treatment with excluded medications. Excluded medications include any other experimental drugs (including ddI), drugs with known nephrotoxic or hepatotoxic potential, and drugs likely to cause peripheral neuropathy. Any = or > Grade 3 laboratory or clinical abnormality or any severe abnormality not listed requires permission from the medical monitor to be entered into this study..

- Unwillingness or deemed unable to sign informed consent.

Overall Status: Completed
Phase: nan

NCTID: NCT00002254
Intervention Type: Drug
Intervention Name: Alovudine
Title: A Multi-Center, Open-Label, Ascending, Multiple Oral Dose, Safety, Tolerance and Pharmacokinetic Study of 3'-Deoxy-3'-Fluorothymidine (FLT) in Patients With Acquired Immune Deficiency Syndrome (AIDS) or AIDS-Related Complex

(ARC)
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Concurrent Medication:

Allowed:

- Aerosolized pentamidine for Pneumocystis carinii pneumonia (PCP) prophylaxis.

- Up to 14 days of systemic therapy for minor opportunistic infections such as candidiasis, mucocutaneous Herpes simplex or cutaneous Herpes zoster infections.

Patients must have the following:

- AIDS or AIDS related complex (ARC) as defined by the CDC.

- Positive antibody to HIV as determined by a commercially licensed ELISA test kit, confirmed by Western blot analysis.

Exclusion Criteria

Co-existing Condition:

Patients with the following conditions or symptoms are excluded:

- Symptomatic visceral Kaposi's sarcoma or progression of Kaposi's sarcoma within the month prior to study entry (progression is defined as more than a 25 percent increase in the product of bidirectional measurement of indicator lesions and/or more than a 25 percent increase in the number of new lesions).

- Concurrent neoplasms other than Kaposi's sarcoma or basal cell carcinoma of the skin. Patients who have had a malignancy in the past that has been in complete remission for 1 year without therapy may be enrolled.

- Signs or symptoms of neuropathy and a Vibratron 2 score = or > 4 for either great toe.

Concurrent Medication:

Excluded:

- Acute therapy for AIDS-related infection.

- Systemic maintenance therapy for AIDS-defining opportunistic infection.

- Recombinant erythropoietin.

- Long term therapy with either aspirin or probenecid.

Concurrent Treatment:

Excluded:

- Blood transfusion more than once per month.

Patients with the following are excluded:

- Symptomatic visceral Kaposi's sarcoma or progression of Kaposi's sarcoma within the month prior to study entry.

- Unwilling to sign an informed consent or patients unwilling to be followed at the medical center where they were enrolled for the duration of the study and follow-up as required.

- History of intolerance to zidovudine (AZT) at any dose as demonstrated by an AZT related decrease in hemoglobin levels of at least 2 g/dl or AZT related depression of neutrophils of at least 200 cells/mm3 to < 750 cells/mm3 which required discontinuation of AZT therapy.

- Diseases or conditions listed in Exclusion Co-Existing Conditions.

Prior Medication:

Excluded:

- Antiretroviral agents within 14 days of study entry.

- Immunomodulating agents or corticosteroids within 30 days prior to study entry.

- Treatment for acute Pneumocystis carinii pneumonia within 2 weeks prior to study entry.

Prior Treatment:

Excluded:

- Blood transfusions within 7 days prior to study entry.

- Radiation therapy for Kaposi's sarcoma within 30 days prior to study entry.

Active substance abuse.
Overall Status: Completed
Phase: nan

NCTID: NCT00002249
Intervention Type: Drug
Intervention Name: Levofloxacin
Title: A Double-Blind Study to Evaluate the Safety and Pharmacokinetics of L-Ofloxacin (RWJ 25213) in Subjects With HIV Infection
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Patients must have the following:

HIV infection.

Exclusion Criteria

Co-existing Condition:

Patients with the following symptoms or conditions are excluded:

- Active opportunistic infection or neoplasm.

- High likelihood of death during study.

- Significant ophthalmologic, renal, hepatic, cardiovascular, hematologic, neurologic, psychiatric,respiratory, or metabolic disease.

- Donation of > 1 unit blood or acute loss of blood within one month of study entry.

Patients with the following prior conditions are excluded:

- History of opportunistic infection.

- Previous allergic reaction to ciprofloxacin, norfloxacin, or any other quinolone.

Prior Medication:

Excluded:

Use of any investigational agent within 7 days of entry into study. Use of any medication within 3 days prior to entry (7 days for AZT). Alcohol or drug abuse.

Overall Status: Completed
Phase: Phase 1

NCTID: NCT00002266
Intervention Type: Drug
Intervention Name: AS-101
Title: An Open Parallel Study to Determine the Optimum Dosing Schedule for AS-101 in AIDS/ARC Patients
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Concurrent Medication:

Allowed:

- Standard therapy for infections.

- Acyclovir.

- Ganciclovir.

- Allowed only with permission of Wyeth-Ayerst medical monitor:

- Zidovudine (AZT).

- Immunomodulators.

- Specific therapy for malignancies (including Kaposi's sarcoma).

Exclusion Criteria

Co-existing Condition:

Patients with the following conditions or symptoms are excluded:

- Evidence of severe liver dysfunction (serum albumin < 3 g/dl, SGOT or SGPT > 5 x upper limit of normal, prothrombin time > 15 seconds), or gastrointestinal, renal, respiratory, endocrine, hematologic, cardiovascular system abnormalities or psychiatric disorder other than abnormalities secondary to AIDS or AIDS related complex (ARC).

- Evidence of AIDS-related central nervous system involvement.

- Disseminated Kaposi's sarcoma.

Concurrent Medication:

Excluded without permission of Wyeth-Ayerst medical monitor:

- Zidovudine (AZT).

- Immunomodulators.

- Specific therapy for malignancies (including Kaposi's sarcoma).

Patients with the following are excluded:

- Evidence of major system abnormalities other than abnormalities secondary to AIDS or AIDS related complex.

- Concomitant conditions as specified in Patient Exclusion Co-existing Conditions.

- Unlikely or unable to comply with the requirements of the protocol.

Prior Medication:

Excluded within 4 weeks of study entry:

- Systemic antiviral agents.

- Immunosuppressive agents.

- Immune stimulators such as BCG vaccine, isoprinosine, or other immunomodulators.

Patients must:

- Have a diagnosis of AIDS or AIDS related complex (ARC).

- Demonstrate intolerance or refusal to take zidovudine (AZT).

- Provide written informed consent.

Overall Status: Completed
Phase: nan

NCTID: NCT00002279
Intervention Type: Drug
Intervention Name: Zalcitabine
Title: A Study of ddC in Patients With AIDS or Advanced AIDS-Related Complex (ARC) Who Have Not Had Success With Zidovudine (AZT)
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Concurrent Medication:

Recommended:

- Aerosolized Pentamidine or other prophylaxis against Pneumocystis carinii pneumonia (PCP).

- Allowed:

- Drugs or treatments that could cause other serious additive toxicity when coadministered with study medication will be allowed for treatment of an acute intercurrent illness or opportunistic infection at the discretion of the investigator.

- Isoniazid, if there is no evidence of peripheral neuropathy at entry and the patient is taking pyridoxine = or > 50 mg/day.

- Metronidazole, only with a study drug interruption; neurological exam should be performed before and after treatment with metronidazole and ddC restarted only if there are no signs, symptoms or neurological findings suggestive of peripheral neuropathy.

- It is recommended that patients requiring amphotericin, pyrimethamine, sulfadiazine, intravenous trimethoprim / sulfamethoxazole, ganciclovir, intravenous pentamidine, intravenous acyclovir or acyclovir = or > 1000 mg/day orally or other bone marrow or renal toxic drugs have an interruption of ddC until they are stable for two weeks on a maintenance dose of the above medications and only then can ddC be restarted.

- Patients on amphotericin, pyrimethamine, sulfadiazine, trimethoprim / sulfamethoxazole, ganciclovir, intravenous acyclovir or acyclovir = or > 1000 mg/day orally or other bone marrow or renal toxic drugs may not tolerate concomitant ddC.

- If these drugs are given concomitantly with ddC, patients should have frequent (weekly) laboratory assessments, as appropriate.

- Drugs that are nephrotoxic or have the potential to cause peripheral neuropathy might be expected to cause increased toxicity when co-administered with ddC.

Concurrent Treatment:

Allowed:

- Radiation therapy with dideoxycytidine (ddC) interruption until stable for 2 weeks on treatment.

AMENDED:

- Treatment categories are now:

- AZT treatment failure. AZT intolerance. AZT ineligibility

Original design:

- Patients must have a diagnosis of AIDS or AIDS-related complex (ARC) and fall into one of the following 2 categories:

- Zidovudine (AZT) treatment failure and dideoxyinosine (ddI) intolerance or AZT intolerance and ddI intolerance. Under 18 years of age must have the consent of a parent or guardian.

Exclusion Criteria

Co-existing Condition:

Patients with the following conditions or symptoms are excluded:

- Any history of peripheral neuropathy due to any cause, even if peripheral neuropathy was not the reason for discontinuation of other anti-HIV therapy.

- Any finding suggestive of peripheral neuropathy found at neurological exam. If patient has an isolated finding of an absent achilles reflex he may be entered if no signs or symptoms and no other findings are suggestive of peripheral neuropathy.

- Neoplasms other than Kaposi's sarcoma or basal cell carcinoma.

Concurrent Medication:

Excluded:

- Other experimental drugs.

- Other retroviral nucleoside analogs.

- Immunomodulators Systemic corticosteroids.

- Drugs with known nephrotoxic or hepatotoxic potential.

- Drugs likely to cause peripheral neuropathy.

- Avoid due to potential to cause peripheral neuropathy:

- Chloramphenicol.

- Iodoquinol.

- Phenytoin.

- Ethionamide.

- Gold.

- Ribavirin.

- Vincristine.

- Cisplatin.

- Dapsone.

- Disulfiram.

- Glutethimide.

- Hydralazine.

- Nitrofurantoin.

Patients with the following are excluded:

- Any history of peripheral neuropathy due to any cause.

- Any finding suggestive of peripheral neuropathy found at baseline neurological exam.

- Neoplasms other than Kaposi's sarcoma or basal cell carcinoma.

- Unwillingness or deemed unable to sign informed consent.

Overall Status: Completed
Phase: nan

NCTID: NCT00002265
Intervention Type: Drug
Intervention Name: Zalcitabine
Title: An Open-Label, Multicenter Study to Evaluate the Safety and Tolerability of Dideoxycytidine (ddC) in Patients With AIDS or Advanced ARC Who Previously Demonstrated Intolerance to Zidovudine (AZT) in Protocol N3300 or N3492
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Concurrent Medication:

Recommended:

- Prophylactic aerosolized pentamidine.

- Allowed for maintenance after recovering from infection for which initially prescribed:

- Pyrimethamine.

- Sulfadiazine.

- Amphotericin.

- Fluconazole.

- Ketoconazole (= or < 400 mg/day).

- Acyclovir (= or < 1000 mg/day).

- Ganciclovir.

- Medications for tuberculosis or Mycobacterium avium infection.

- Allowed:

- Erythropoietin.

- Megace.

- Trimethoprim/sulfamethoxazole < or = 20 mg/kg/day.

- Nystatin.

- Low dose acetaminophen or non-steroidal anti-inflammatory agents (= or < 3 g/day).

- Medications on which patient has been stable for 14 days prior to study entry.

- Allowed if no evidence of peripheral neuropathy at study entry:

- Isoniazid (must be receiving pyridoxine = or > 50 mg/day concomitantly).

- Phenytoin, if stable for = or > 3 months.

- Metronidazole with a study medication interruption and pre and post testing for peripheral neuropathy. Any signs of this and the patient will not be restarted on study medication.

- REFER TO NOTE OF CAUTION IN PROTOCOL SUMMARY.

Patients must have the following:

- Previously enrolled in NIAID ACTG 114 or NIAID ACTG 119.

- Experienced = or > grade 3 zidovudine (AZT) related toxicity while enrolled in the assigned protocol and followed the procedures for the study drug dose reduction, interruption, rechallenge and permanent discontinuation as per NIAID ACTG 114 or NIAID ACTG 119.

- NOTE:

- After permanent study drug discontinuation from NIAID ACTG 114 the drug code may be broken ONLY after discussion with Hoffmann-La Roche regarding toxicity management and probable relationship to AZT. Although NIAID ACTG 119 is an open-label study, investigators should also contact Hoffmann-La Roche prior to entering any patient into this protocol.

- Toxicities must be "probably" AZT related (as determined by the investigator and following discussion by sponsor) for patients to be eligible for inclusion into this protocol.

- Toxicities must be resolved to = or < grade 2 within 45 days of discontinuation from AZT in NIAID ACTG 114 or NIAID ACTG 119.

Exclusion Criteria

Co-existing Condition:

Patients with the following conditions or symptoms are excluded:

- An active AIDS defining opportunistic infection or other active intercurrent illnesses if their ongoing treatment requires the use of excluded medications (see Exclusion - Concurrent Medications).

- Baseline fever > 38.5 C if caused by an occult opportunistic infection or neoplasm and requiring continuous treatment with excluded medications. If the evaluation for infection is unrevealing, the patient may be entered after the evaluation is completed but while mycobacterial cultures are still pending. Patients with a history of unexplained fever > 38.5 C should be evaluated as above and/or be afebrile (T < 38.0 C) for 2 weeks prior to study entry.

- Severe AIDS dementia complex as defined by a score of < 23 on the Mini-Mental State Exam at the time of discontinuation from NIAID ACTG 114 or NIAID ACTG 119.

- Any history of peripheral neuropathy or moderate to severe peripheral neuropathy as defined below:

- A score of = or > 4 in any one category or a score of = or > 2 in two categories of the peripheral neuropathy segment of the Signs and Symptoms Questionnaire.

- Accompanied by:

- Results on the Standardized Neurological exam indicative of a moderate abnormality, particularly impaired sensation of sharp pain, light touch or vibration in lower extremities, distal extremity weakness or distal extremity hyporeflexia.

- Significant cardiac disease, defined as history of ventricular arrhythmias requiring medication, prior myocardial infarct or history of angina or ischemia changes on EKG.

- Significant liver disease, as defined by transaminases > 5 x upper limit of normal or a history of cirrhosis or ascites.

- Significant renal disease as defined by an estimated creatinine clearance < 50 ml/min.

Concurrent Medication:

Excluded:

- Other antiretroviral agents.

- Biologic modifiers.

- Corticosteroids.

- Other experimental agents including:

- Foscarnet.

- Ribavirin.

- ddI.

- Drugs that could cause peripheral neuropathy including:

- Hydralazine.

- Nitrofurantoin.

- Vincristine.

- Cisplatin.

- Dapsone.

- Disulfiram.

- Diethyldithiocarbamate.

Patients with the following are excluded:

- An active AIDS defining opportunistic infection or other active intercurrent illnesses
if their ongoing treatment requires the use of excluded medications (see Exclusion -
Concurrent Medications). Such patients will be allowed into the study if they have
completed therapy with an excluded concomitant medication and are stable for 14 days.
Had to discontinue study medication in NIAID ACTG 114 or NIAID ACTG 119 because of an
opportunistic infection or intercurrent illness which required continuous treatment
with medications allowed for concomitant administration in NIAID ACTG 114 or ACTG 119.
Symptoms and conditions defined in patient Exclusion - Co-Existing Condition. Active
substance or alcohol abuse. Unwillingness or deemed unable to sign informed consent.

Prior Treatment:

Excluded within 30 days of study entry:

- Radiation therapy.

Active substance or alcohol abuse.
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00002285
Intervention Type: Drug
Intervention Name: Zidovudine
Title: A Study of Zidovudine and T Lymphocyte Transfer in the Treatment of HIV

Type III in Patients With AIDS
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Co-existing Condition:

Patients with the following are excluded:

- Lymphoma. Active central nervous system (CNS) infection by bacteria, varicella zoster virus, herpes simplex virus, or Cryptococcus neoformans. Any prior CNS infection due to Toxoplasma gondii. Any active life-threatening infection including Pneumocystis carinii pneumonia (PCP) (if prior PCP then pre-PCP arterial PO2 must be above 80), disseminated cryptococcosis (if there was a prior cryptococcosis infection the patient must have had a negative blood and cerebrospinal fluid (CSF) culture taken more than 6 weeks after the last antifungal therapy).

Any prior mycobacterium avium-intracellulare isolation.

Patients with the following conditions are excluded:

- Lymphoma. Active central nervous system (CNS) infection by bacteria, varicella zoster virus, herpes simplex virus, or Cryptococcus neoformans. Any prior CNS infection due to Toxoplasma gondii. Any active life-threatening infection including Pneumocystis carinii pneumonia (PCP) (if prior PCP then pre-PCP arterial PO2 must be above 80), disseminated cryptococcosis (if there was a prior cryptococcosis infection the patient must have had a negative blood and cerebrospinal fluid (CSF) culture taken more than 6 weeks after the last antifungal therapy).

Any prior mycobacterium avium-intracellulare isolation. Patients accepted for allogenic cell transfer must meet the CDC criteria for AIDS. Those patients who meet the criteria only because of Kaposi's sarcoma must also have a history of generalized lymphadenopathy (CDC category III), neurologic disease (CDC category IV-B), or constitutional disease (CDC category IV-A). Patients may be accepted for syngeneic cell transfer even if they have not met the CDC AIDS criteria, provided they have had constitutional disease (CDC category IV-A) or a specified non-AIDS defining secondary infection (CDC category IV-C2).

Patients must have a positive blood culture for the AIDS virus before the beginning of therapy.

Patients must be skin test negative for PPD. Patients must have a life expectancy of at least 6 months and a Karnofsky status of 60 or above.

Patients must sign an informed consent agreement. From eligible patients

precedence will be
        given to those with identical twin donors, then to Minnesota residents. The first patient
        must have an identical twin donor. Among eligible Minnesota patients without identical twin
        donors, the order of enrollment will be determined by overall good health, the presence of
        Kaposi's sarcoma (which permits monitoring of response by measuring lesions) and/or the
        presence of cytomegalovirus (CMV) viremia (which permits monitoring of response by
        remission of CMV viremia).
Overall Status: Completed
Phase: nan

NCTID: NCT00002295
Intervention Type: Drug
Intervention Name: Inosine pranobex
Title: A Study of Isoprinosine in Patients With Severe AIDS
Condition: HIV Infections
Eligibility Criteria: Exclusion Criteria

        Co-existing Condition:

        Patients with a history of gout, urolithiasis, nephrolithiasis, renal dysfunction, and
        severe gastric ulcer are excluded.

        Concurrent Medication:

        Excluded:

          - Steroids.

          - Cytotoxic immunosuppressive agents.

          - Radiotherapy.

        The following are excluded:

          - Critically ill patients.

          - Patients receiving steroids, cytotoxic immunosuppressive agents, radiotherapy.

          - Patients who have received any other immunotherapy.

          - Patients with a history of gout, urolithiasis, nephrolithiasis, renal dysfunction, and
            severe gastric ulcer.

        Prior Medication:

        Excluded:

          - Any other immunotherapy.

        Patients with severe AIDS and specified laboratory immunologic defects.
Overall Status: Completed
Phase: nan

NCTID: NCT00002308
Intervention Type: Drug
Intervention Name: Stavudine

Title: A Study of Stavudine in HIV-Infected Patients Who Have Not Had Success With Other Anti-HIV Drugs
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Patients must have:

- HIV positivity with CD4 count < 300 cells/mm3.

- Intolerance to or failure on approved antiretroviral therapy.

- Ability to provide informed consent (of parent or guardian if appropriate).

NOTE:

- Incarcerated persons may be eligible to participate.

Exclusion Criteria

Co-existing Condition:

Patients with the following symptoms or conditions are excluded:

- Grade 2 or worse disease-related peripheral neuropathy.

- Unresolved drug-related peripheral neuropathy of any severity that is attributable to other nucleoside analogs (AZT, ddC, ddI).

- Malignancy likely to require systemic chemotherapy with myelosuppressive or neurotoxic drugs in the first 3 months of stavudine treatment.

- Pregnancy (physicians of pregnant patients may contact Bristol-Myers to determine eligibility for stavudine therapy in another protocol).

Strongly discouraged:

- AZT, ddI, ddC, and other antiretroviral agents.
Overall Status: Completed
Phase: nan

NCTID: NCT00002287
Intervention Type: Drug
Intervention Name: Zidovudine
Title: A Study of Retrovir in the Prevention of HIV Infection in Health Care Workers Accidentally Exposed to the Virus
Condition: HIV Infections
Eligibility Criteria: Exclusion Criteria

Co-existing Condition:

Patients with the following are excluded:

- A prior history of a malignancy other than cutaneous basal cell or cervical carcinomas.

- Other significant, chronic underlying medical illness which, in the physician's judgment, would impair study completion.

- Evidence of compromised bone marrow function (lab results) with a blood transfusion within the last month.

- Liver dysfunction as indicated by lab results.

Patients are excluded if there is a prior diagnosis of HIV infection by one of the following criteria:

- HIV antibody positive by ELISA and Western blot assays or by other certified test method. (Patients who are ELISA positive but Western blot or other confirmatory tests are negative may continue in study).

- HIV antigen positive.

- Clinical symptoms which lead to a diagnosis by a licensed physician of AIDS or AIDS related complex or AIDS-related dementia. Also excluded are individuals who have experienced similar HIV exposure as described in this protocol in the past month and individuals who have previously been enrolled in this study. The purpose of these exclusions is to eliminate possible seroconversion in an individual that could be attributed to HIV exposure other than the single exposure experienced just prior to entry into the study.

Prior Medication:

Excluded within 4 weeks of study entry:

- Any potentially myelosuppressive drug.

- Nephrotoxic agent.

- Other experimental therapy.

Exposure of a health care worker to HIV-contaminated blood or blood component within 5 days prior to beginning therapy, defined as one of the following:

- Penetrating wound from needle recently removed from patient or sample container (e.g., blood bag, blood tube) or from sharp object visibly contaminated with HIV-positive blood or blood component. In the case of needlesticks or cuts with sharp objects, blood or blood component must not have been exposed to the air for more than 1 hour. If actual infusion of blood occurs, the 1-hour time limit does not apply.

- Hypodermic needles should come in contact with the blood and blood component from an HIV source but need not be visibly contaminated with blood to be considered a source of contamination.

- Significant exposure to HIV-positive blood or blood component as

the result of splash
on abraded skin.

- Significant exposure to HIV-positive blood or blood component as the result of splash
on mucous membranes.

- Participant must be able to give informed consent.

Active drug or alcohol abuse sufficient in the physician's opinion to prevent compliance
with the study regimen.
Overall Status: Completed
Phase: nan

NCTID: NCT00002298
Intervention Type: Drug
Intervention Name: Ribavirin
Title: The Safety and Effectiveness of Ribavirin in the Early Stages of HIV-Infection
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Concurrent Medication:

Allowed:

- Acyclovir.

Exclusion Criteria

Co-existing Condition:

Patients with the following symptoms and conditions are excluded:

- CDC classification group IV A (ARC).

- CDC classification group IV C-1 (AIDS) and IV C-2 (including Thrush or Herpes zoster
during the past 2 years). Positive plasma p24 antigen.

- Unstable medical condition, including serious cardiovascular, renal, hepatic,
neurologic, infectious, or oncologic condition even if unrelated to HIV infection.

- Splenectomy.

Concurrent Medication:

Excluded:

- Isoprinosine.

Patients with the following are excluded:

- Failure to give informed consent.

- CDC classification group IV A (ARC).

- CDC classification group IV C-1 (AIDS) and IV C-2 (including Thrush or Herpes zoster
during the past 2 years).

Positive plasma p24 antigen.

- Unstable medical condition, including serious cardiovascular, renal, hepatic, neurologic, infectious, or oncologic condition even if unrelated to HIV infection.

- Splenectomy.

Prior Medication:

Excluded within 4 weeks of start of screening tests:

- Zidovudine.

- Other drug with scientifically accepted anti-HIV properties.

- Scientifically accepted immunostimulant treatment.

- Immunosuppressant.

- Myelosuppressant or other known toxic drugs.

HIV infection group II (CDC), asymptomatic HIV infection.

- HIV antibody positive by Western blot with antibodies to p24 band and GP160 band and/or GP41. Two positive tests during screening will be required. CDC HIV infection group II, asymptomatic HIV infection, as defined in Appendix A, or CDC HIV infection group III, persistent generalized lymphadenopathy (PGL, formerly LAS).

- OKT4+ lymphocyte count greater than 300 cells/mm3 and less than 600 cells/mm3. The counts will be determined on three separate evaluations separated by at least 7 days between evaluations. These three counts will be averaged and for inclusion in the study the mean of the OKT4+ lymphocyte count must be greater than 200 cells/mm3 and less than 600 cells/mm3. Conclusion of screening tests:

- Within 42 days of starting them. Patients must be entered into the study within 14 days of screening completion. Ability to participate as outpatient:

- Ambulatory, competent to sign informed consent, and able to cooperate with the treatment plan and evaluation schedule. Informed consent:

- Must be signed before randomization to treatment. Physical activity evaluation with Karnofsky score greater than or equal to 90.

Overall Status: Terminated
Phase: nan

NCTID: NCT00002288
Intervention Type: Drug
Intervention Name: Zidovudine
Title: The Safety and Effectiveness of Retrovir in HIV-Infected Patients Who Have Problems Related to the Nervous System
Condition: HIV Infections

Eligibility Criteria: Exclusion Criteria

Co-existing Condition:

Patients with the following are excluded:

- Neuropsychological (NP) impairments more severe than described in the Inclusion Criteria.

- Evidence of nervous system dysfunction being caused by factors other than HIV infection, including history of head trauma, multiple sclerosis, epilepsy, or presence of concurrent central nervous system (CNS) infections or neoplasms, e.g., toxoplasmosis, primary or metastatic CNS lymphoma, progressive multifocal leukoencephalopathy, cryptococcal or other fungal meningitis, and CNS tuberculous infections.

- Lymphoma or other tumor requiring cytotoxic chemotherapy.

Concurrent Medication:

Excluded:

- Other antiretroviral agents.

Patients with the following are excluded:

- AIDS or advanced ARC.

- Neuropsychological (NP) impairments more severe than described above; i.e., defective performance on NP test battery in 3 or more NP areas on the NP screening battery at 2 standard deviations below the mean.

- Evidence of nervous system dysfunction being caused by factors other than HIV infection, including history of head trauma, multiple sclerosis, epilepsy, or presence of concurrent central nervous system (CNS) metastatic CNS lymphoma, progressive multifocal leukoencephalopathy, cryptococcal or other fungal meningitis, and CNS tuberculous infections.

Prior Medication:

Excluded:

- Antiretroviral agents including zidovudine (AZT).

Prior Treatment:

Excluded within 3 months of study entry:

- Blood transfusion.

Impaired performance on a defined neuropsychological test battery.

- Asymptomatic HIV infection.

- Persistent generalized lymphadenopathy (PGL).

- Early AIDS related complex (ARC).

- Seropositive for human immunodeficiency virus (HIV) demonstrated by positive ELISA
test and confirmed by Western blot with no or minimal symptomatology or HIV infection.

- Ability to give informed consent or a person with durable power of attorney who can
give informed consent.

- Willingness to be followed by the originating medical center for 1 year.

History of drug or alcohol abuse.
Overall Status: Completed
Phase: nan

NCTID: NCT00002289
Intervention Type: Drug
Intervention Name: Thymopentin
Title: The Effects of Thymopentin on HIV Infectivity of Blood Cells and Semen in HIV-Infected Patients
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Concurrent Medication:

Allowed:

- Aerosolized pentamidine.

Patients must have the following:

- Seropositive for HIV-1 (ELISA assay) confirmed by Western blot.

- HIV-1 p24 antigen must be detected in supernatant fluids from co-cultures of patients'
peripheral blood monocytes (PBMC) on two separate occasions.

- Voluntarily sign consent.

- Patients with HIV "wasting syndrome" are allowed.

Prior Medication:

Allowed:

- Aerosolized pentamidine.

Exclusion Criteria

Co-existing Condition:

Patients with the following are excluded:

- AIDS as defined by the CDC.

- Significant hepatic disease.

- Thrombocytopenia.

- Hypersensitivity to thymopentin.

- Hemophilia A or B or other hematologic disorders requiring current or previous administration of blood products.

- Abnormal chest x-ray (indicative of active disease (opportunistic infection)) within 30 days prior to study entry.

Patients with the following are excluded:

- AIDS as defined by the CDC.

- Significant hepatic disease.

- Thrombocytopenia.

- Hypersensitivity to thymopentin.

- Hemophilia A or B or other hematologic disorders requiring current or previous administration of blood products.

- Abnormal chest x-ray (indicative of active disease (opportunistic infection)) within 30 days prior to study entry.

Prior Medication:

Excluded within 30 days of study entry:

- Immunomodulatory or experimental therapy.

- Excluded within 90 days of study entry:

- Zidovudine (AZT).

Intravenous drug abuse.
Overall Status: Completed
Phase: nan

NCTID: NCT00002311
Intervention Type: Drug
Intervention Name: Wobenzym
Title: The Safety of Four Different Dose Levels of Wobenzym in HIV-Positive Patients
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Patients must have:

HIV seropositivity with CD4 counts between 250 and 400 cells/mm3.

Exclusion Criteria

Co-existing Condition:

Patients with the following symptoms or conditions are excluded:

- Known hypersensitivity to hydrolytic enzymes such as Wobenzym.

- Known sensitivity to lactose.

- Presumption that the patient will not comply with the dosing schedule or follow-up appointments.

Concurrent Medication:

Excluded:

- Concurrent use of immunosuppressive therapy or steroids.

Overall Status: Completed
Phase: Phase 1

NCTID: NCT00002338
Intervention Type: Drug
Intervention Name: Raluridine
Title: The Safety and Effectiveness of 935U83 in HIV-Infected Patients
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Concurrent Medication:

Recommended:

- PCP prophylaxis for patients whose CD4 counts fall below 200 cells/mm3 or who develop PCP during study participation.

Allowed:

- Acute treatment and secondary prophylaxis for tuberculosis, Mycobacterium avium intracellulare, toxoplasmosis, histoplasmosis, cryptococcosis, disseminated candidiasis, or cytomegalovirus infection.

Patients must have:

- HIV infection.

- CD4 count 200 - 500 cells/mm3.

- No history of or current AIDS-defining indicator disease by CDC criteria.

- No antiretroviral therapy within the past 6 months.

- Consent of parent or guardian if less than 18 years of age.

Exclusion Criteria

Co-existing Condition:

Patient with the following symptoms or conditions are excluded:

- Current evidence of chronic hepatitis of any etiology.

- Seropositivity for HBsAg or hepatitis C virus by second generation ELISA.

Concurrent Medication:

Excluded:

- Cytotoxic chemotherapy.

- Other antiretroviral drugs.

- Immunomodulators.

- Foscarnet.

- GM-CSF or G-CSF.

- Erythropoietin.

Concurrent Treatment:

Excluded:

- Radiation therapy.

Patients with the following prior conditions are excluded:

History of chemical, viral, or alcohol-induced clinical hepatitis within the past 3 years.

Prior Medication:

Excluded within the past 6 months:

- Any antiretroviral therapy.

- HIV immunotherapeutic vaccine.

Excluded within the past 4 weeks:

- Cytotoxic chemotherapy.

- Immunomodulating agents such as systemic corticosteroids, IL-2, alpha interferon, beta interferon, or gamma interferon.

Prior Treatment:

Excluded within the past 4 weeks:

- Radiation therapy. Current alcohol or illicit drug use that may interfere with study compliance.

Overall Status: Completed
Phase: Phase 1

NCTID: NCT00002335
Intervention Type: Drug
Intervention Name: Emtricitabine
Title: The Safety and Effectiveness of 524W91
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Patients must have:

- Documented HIV infection.

- CD4 count >= 200 cells/mm3.

- No active opportunistic infection.

Exclusion Criteria

Co-existing Condition:

Patients with the following symptoms or conditions are excluded:

- Malignancy or other condition that would confound study assessment or interfere with ability to complete the study.

- Malabsorption syndrome or other gastrointestinal dysfunction that might interfere with gastrointestinal absorption.

Concurrent Medication:

Excluded on the day of each dose:

- Antiretrovirals.

- Any prescription or over-the-counter medication.

- Alcoholic beverages.

- Coffee, tea, and other xanthine-containing beverages and foods.

Patients with the following prior conditions are excluded:

History of hepatitis, pancreatitis, or cardiomyopathy within the past 5 years.

Prior Medication:

Excluded:

- Antiretrovirals within 24 hours prior to each dose.

- Any prescription or over-the-counter medications within 48 hours prior to each dose.

- Alcoholic beverages within 48 hours prior to each dose. Current alcohol or illicit drug use that may affect patient compliance.

Overall Status: Completed
Phase: Phase 1

NCTID: NCT00002329
Intervention Type: Drug
Intervention Name: Celgosivir hydrochloride
Title: A Study of MDL 28,574A in HIV-Infected Patients
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Patients must have:

- HIV infection.

- CD4 count >= 500 cells/mm3.

- No evidence of AIDS.

- No antiretroviral therapy within 30 days prior to study entry.

NOTE:

- Presence of lymphadenopathy in two or more extrainguinal sites, at least 1 cm in diameter for 3 or more months, is permitted.

Exclusion Criteria

Co-existing Condition:

Patients with the following symptoms or conditions are excluded:

- Clinically significant abnormalities on routine hematology (other than CD4 count and Western blot), serum chemistry, and urinalysis.

- Abnormal EKG.

- Positive stool guaiac.

- Abnormal medical history or physical exam including temperature, heart rate, and blood pressure.

- Clinically significant organ abnormality or disease.

- Positive urine drug screen for illicit drugs.

- Inability to comply with study procedures.

Concurrent Medication:

Excluded:

- Routine treatment with nonprescription medications.

- Treatment with other medications except with approval of the investigator.

Patients with the following prior conditions are excluded:

- Prior participation in this trial.

- Serious physical or mental illness within 1 year prior to study entry that would confound interpretation of data.

Prior Medication:

Excluded:

- Antiretroviral therapy within 30 days prior to study entry.

- Known medications that alter renal, hepatic, or hematologic/immunologic function (such as barbiturates, phenothiazines, cimetidine, and immunomodulators) within 14 days prior to study entry.

- Routine treatment with nonprescription medications within 3 days prior to study entry.

History of alcohol or drug abuse within the past year.
Overall Status: Completed

Phase: Phase 1

NCTID: NCT00002346
Intervention Type: Drug
Intervention Name: Adefovir dipivoxil
Title: The Safety and Effectiveness of Bis-POM PMEA in HIV-Infected Patients
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Concurrent Medication:

Allowed:

- Prophylaxis with aerosolized pentamidine, fluconazole, ketoconazole, trimethoprim/sulfamethoxazole, or dapsone, provided a stable regimen has been maintained for at least 4 weeks prior to study entry.

Patients must have:

- HIV seropositivity.

- CD4 count >= 100 cells/mm3.

- p24 antigen (immune-complex dissociated) >= 50 pg/ml.

- Life expectancy of at least 6 months.

Prior Medication:

Allowed:

- Prior prophylaxis with aerosolized pentamidine, fluconazole, ketoconazole, trimethoprim/sulfamethoxazole, or dapsone.

Exclusion Criteria

Co-existing Condition:

Patients with the following symptoms or conditions are excluded:

- Active, serious infection (other than HIV infection) requiring parenteral antibiotic therapy.

- Malignancy other than cutaneous Kaposi's sarcoma.

- Clinically significant cardiac disease, including symptoms of ischemia, congestive heart failure, or arrhythmia.

- Gastrointestinal malabsorption syndrome.

- Inability to take oral medication.

Concurrent Medication:

Excluded:

- Any parenteral antibiotic therapy.

- Diuretics.

- Amphotericin B.
- Didanosine (ddI).
- Fluconazole.
- Foscarnet.
- Ganciclovir.
- Interferon-alpha.
- Interferon-beta.
- Isoniazid.
- Aminoglycoside antibiotics.
- Ketoconazole (topical allowed).
- Itraconazole.
- Rifabutin.
- Rifampin.
- Stavudine (d4T).
- Zalcitabine (ddC).
- Zidovudine (AZT).
- Lamivudine (3TC).
- Any investigational agents (except with sponsor approval).
- Systemic therapy for Kaposi's sarcoma.

Patients with the following prior condition are excluded:

History of lactose intolerance.

Prior Medication:

Excluded within 2 weeks prior to study entry:

- Any parenteral antibiotic therapy.
- Diuretics.
- Amphotericin B.
- Didanosine (ddI).
- Fluconazole.
- Foscarnet.
- Ganciclovir.
- Interferon-alpha.
- Interferon-beta.

- Isoniazid.

- Aminoglycoside antibiotics.

- Ketoconazole (topical allowed).

- Itraconazole.

- Rifabutin.

- Rifampin.

- Stavudine (d4T).

- Zalcitabine (ddC).

- Zidovudine (AZT).

- Lamivudine (3TC).

- Any investigational agents (except with sponsor approval).

Excluded within 4 weeks prior to study entry:

Systemic therapy for Kaposi's sarcoma. Active substance abuse (including alcohol) as
determined by questionnaire or positive drug screen.
Overall Status: Completed
Phase: Phase 1

NCTID: NCT00002332
Intervention Type: Drug
Intervention Name: Thymopentin
Title: A Study of Timunox (Thymopentin) in HIV-Infected Patients Receiving Other Anti-HIV Drugs
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Patients must have:

- Asymptomatic or minimally symptomatic HIV infection (no evidence of AIDS).

- CD4 count <= 400 cells/mm3 within 6 weeks prior to study entry (CD4 count changed to
100 - 400 cells/mm3 per amendment).

- Tolerated the current nucleoside analog antiretroviral treatment for at least 4 weeks
prior to study entry.

Exclusion Criteria

Co-existing Condition:

Patients with the following symptoms or conditions are excluded:

- Known hypersensitivity to thymopentin or any component of the formulation.

- Significant chronic underlying medical illness that would impede study participation.

- Grade 2 or higher peripheral neuropathy related to nucleoside analog antiretroviral
  treatment.

Concurrent Medication:

Excluded:

- Any antiretroviral agents other than zidovudine, didanosine, or dideoxycytidine.

- HIV vaccines or any investigational or non-FDA approved medication or immunomodulatory
  or experimental therapy within 30 days prior to study entry.

Patients with the following prior condition are excluded:

Abnormal chest x-ray consistent with active opportunistic infection within 6 weeks prior to
study entry.

Prior Medication:

Excluded:

- Any prior antiretroviral agents other than zidovudine, didanosine, or dideoxycytidine
  within 30 days prior to study entry.

Required:

- Current nucleoside analog antiretroviral treatment.

Required:

- Nucleoside analog antiretroviral treatment for at least 4 weeks prior to study entry.

Significant active alcohol or drug abuse sufficient to prevent study compliance.
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00002337
Intervention Type: Drug
Intervention Name: Vesnarinone
Title: A Study of Multiple Doses of Vesnarinone in Advanced HIV Disease
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Concurrent Medication:

Allowed:

- Chemoprophylaxis for Pneumocystis carinii, candida, mycobacteria, and other
  opportunistic infections.

- Acyclovir for up to 14 days for acute herpes outbreaks.

Patients must have:

- Documented HIV infection.

- CD4 count 50 - 300 cells/mm3.

- No active opportunistic infections.

- No fever, diarrhea, or Herpes zoster.

Exclusion Criteria

Co-existing Condition:

Patients with the following symptoms or conditions are excluded:

- Clinically significant current cardiac disease, including patients who exhibit long QTC syndrome on EKG screening and who have an abnormal cardiothoracic ratio on chest x-ray at baseline.

- Active malignancy (other than cutaneous Kaposi's sarcoma or cutaneous basal cell carcinoma or in situ carcinoma of the cervix).

Concurrent Medication:

Excluded:

- Antiretroviral agents, including ddI, ddC, AZT, and d4T.

- Immunosuppressive agents.

- Investigational HIV drugs/therapies including vaccines.

- Interferon or other immunomodulating agents.

- Corticosteroids (other than topical).

- Hematopoietins.

- Megestrol acetate.

- Agents known to cause neutropenia.

- Trimethoprim/sulfamethoxazole in excess of 160 mg trimethoprim and 800 mg sulfamethoxazole thrice weekly.

- Cytotoxic chemotherapy.

Concurrent Treatment:

Excluded:

- Radiation therapy.

Patients with the following prior conditions are excluded:

- Prior history of cardiac disease.

- History of agranulocytosis or severe (grade 3 or worse) drug-induced neutropenia or documented abnormalities in granulocyte function.

Prior Medication:

Excluded:

- AZT, ddI, ddC, d4T, or other nucleoside analog antiretroviral therapy within 14 days prior to study entry.

- Prior cytotoxic chemotherapy.

- Acyclovir for herpes prophylaxis within 48 hours prior to study entry.

Prior Treatment:

Excluded within 30 days prior to study entry:

- Erythropoietin, transfusion, or blood product use.

- Radiation therapy (including electron beam irradiation). Active use of illicit drugs (specifically cocaine, amyl nitrate, heroin, and other cardioactive agents).

Overall Status: Completed
Phase: Phase 1

NCTID: NCT00002370
Intervention Type: Drug
Intervention Name: Itraconazole
Title: Study of Itraconazole in Patients With Advanced HIV Infection
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Concurrent Medication:

Allowed:

Antiretroviral therapy providing patient has already been on a stable, unchanged regimen for 8 weeks prior to study entry.

Patients must have:

- Documented HIV infection.

- CD4 lymphocyte count < 300 cells/mm3.

- No clinically significant abnormalities, elicited by history and physical examination.

- No clinically significant abnormalities in blood count, biochemical profile, or urinalysis within 2 weeks of study entry.

- Negative urine screening.

- No clinically significant abnormalities of electrocardiogram.

Prior Medication:

Allowed:

Antiretroviral therapy providing patient has been on a stable, unchanged regimen for 8 weeks prior to study entry.

Exclusion Criteria

Co-existing Condition:

Patients with the following symptoms and conditions are excluded:

- Acute opportunistic infection or other significant concurrent illness that would preclude participation for the required 36 days.
- Unable to swallow oral solution.
- Obesity greater than 25% of ideal body weight.

Concurrent Medication:

Excluded:

- Rifampin.
- Rifabutin.
- Phenobarbital.
- Phenytoin.
- Carbamazepine.
- Digoxin.
- Warfarin.
- Midazolam.
- Triazolam.
- Terfenadine.
- Astemizole.
- Cisapride.
- H2 blockers.
- Omeprazole.
- Continual antacids.
- Didanosine.
- Any medication known to affect absorption, metabolism or excretion of imidazole or azole compounds.

Patients with the following prior symptoms and conditions are excluded:

- Previous hypersensitivity to azole antifungals.
- History of surgical procedure that may interfere with absorption of itraconazole.
- History of significant blood loss in the previous 30 days.

Prior Medication:

Excluded:

Excluded within 15 days prior to study entry:

- Rifampin.
- Rifabutin.
- Phenobarbital.
- Phenytoin.
- Carbamazepine.
- Digoxin.
- Warfarin.
- Midazolam.
- Triazolam.

Excluded within 8 weeks prior to study entry:

- Change in antiretroviral therapy.

Risk Behavior:

Excluded:

Patients who chew tobacco or regularly smoke more than 10 cigarettes per day.
Overall Status: Completed
Phase: nan

NCTID: NCT00002351
Intervention Type: Drug
Intervention Name: Indinavir sulfate
Title: A Study of L-735,524 in HIV-Positive Children and Adolescents
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Patients must have:

- HIV positivity.
- No active opportunistic infection within the past 30 days, other than superficial candidiasis of the oral cavity or vagina.
- Body surface area at least 1.0 sqm.
- Consent of parent or guardian.

Prior Medication:

Allowed:

- Aerosolized pentamidine.
- Topical antifungals.
- TMP / SMX.

- AZT.

Exclusion Criteria

Co-existing Condition:

Patients with the following symptoms or conditions are excluded:

- Significant hepatic disease including HBsAg or hepatitis C positivity.

- Significant neurologic disease such as loss of intellectual ability, motor deficits, or seizure disorder.

- Significant cardiac disease including dysrhythmia or cardiomyopathy.

- Significant medical condition or laboratory abnormality that may pose additional risk to patient on study or confound the results.

- Has a social situation that may interfere with study participation.

Concurrent Medication:

Excluded:

- Oral contraceptives.

Patients with the following prior conditions are excluded:

- History of serious allergic drug reactions.

- History of significant cardiac disease.

- Participation on another clinical trial within the past 4 weeks.

- Donated blood within the past 4 weeks.

Prior Medication:

Excluded within the past 4 weeks:

- Hematopoietic growth factors.

Excluded within the past 2 weeks:

- Antiretroviral agent other than zidovudine.

- Oral contraceptives.

- Prophylaxis for opportunistic infections, other than aerosolized pentamidine, topical antifungals, and TMP/SMX.

- Any other medication unless approved by Merck clinical monitor. Current illicit drug use.

Overall Status: Completed
Phase: Phase 1

NCTID: NCT00002364

Intervention Type: Drug
Intervention Name: Abacavir sulfate
Title: A Study of 1592U89 Combined With Other Anti-HIV Drugs in Patients Who Have Taken Anti-HIV Drugs
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Patients must have:

- CD4+ cell count >= 100 /mm3.

- Plasma HIV RNA >= 30,000 copies/ml.

- Study participants may be recruited from all clinical categories, provided they do not meet any of the exclusion criteria.

- Parent or legal guardian to sign written, informed consent for patients under the age of 18.

Exclusion Criteria

Co-existing Condition:

Patients with any of the following symptoms or conditions are excluded:

- Patients with active or ongoing AIDS-defining opportunistic infection or disease. NOTE:

- For this study, a CD4+ cell count <= 200 cells/mm3 in the absence of any other AIDS defining indicator condition is not considered an AIDS defining event.

- Malabsorption syndrome or other gastrointestinal dysfunction that might interfere with drug absorption.

- Patients with life threatening infection or other serious medical conditions whose participation may compromise patient safety.

Concurrent Medication:

Excluded:

- Treatment with cytotoxic chemotherapeutic agents within the 24 weeks of the study.

- Patients receiving other investigational drugs.

- Foscarnet therapy or therapy with other agents with documented activity against HIV in vitro.

- Treatment with immunomodulators.

- Patients on methadone.

Concurrent Treatment:

Excluded:

- Treatment with radiation therapy within the 24 weeks of the study.

NOTE:

- Localized radiation therapy may be permitted following consultation with the sponsor.

Patients with any of the following prior conditions are excluded:

- Subjects with a history of lymphoma.

- Subjects with a history of clinically apparent pancreatitis or hepatitis within the last 6 months.

Prior Medication:

Excluded:

- Treatment with any antiretroviral therapy with NRTIs (alone or in combination) other than those defined for each treatment group.

- Treatment with any non-nucleoside RT inhibitors or protease inhibitors.

- Treatment with cytotoxic chemotherapeutic agents within 1 month prior to study entry.

- Investigational HIV vaccine within the past 3 months.

- Immunomodulating agents such as systematic corticosteroids, interleukins, thalidomide, anticytokine agents, anti-oxidants or interferons within 1 month of study entry.

Prior Treatment:

Excluded:

- Treatment with radiation therapy within 1 month of entry.

Risk Behavior:

Excluded:

Patients with current alcohol or illicit drug use that, in the opinion of the principal investigator, may interfere with the patient's ability to comply with the study protocol.

Overall Status: Completed
Phase: Phase 2

NCTID: NCT00002360
Intervention Type: Drug
Intervention Name: Didanosine
Title: A Study Comparing Two Forms of Didanosine in HIV-infected Patients
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Patients must have:

- HIV infection.

- CD4 cell counts of at least 200 cells/mm3.

Exclusion Criteria

Co-existing Condition:

Patients with the following symptoms or conditions are excluded:

- Any evidence of organ dysfunction.

- Any clinically significant deviations from specified baseline requirements for physical examinations, laboratory tests, or 12-lead electrocardiogram.

Overall Status: Completed
Phase: Phase 1

NCTID: NCT00002349
Intervention Type: Drug
Intervention Name: Stavudine
Title: A Pilot Study to Compare the Antiviral and Immunologic Effects of Stavudine (d4T) Versus Placebo in Subjects With Evidence of Recent HIV Infection.
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Patients must have:

- Recent HIV infection.

- No prior antiretroviral therapy.

- No acute opportunistic infection at study entry.

Exclusion Criteria

Co-existing Condition:

Patients with the following symptoms or conditions are excluded:

- Intractable diarrhea.

- Bilateral peripheral neuropathy.

- Any other condition that would preclude study therapy.

Concurrent Medication:

Excluded:

- Myelosuppressive, neurotoxic, or hepatotoxic drugs.

Patients with the following prior condition are excluded:

History of bilateral peripheral neuropathy.

Prior Medication:

Excluded:

- Prior antiretroviral therapy.

- Myelosuppressive, neurotoxic, or cytotoxic agents within 3 months prior to study

entry.
Overall Status: Completed
Phase: nan

NCTID: NCT00002363
Intervention Type: Drug
Intervention Name: Peptide Construction 3, Synthetic
Title: The Safety and Effectiveness of SPC3 in HIV-1 Infected Patients
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Concurrent Medication:

Allowed:

- Antiretrovirals provided regimen has been stable for at least 6 weeks prior to study screening.

Patients must have:

- HIV seropositivity for at least 6 months.

- CD4 >= 100 cells/mm3.

- HIV RNA PCR (Amplicor) > 10,000 copies/ml.

- No significant active opportunistic infection or tumor at study entry.

FDA DISCLAIMER:

- The FDA encourages the inclusion of females of childbearing potential in study protocols, but the sponsor of this protocol specifically excludes females of childbearing potential from this study and includes only females who are sterile. Any questions about these inclusion/exclusion criteria should be directed to the study's contact person.

Prior Medication:

Allowed:

- Prior antiretrovirals.

Exclusion Criteria

Co-existing Condition:

Patients with the following conditions are excluded:

Inability to communicate with investigator or deemed likely to be noncompliant on study.

Concurrent Medication:

Excluded:

- Any drug that may interact with SPC3 (e.g., suramin).

Patients with the following prior condition are excluded:

History of relevant drug hypersensitivity.

Prior Medication:

Excluded:

- Investigational drug within the past 4 weeks.

Overall Status: Completed
Phase: Phase 1

NCTID: NCT00002365
Intervention Type: Drug
Intervention Name: LXR015-1
Title: A Study of LXR015-1 in HIV-Infected Patients
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Patients must have:

- Documented HIV infection.

- CD4 cell count less than 200 cells/mm3.

Prior Medication:

Allowed:

Acute therapy for opportunistic infections or serious AIDS defining infections must be completed at least 28 days before study entry.

Exclusion Criteria

Co-existing Condition:

Patients with the following symptoms or conditions are excluded:

- Patients that are unable to take adequate oral intake (i.e. unable to eat 1 or more meals a day because of chronic nausea, emesis, or abdominal/oral/esophageal discomfort).

- Patients who have severe diarrhea as defined as >= 7 stools per day, or acute diarrhea due to a treatable cause.

NOTE:

- If the patient has Cryptosporidia, Mycobacterium avium, or Cytomegalovirus that is unresponsive to treatment and has less than 7 stools per day, the patient may participate in this study.

- Patients who have any severe or life-threatening laboratory or clinical abnormality, or are not expected to live for 8 weeks.

- Patients who have an active opportunistic infection, including tuberculosis, cryptococcosis, or other serious AIDS defining infections requiring immediate

treatment. Acute therapy must be completed at least 28 days before study entry.

- Patients with unexplained elevated temperature >= 38.5 degrees C that persists for 7 days or more within 14 days before study entry.

- Patients with malignancy other than squamous or basal carcinomas of the skin. Patients with visceral Kaposi's sarcoma or lymphoma requiring systemic chemotherapy or radiation treatment will be excluded. Patients with Kaposi's of the skin or mucous membranes may enroll in this study.

- Patients, who in the judgment of the investigator are unable to comply with the protocol.

Concurrent Treatment:

Excluded:

Radiation therapy.

Patients with the following prior condition are excluded:

A known history of hypersensitivity reaction to soy protein or soy lecithin. NOTE:

- This hypersensitivity is identified through medical history, not skin testing.

Excluded:

- Systemic chemotherapy.

- Acute therapy for opportunistic infections or other serious AIDS defining infections.

- Intravenous rehydration as treatment for diarrhea.

Required:

Patient must be taking a stable regimen (about 8 weeks) of anti-viral, anti-opportunistic infection and/or anti-diarrheal (if patient has diarrhea) medications.
Overall Status: Completed
Phase: Phase 1

NCTID: NCT00002388
Intervention Type: Drug
Intervention Name: Abacavir sulfate
Title: A Study of 1592U89 in HIV-Infected Patients
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Concurrent Medication:

Allowed:

Prophylaxis for opportunistic infections.

Patients must have:

- HIV-1 infection.

- CD4 cell count 100 - 500 cells/mm3 within 3 to 5 weeks prior to study drug administration.

- No active diagnosis of AIDS (other than non-visceral Kaposi's sarcoma) according to the 1993 CDC AIDS surveillance definition.

Exclusion Criteria

Co-existing Condition:

Patients with the following conditions and symptoms are excluded:

- Malabsorption syndrome or other gastrointestinal dysfunction that may interfere with drug absorption.

- Chronic disease such as diabetes, congestive heart failure, cardiomyopathy, or other cardiac dysfunction that in the opinion of the investigator, would compromise the safety of the patient.

Concurrent Medication:

Excluded:

- Immunomodulating agents.

- Chemotherapeutic agents.

- Antiretroviral therapy. NOTE:

- Patients who elect to continue study treatment into the extended phase may, after consultation with their primary physician, combine 1592U89 at a recommended dose of 300 mg bid with other licensed antiretroviral drugs.

Concurrent Treatment:

Excluded:

Radiation therapy.

Patients with the following prior conditions are excluded:

- History of clinically relevant hepatitis or pancreatitis within 6 months prior to study drug administration.

- History of hypersensitivity, anaphylactic, or idiosyncratic reaction to nucleoside analogs.

Prior Medication:

Excluded:

- Treatment with immunomodulating or cytotoxic chemotherapeutic

agents within six weeks
prior to study drug administration.

- Antiretroviral therapy within 2 weeks prior to administration of study drugs.

Prior Treatment:

Excluded:

Radiation therapy within six weeks prior to study drug administration. Current alcohol or
illicit controlled substance use that in the opinion of the investigator, may interfere
with the patient's ability to complete the study.
Overall Status: Completed
Phase: Phase 1

NCTID: NCT00002406
Intervention Type: Drug
Intervention Name: Indinavir sulfate
Title: A Comparison of Two Dose Levels of Indinavir Combined With Two Nucleoside Analogue Reverse Transcriptase Inhibitors (NRTIs) in HIV-Infected Patients
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Patients must have:

- Documented HIV-1 seropositive status.

- CD4 count greater than 100 cells/mm3.

- Parental consent for patients under 18.
Overall Status: Completed
Phase: Phase 3

NCTID: NCT00002383
Intervention Type: Drug
Intervention Name: Saquinavir
Title: A Comparison of Saquinavir Hard- and Soft-Gelatin Capsules in HIV-Infected Patients
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Patients must have:

- CD4 count of 100 to 500 cells/mm3.

- Greater than 20,000 HIV-RNA copies/ml.

Exclusion Criteria

Prior Medication:

Excluded:

Prior treatment with protease inhibitors.

Required:

- Less than 8 weeks prior antiretroviral treatment (For at least 25% of patients).

- At least 8 weeks prior antiretroviral treatment (For at least 25%

of patients).
Overall Status: Completed
Phase: Phase 1

NCTID: NCT00002392
Intervention Type: Drug
Intervention Name: Thalidomide
Title: A Study of Thalidomide in HIV-Infected Patients Who Are Receiving HAART
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Patients must have:

- Documented HIV infection.

- CD4+ cell count between 300 and 500 cells/mm3.

- HIV-1 RNA < 500 by the branched-chain DNA assay (bDNA assay, Chiron) within 21 days of study entry [AS PER AMENDMENT 11/25/98:

- Undetectable-plasma HIV titers (as defined by the FDA) by the branched-chain DNA test].

- Established B cell lines [deleted AS PER AMENDMENT 11/25/98].

- Response to at least one recall antigen in an in vitro assay of lymphocyte proliferative responses.

- Life expectancy > 6 months [deleted AS PER AMENDMENT 11/25/98].

Exclusion Criteria

Co-existing Condition:

Patients with the following conditions or symptoms are excluded:

- Active opportunistic infection or HIV-related malignancy [HIV-related malignancy deleted AS PER AMENDMENT 11/25/98].

- Peripheral neuropathy of grade 2 or higher by Division of AIDS toxicity criteria.

Concurrent Medication:

Excluded:

- Other investigational HIV-drugs.

- Immunomodulatory or potentially immunomodulatory drugs, such as glucocorticoids, hematopoietins, interleukin-2, interferon, or pentoxifylline.

Patients with the following prior conditions are excluded:

History of serious hypersensitivity to tetanus toxoid or any of the vaccine components.

Prior Medication:

Excluded:

- Previous immunization with pneumococcal polysaccharide vaccine [or, AS PER AMENDMENT 11/25/98, keyhole limpet hemocyanin vaccine].

- Tetanus toxoid booster within 5 years [deleted AS PER AMENDMENT 11/25/98].

- Other investigational HIV-drugs within 6 weeks of enrollment.

- Immunomodulatory or potentially immunomodulatory drugs, such as glucocorticoids, hematopoietins, interleukin-2, interferon, or pentoxifylline within 6 weeks of enrollment.

Risk Behavior:

Excluded:

Active drug or alcohol abuse.

Required:

Effective combination antiretroviral therapy including two nucleoside analog agents (ZDV, 3TC, ddI, ddC, or d4T) and nelfinavir or indinavir, for at least one month prior to study entry. [AS PER AMENDMENT 11/25/98:

- On stable, effective, highly-active antiretroviral therapy with combinations of any FDA-approved anti-HIV drugs for at least 3 months prior to entry.]

Overall Status: Completed
Phase: nan

NCTID: NCT00002405
Intervention Type: Drug
Intervention Name: Amprenavir
Title: A Study of Amprenavir in HIV-Infected Patients
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Patients must have:

- Documented HIV-1 infection.

- Evidence of failure or intolerance (have experienced a treatment-limiting toxicity) to standard protease inhibitor therapy and, in the judgment of the physician, be unable to construct a viable treatment regimen without APV.

- Consent of parent or guardian if less than 18 years old.

Exclusion Criteria

Co-existing Condition:

Patients with the following symptoms or conditions are excluded:

- Malabsorption syndrome or other gastrointestinal dysfunction which might interfere with drug absorption or render the patient unable to take oral

medication.

- Serious medical conditions such as diabetes, congestive heart failure, cardiomyopathy, or other cardiac dysfunction, which, in the opinion of the investigator, would compromise the safety of the patient.

- Hepatic failure.

- Renal failure requiring dialysis.

Patients with the following prior conditions are excluded:

History of clinically relevant pancreatitis or hepatitis within the last 6 months.

Prior Medication:

Excluded:

- Previous treatment with APV.

- Patients currently participating in, or who would qualify for or have access to, an enrolling study of APV (ACTG 398 and ACTG 400).

Risk Behavior:

Excluded:

Patients with current alcohol or illicit drug use which, in the investigator's opinion, may interfere with the patient's ability to comply with the requirements of the study.

Required:

Currently taking at least one nucleoside analogue or protease inhibitor, in addition to amprenavir.

Required:

- Received prior treatment with one or more protease inhibitors.

- Patient must be naive to at least one or more nucleoside analogue, non-nucleoside analogue, or protease inhibitor drugs.

Overall Status: Completed
Phase: nan

NCTID: NCT00002382
Intervention Type: Drug
Intervention Name: Saquinavir
Title: A Study of Saquinavir Used Alone or in Combination With Other Anti-HIV Drugs in HIV-Infected Patients
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Patients must have:

- Sero-positivity for HIV -1 antibody by an ELISA test, with confirmation by an

alternative method.

- CD4 count <= 300 cells/mm3 (within 4 weeks prior to entry).

- Signed, informed consent from a parent or legal guardian for patients < 18 years of age.

- Failed previous therapy with or be intolerant to other registered anti-retroviral drugs.

Exclusion Criteria

Co-existing Condition:

Patients with the following conditions or symptoms are excluded:

- Eligibility for any controlled clinical study of any experimental HIV therapy.

- Grade 4 hematologic and/or Grade 3 hematologic toxicity at baseline.

Patients with the following prior conditions are excluded:

Known hypersensitivity to saquinavir or other protease inhibitors. 1. Drugs, such as rifampin and rifabutin, which induce hepatic enzymes are likely to result in decreased levels of saquinavir and, therefore, should be avoided where possible.

- Concomitant therapy and treatment should be kept at a minimum.

- Current participation in any study formally excluding concomitant treatment with experimental drugs.

1. Saquinavir can be used in combination with other registered anti-retroviral drugs such as ZDV, ddC and/or ddI. Other not yet registered anti-retroviral drugs can be used in combination with saquinavir when these drugs are widely available in the respective country or when they are allowed in combination treatment in any on-going clinical study.

- Prophylactic treatment for any opportunistic infections.
Overall Status: Completed
Phase: Phase 3

NCTID: NCT00002390
Intervention Type: Drug
Intervention Name: Abacavir sulfate
Title: A Study of the Safety and Effectiveness of Different Doses of 1592U89 in HIV-Infected Patients
Condition: HIV Infections
Eligibility Criteria: nan
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00002396
Intervention Type: Drug

Intervention Name: Tenofovir disoproxil fumarate
Title: The Safety and Effectiveness of PMPA Prodrug in HIV-Infected Patients
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Patients must have:

- HIV infection, as indicated by seropositivity for HIV infection (ELISA and Western blot), positive HIV culture, or positive plasma HIV RNA.

- CD4 cell count of 200 or more cells/mm3 within 28 days prior to study entry.

- Plasma HIV RNA of 10,000 or more copies/ml within 28 days of study entry.

- Minimum life expectancy of 12 months.

Exclusion Criteria

Co-existing Condition:

Patients with any of the following symptoms or conditions are excluded:

- Active, serious infections (other than HIV infection) that require parenteral antibiotic therapy. Patients should be considered recovered if at least 2 weeks have elapsed following the cessation of parenteral antibiotic therapy before enrollment.

- Active clinically significant medical problems including cardiac disease (e.g., symptoms of ischemia, congestive heart failure, or arrhythmia).

- Positive test for Hepatitis B surface antigen (HBsAg).

- Malignancy other than basal cell carcinoma or cutaneous Kaposi's sarcoma.

Prior Medication:

Excluded:

- Adefovir dipivoxil (bis-POM PMEA) for more than 14 days.

Within 2 weeks prior to entry:

- Antiretroviral therapy, including nucleoside analogues, nonnucleoside reverse transcriptase inhibitors, protease inhibitors, or investigational antiretroviral agents.

- Interferon (alpha, beta, or gamma) or interleukin (e.g., IL-2) therapy, aminoglycoside antibiotics, amphotericin B, cidofovir, diuretics, foscarnet, ganciclovir, itraconazole, fluconazole, ketoconazole (topical allowed), isoniazid, rifampin, rifabutin, clarithromycin, azithromycin, systemic chemotherapeutic agents, systemic corticosteroids, other agents with significant nephrotoxic

potential, other agents
that may inhibit or compete for elimination via active renal tubular secretion (e.g.,
probenecid), and other investigational agents.

Risk Behavior:

Excluded:

Active drug or alcohol abuse as demonstrated by a positive screening test for drugs of
abuse (except marijuana or drugs used for medical indications) or substance abuse
considered sufficient to hinder patient compliance.

Patients who are receiving:

- Antiretroviral therapy, including nucleoside analogues, nonnucleoside reverse
transcriptase inhibitors, protease inhibitors, or investigational antiretroviral
agents. NOTE:

- Antiretroviral therapy may be started after completion of the Day 49 follow-up visit
(i.e., not earlier than 14 days after completion of dosing).

- Interferon (alpha, beta, or gamma) or interleukin (e.g., IL-2) therapy, aminoglycoside
antibiotics, amphotericin B, cidofovir, diuretics, foscarnet, ganciclovir,
itraconazole, fluconazole, ketoconazole (topical allowed), isoniazid, rifampin,
rifabutin, clarithromycin, azithromycin, systemic chemotherapeutic agents, systemic
corticosteroids, other agents with significant nephrotoxic potential, other agents
with significant nephrotoxic potential, other agents that may inhibit or compete for
elimination via active renal tubular secretion (e.g., probenecid), and other
investigational agents.
Overall Status: Unknown status
Phase: Phase 1

NCTID: NCT00002385
Intervention Type: Drug
Intervention Name: Fozivudine tidoxil
Title: The Safety and Effectiveness of Fozivudine Tidoxil in HIV-1 Infected Patients
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Concurrent Medication:

Allowed:

Primary and secondary prophylaxis for opportunistic infection if stable and initiated at
least 3 months prior to study drug administration.

Patients must have:

- HIV-positive status.

- One HIV RNA count > 10,000 copies/ml within 30 days prior to entry, with a second count at least 3-fold above or below the first value.

Exclusion Criteria

Co-existing Condition:

Patients with the following conditions or symptoms are excluded:

- Active medical problems including chronic diarrhea and active opportunistic infections such as cryptococcosis, Pneumocystis carinii, histoplasmosis, etc..

- Malignancy for which systemic therapy or radiation therapy is expected to be required during the study.

- Any other disease or condition that would place a patient at undue risk or confound the results of the study.

Concurrent Medication:

Excluded:

Systemic therapy for malignancy.

Prior Medication:

Excluded:

- Zidovudine or any other nucleoside reverse transcriptase inhibitor.

- Immunomodulators within one month prior to study drug administration.

- Investigational drugs within 30 days prior to study drug administration.

- Systemic cytotoxic chemotherapy within 3 months prior to study drug administration.

Prior Treatment:

Excluded:

- Extended-field radiation therapy within 3 months prior to study drug administration.

- Blood transfusion within 2 weeks prior to study drug administration.

Overall Status: Completed
Phase: nan

NCTID: NCT00002403
Intervention Type: Drug
Intervention Name: Zintevir
Title: Safety and Effectiveness of Zintevir (AR177) Given to HIV-Infected Patients
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

You may be eligible for this study if you:

- Are HIV-positive, but do not have any symptoms of HIV infection.
- Have a CD4 count greater than 200 cells/mm3.
- Have a viral load (level of HIV in the body) greater than 4,000 copies/ml.
- Are at least 18 years old.

Exclusion Criteria

You will not be eligible for this study if you:

- Tend to have abnormal bleeding or other blood problems.
- Have an active AIDS-defining illness.
- Have a history of serious disease or illness.
- Abuse alcohol or drugs.
- Have received certain medications.

Overall Status: Completed
Phase: Phase 1

NCTID: NCT00002415
Intervention Type: Drug
Intervention Name: Tenofovir disoproxil fumarate
Title: Safety and Effectiveness of Adding PMPA Prodrug to an Anti-HIV Drug Combination to Treat HIV-Infected Patients
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

You may be eligible for this study if you:

- Are HIV-positive.
- Have an HIV count of 400 - 50,000 copies/ml.
- Are expected to live for at least 1 year.
- Have been taking the same anti-HIV drug combination (made up of no more than 3 anti-HIV drugs) for at least 8 weeks prior to study entry.
- Are at least 18 years old.
- Agree to use effective methods of birth control during the study.

Exclusion Criteria

You will not be eligible for this study if you:

- Have taken medications for certain infections within 15 days prior to study entry.
- Have a history of cancer, except Kaposi's sarcoma (KS) or skin cancer.
- Develop a new AIDS-related condition within 30 days of study entry.
- Have certain serious medical conditions, including severe nausea,

vomiting, or other
stomach problems that make you unable to take medications by mouth.

- Have received a vaccine within 30 days prior to study entry.

- Have taken certain medications, including those that may affect your kidneys.

- Abuse alcohol or drugs.

- Are pregnant.

Overall Status: Completed
Phase: Phase 2

NCTID: NCT00002425
Intervention Type: Drug
Intervention Name: Saquinavir
Title: The Safety and Effectiveness of Saquinavir Soft Gelatin Capsules Combined With Other Anti-HIV Drugs
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Concurrent Medication:

Allowed:

Antiretroviral treatments other than PIs.

Patients must have:

- HIV infection.

- No prior experience with PIs. (Note:

- At least 75 percent of patients must be naive to PIs.)

Exclusion Criteria

Concurrent Medication:

Excluded:

PIs other than SQV.

Prior Medication:

Excluded:

Any PIs (see note in General Criteria--Inclusion).

Overall Status: Completed
Phase: Phase 4

NCTID: NCT00002426
Intervention Type: Drug
Intervention Name: Adefovir dipivoxil
Title: A Study on the Safety and Effectiveness of Adefovir Dipivoxil in Combination With Anti-HIV Therapy (HAART) in HIV-Positive Patients
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

You may be eligible for this study if you:

- Are HIV-positive.

- Have been on a stable HAART regimen consisting of at least 3 antiretroviral drugs for at least 16 weeks prior to study entry.

- Have a CD4 count of 50 cells/mm3 or more.

- Have a viral load greater than 50 and less than or equal to 400 copies/ml within 14 days prior to study entry.

- Have had at least 1 additional viral load in the past that was less than or equal to 400 copies/ml while on your current stable HAART regimen.

Overall Status: Completed
Phase: nan

NCTID: NCT00002422
Intervention Type: Drug
Intervention Name: HE2000
Title: A Study on the Safety and Anti-HIV Activity of HE2000 in HIV-Infected Patients on Salvage Therapy
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Patients may be eligible for this study if they:

- Are at least 18 years old.

- Are HIV-positive.

- Have been on their current anti-HIV drug combination for at least 30 days prior to the screening visit.

- Are currently failing at least their second anti-HIV drug treatment.

- Are not responding to their current anti-HIV treatment, have failed at least 1 anti-HIV combination, and do not have many options for treatment (Groups 3 and 4 only).

- Are willing to not make any changes in their anti-HIV treatment until at least Day 50 during the study.

- Have a CD4 count of at least 100 cells/mm3 at study entry.

- Have a viral load (level of HIV in the body) between 5,000 and 250,000 copies/ml at study entry.

- Agree to use barrier methods of birth control (e.g., condoms) during the study.

Exclusion Criteria

Patients will not be eligible for this study if they:

- Have hepatitis B or C.

- Have been treated for cancer within 4 weeks prior to study entry, or will need to be

treated during the study. (Patients with Kaposi's sarcoma are eligible but must not have received any treatment within 4 weeks before study entry or require treatment during the study.)

- Have received certain medications including those affecting the immune system.

- Are pregnant or breast-feeding.

- Have an active, serious infection, including opportunistic (AIDS-defining) infection that requires treatment during the study or during the 2 weeks prior to study entry.

- Have a condition or are receiving therapy that would prevent them from completing the study.

Overall Status: Completed
Phase: Phase 1

NCTID: NCT00002417
Intervention Type: Drug
Intervention Name: Amprenavir
Title: A Study of Amprenavir in Patients With Protease Inhibitor-Related Complications
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Patients must have:

- Documented HIV-1 infection.

- Two consecutive (at least 4 weeks apart) screening HIV-1 plasma RNA levels less than or equal to 10,000 copies/ml prior to open-label drug administration.

- Hyperlipidemia with or without lipodystrophy (Grade 1-4 toxicity for triglycerides or total cholesterol), be intolerant to standard protease inhibitor therapy and, in the judgment of the physician, be unable to construct a viable treatment regimen without APV.

Exclusion Criteria

Co-existing Condition:

Patients with the following symptoms and conditions are excluded:

- Renal failure requiring dialysis.

- Hepatic failure.

- Serious medical conditions such as diabetes, congestive heart failure, cardiomyopathy, or other cardiac dysfunction which, in the opinion of the investigator, would compromise the safety of the patient.

- Malabsorption syndrome or other gastrointestinal dysfunction, which

might interfere
with drug absorption or render the patient unable to take oral medication.

Concurrent Treatment:

Excluded:

Concomitant use of another protease inhibitor.

Patients with the following prior condition are excluded:

Clinically relevant history of pancreatitis or hepatitis within the last 6 months.

Prior Treatment:

Excluded:

Previous treatment with APV.

Risk Behavior:

Excluded:

Patients currently using alcohol or illicit drugs which, in the investigator's opinion, may
interfere with the patient's ability to comply with the requirements of the study.

Included:

Prior treatment with at least one protease inhibitor.
Overall Status: Completed
Phase: nan

NCTID: NCT00002414
Intervention Type: Drug
Intervention Name: CPI-1189
Title: Safety and Effectiveness of Giving CPI-1189 to HIV-Infected Patients With AIDS Dementia
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

You may be eligible for this study if you:

- Are HIV-positive.

- Are at least 18 years old.

- Have symptoms of AIDS dementia including forgetfulness, loss of concentration, slow
mental processing, or a loss of muscle control.

- Have been on stable anti-HIV drug therapy for the past 6 weeks (if you are taking
anti-HIV drugs).

Exclusion Criteria

You will not be eligible for this study if you:

- Have certain serious medical conditions, such as a mental disorder or an opportunistic

(AIDS-related) infection.
Overall Status: Unknown status
Phase: Phase 2

NCTID: NCT00002433
Intervention Type: Drug
Intervention Name: Interferon gamma-1b
Title: The Effects of r-metHuIFN-Gamma on the Lungs of Patients With AIDS
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Patients must have:

- Diagnosis of AIDS with one or more opportunistic infections.
- Kaposi's sarcoma with prior history of opportunistic infection.
- Stable dose of zidovudine (AZT) therapy.
- Preserved pulmonary, renal and hepatic function.

Exclusion Criteria

Co-existing Condition:

Patients with the following conditions or symptoms are excluded:

- Presence of active infection.
- Active opportunistic infections.
- Cardiac disease.
- Central nervous system disorders.
- History of seizures.
- Irreversible airway disease.

Patients with the following are excluded:

- Co-existing conditions and symptoms listed in Patient Exclusion Co-existing Conditions.

Prior Medication:

Excluded within 4 weeks of study entry:

- Immunosuppressive therapy.
- Cytotoxic therapy.
- Excluded:
- Interferon gamma therapy.

Overall Status: Completed
Phase: nan

NCTID: NCT00002413
Intervention Type: Drug
Intervention Name: Emivirine
Title: A Study of MKC-442 in HIV-Positive Patients
Condition: HIV Infections

Eligibility Criteria: Inclusion Criteria

Concurrent Medication:

Allowed:

Based on medical history, medical condition, prior use of antiretroviral drugs, and genotypic analysis of the predominant strain of HIV-1 isolated from plasma, administration of at least 2 available antiviral agents by prescription may be given with MKC-422.

Patients must have:

- HIV infection with HIV-1 RNA greater than or equal to 2,000 by Roche Amplicor method, within 30 days of entry.

Prior Medication:

Allowed:

- Prior nucleoside reverse transcriptase and protease inhibitors.

- Cytotoxic chemotherapy more than 30 days prior to entry.

Exclusion Criteria

Co-existing Condition:

Patients with the following symptoms or conditions are excluded:

- Malabsorption or severe chronic diarrhea within 30 days prior to entry, or inability to consume adequate oral intake because of chronic nausea, emesis, or abdominal or esophageal discomfort.

- Inadequately controlled seizure disorder.

- Acute and clinically significant medical event within 30 days of screening.

- Any clinical or laboratory abnormality greater than Grade 3 toxicity, with the exception of the listed laboratory values.

Prior Medication:

Excluded:

- Non-nucleoside reverse transcriptase inhibitor therapy.

- Any unapproved experimental antiretroviral therapy.

Prior Treatment:

Excluded:

- Radiation therapy within 30 days of entry, except to a local lesion.

- Transfusion of blood or blood products within 21 days of screening.

Risk Behavior:

Excluded:

Active substance abuse that may interfere with compliance or protocol evaluations.
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00002444
Intervention Type: Drug
Intervention Name: Nitazoxanide
Title: A Study of Nitazoxanide in the Treatment of AIDS-Related Diarrhea
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Patients must have:

- AIDS diagnosis according to CDC criteria.

- CD4 count less than or equal to 200 cells/mm3 or CD4 count greater than or equal to 200 cells/mm3 and documented cryptosporidiosis for a minimum of 4 weeks.

- Cryptosporidial diarrhea as defined by:

- (1) presence of Cryptosporidium oocytes in a stool specimen within 14 days of enrollment; and (2) chronic diarrhea (i.e., an average of at least 4 bowel movements per day for a minimum of 2 weeks).

- Life expectancy of at least 1 month.

- Ability to tolerate food by mouth.

Prior Medication:

Required:

- Any anti-diarrheal or anti-emetic medication for which the dosage regimen has been stable for at least 1 week prior to enrollment.

- Any antiretroviral medications (e.g., zidovudine, ddI, ddC) for which the dosage regimen has been stable for at least 3 weeks prior to enrollment.

Allowed:

Medication for prophylaxis or maintenance therapy of opportunistic infection, stable for at least 2 weeks prior to enrollment.

Exclusion Criteria

Co-existing Condition:

Patients with the following symptoms or conditions are excluded:

Grade 4 (hematologic) or Grade 3 (for all others) toxicity. (Patients with Grade 3 toxicity

for hepatic parameters may be enrolled if, in the investigator's judgment, the abnormalities are due to biliary cryptosporidiosis.)

Patients with the following prior conditions are excluded:

- Presence of Salmonella, Shigella, Campylobacter, Yersinia, Giardia lamblia, Entamoeba histolytica, Microsporidia, Isospora, Cyclospora, or Clostridium difficile toxin in stool (based on assessment within 14 days prior to enrollment by stool ova and parasite examination, culture, and C. difficile assay).

- History of intestinal Mycobacterium avium intracellular infection or intestinal Kaposi's sarcoma.

- History of Cytomegalovirus colitis, unless 28 days of therapy with ganciclovir or foscarnet completed subsequent to diagnosis.

Prior Medication:

Excluded:

- Investigational drug therapy within 14 days of enrollment, unless available under an FDA-authorized expanded access program.

- Any drug or therapy with possible anticryptosporidial activity (e.g., paromomycin, spiramycin, azithromycin, clarithromycin, hyperimmune bovine colostrum) within 14 days of enrollment.

Overall Status: Completed
Phase: Phase 1

NCTID: NCT00002450
Intervention Type: Drug
Intervention Name: Tenofovir disoproxil fumarate
Title: Safety and Effectiveness of Tenofovir Disoproxil Fumarate (Tenofovir DF) Plus Other Anti-HIV Drugs in HIV-Infected Patients
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Patients may be eligible for this study if they:

- Are HIV-positive.

- Have been on stable anti-HIV therapy for at least 8 weeks with no more than 4 anti-HIV drugs at the time of study entry.

- Have a viral load (level of HIV in the blood) between 400 and 10,000 copies/ml.

- Have good kidney function.

- Are 18 to 65 years old.

- Agree to use a barrier method of birth control (such as condoms) during the study and for 30 days after.

Exclusion Criteria

Patients will not be eligible for this study if they:

- Have a new AIDS-related illness diagnosed within 30 days of study entry.

- Have any other serious medical conditions, including kidney or bone disease, an active infection requiring antibiotics, or cancer (other than Kaposi's sarcoma or certain skin cancers).

- Have received a vaccine within 30 days of study entry.

- Are unable to take medications by mouth.

- Have ever taken tenofovir or adefovir dipivoxil.

- Have taken certain medications within 30 days of study entry, such as chemotherapy, corticosteroids, medications that affect the kidneys, treatment for Kaposi's sarcoma, or certain experimental drugs.

- Abuse alcohol or drugs.

- Are pregnant or breast-feeding.

Overall Status: Completed
Phase: Phase 3

NCTID: NCT00002449
Intervention Type: Drug
Intervention Name: Aldesleukin
Title: Safety and Effectiveness of L2-7001 (Interleukin-2) in HIV-Positive Patients Receiving Anti-HIV Therapy
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Patients may be eligible for this study if they:

- Are HIV-positive.

- Have a viral load below 10,000 copies/ml.

- Have a CD4 count between 300 and 500 cells/mm3.

- Have been on stable anti-HIV therapy for 4 months. Patients must be taking at least 2 drugs, 1 of which must be a protease inhibitor or a nonnucleoside drug (NNRTI).

- Are at least 18 years old.

- Agree to use an effective barrier method of birth control, such as condoms, during the study.

Exclusion Criteria

Patients will not be eligible for this study if they:

- Have an AIDS-defining illness. (Patients who have had an AIDS-

defining illness that
was cured may still be eligible.)

- Have an alcohol or drug abuse problem that the doctors feel would affect their ability
to participate.

- Have cancer requiring chemotherapy.

- Have a history of autoimmune disease.

- Have uncontrolled diabetes or certain thyroid problems.

- Have mental illness or other serious medical condition that the doctors feel would
affect their ability to participate.

- Have received IL-2 in the past.

- Have taken corticosteroids or certain medications that affect the immune system in the
past 4 weeks.

- Have taken hydroxyurea in the past 4 months.

- Are pregnant or breast-feeding.

Overall Status: Unknown status
Phase: Phase 1

NCTID: NCT00002453
Intervention Type: Drug
Intervention Name: Tenofovir disoproxil fumarate
Title: A Compassionate Use Study of Tenofovir Disoproxil Fumarate as Treatment for HIV Infection
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

You may be eligible for this study if you:

- Are HIV-positive.

- Have a viral load greater than or equal to 10,000 copies/ml.

- Have a CD4 count less than or equal to 50 cells/mm3, or have a CD4 count greater than
50 and no more than 200 cells/mm3 with an opportunistic (AIDS-related) infection
within 90 days of study entry. (Patients with a CD4 count above 200 cells/mm3 may be
considered depending on drug supply.)

- Are at least 18 years old.

- Agree to use barrier methods of birth control (such as condoms) while on the study and
for 30 days afterward.

- Have a life expectancy of at least one year.

Exclusion Criteria

You will not be eligible for this study if you:

- Have a history of a serious kidney or bone disease.

- Have severe nausea, vomiting, or trouble taking medications by mouth.

- Are pregnant or breast-feeding.

- Abuse alcohol or other substances that your doctor thinks would interfere with taking this medicine.

- Are taking any medicines that interfere with kidney functions.

Overall Status: Completed
Phase: nan

NCTID: NCT00002585
Intervention Type: Drug
Intervention Name: pyrazoloacridine
Title: Pyrazoloacridine in Treating Women With Metastatic Breast Cancer
Condition: Breast Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS: Histologically documented breast adenocarcinoma Clinical or radiologic evidence of metastatic disease required Histologic confirmation recommended if evidence is equivocal Bidimensionally measurable disease required, i.e.: Lesion with clearly defined margins on physical exam or radiologic evaluation with 1 diameter greater than 0.5 cm Lytic bone metastases only if measurable on bone x-ray/survey Lesion previously irradiated only if subsequent measurable progression New measurable lesion in previously irradiated field The following are not considered measurable: Unidimensionally measurable lesions Palpable nodal disease not measurable on CT Masses with margins not clearly defined Lesions with both diameters less than 0.5 cm Bone disease other than lytic bone disease Pleural effusions or ascites Disease identified by bone scan only History of bilateral breast cancer allowed No brain metastases CT required if clinically indicated No meningeal carcinomatosis Hormone receptor status: Any status

PATIENT CHARACTERISTICS: Age: Over 18 Sex: Women only Menopausal status: Not specified Performance status: Zubrod 0-2 Life expectancy: At least 12 weeks Hematopoietic: Absolute granulocyte count at least 2,000/mm3 Platelet count at least 100,000/mm3 Hepatic: Bilirubin less than 2.0 mg/dL Renal: Creatinine less than 1.5 mg/dL Other: No second malignancy within 5 years except: Adequately treated nonmelanomatous skin cancer Adequately treated carcinoma in situ of the cervix Not pregnant or nursing Negative pregnancy test required of premenopausal women Appropriate contraception required of fertile women Blood/body fluid analyses to determine eligibility and physical exams for tumor measurement completed within 7 days prior to registration; imaging studies to evaluate and document measurable disease completed within 4 weeks prior to registration

PRIOR CONCURRENT THERAPY: Biologic therapy: Not specified Chemotherapy:

No more than 1
prior chemotherapy for metastatic disease allowed At least 4 weeks since adjuvant
chemotherapy Endocrine therapy: Prior hormonal therapy allowed At least 4 weeks since
hormonal therapy for patients with partial or complete response to most recent maneuver
Radiotherapy: Prior radiotherapy for metastatic disease allowed At least 4 weeks since
radiotherapy and recovered Surgery: Not specified
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00002632
Intervention Type: Drug
Intervention Name: paclitaxel
Title: Paclitaxel in Treating Patients With Metastatic or Recurrent Salivary Gland Cancer
Condition: Head and Neck Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS: Histologically confirmed salivary gland carcinoma that is
metastatic or recurrent, including the following types: Mucoepidermoid carcinoma
Adenocarcinoma Pathology review required Measurable disease required Lesion in a previously
irradiated field must be progressing and biopsy- proven

PATIENT CHARACTERISTICS: Age: 18 and over Performance status: ECOG 0-2 Hematopoietic: WBC
at least 3,000/mm3 ANC at least 1,500/mm3 Platelet count at least 100,000/mm3 Hb at least
10 g/dL Hepatic: Bilirubin no greater than 1.5 mg/dL Renal: Creatinine no greater than 2.0
mg/dL Cardiovascular: No MI within the past 6 months No CHF No unstable arrhythmia No
current antiarrhythmic, inotropic, or antianginal medication Other: No history of allergy
to Cremophor No prior malignancy within 5 years except: Curatively treated nonmelanomatous
skin cancer Curatively treated in-situ cancer of the cervix No concurrent malignancy Not
pregnant or nursing Effective contraception strongly advised for fertile patients
Blood/body fluid analyses to determine eligibility and imaging studies and scans/x-rays for
tumor measurement completed within 14 days prior to registration

PRIOR CONCURRENT THERAPY: Biologic therapy: Prior biological response modifier therapy
allowed Chemotherapy: No prior chemotherapy Endocrine therapy: Not specified Radiotherapy:
Prior radiotherapy allowed with recovery Surgery: Prior surgery allowed with recovery
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00002656
Intervention Type: Drug
Intervention Name: pyrazoloacridine
Title: Pyrazoloacridine in Treating Patients With Advanced Non-small Cell Lung Cancer
Condition: Lung Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS: Histologically confirmed non small cell lung cancer ineligible for

higher priority protocols Sputum cytology acceptable Stage IIIB/IV Must have measurable or evaluable disease Lesion outside prior radiotherapy fields Cytology-positive pleural effusion and ascites are neither measurable nor evaluable No brain metastases on CT

PATIENT CHARACTERISTICS: Age: Over 18 Performance status: Zubrod 0-2 Life expectancy: At least 12 weeks Hematopoietic: Absolute granulocyte count greater than 2,000/mm3 Platelet count greater than 100,000/mm3 Hepatic: Bilirubin less than 2.0 mg/dL Renal: Creatinine less than 1.5 mg/dL Other: No pregnant or nursing women Negative pregnancy test required of fertile women Effective contraception required of fertile patients Blood/body fluid analyses within 7 days prior to registration Imaging/exams for tumor measurement within 28 days prior to registration

PRIOR CONCURRENT THERAPY: Biologic therapy: Not specified Chemotherapy: One prior adjuvant or neoadjuvant chemotherapy allowed Endocrine therapy: Not specified Radiotherapy: At least 4 weeks since radiotherapy and recovered AND Progressive disease outside of radiation port Surgery: Recovered from any prior surgery
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00002671
Intervention Type: Drug
Intervention Name: aminocamptothecin
Title: Aminocamptothecin in Treating Patients With Recurrent or Unresectable Epithelial Ovarian Cancer
Condition: Ovarian Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS: Histologically proven advanced, recurrent, or inoperable ovarian epithelial cancer Previously treated with 1 platinum-containing chemotherapy regimen Bidimensionally measurable or reproducibly measurable disease in 2 dimensions on CT scan (The measurable disease stratum closed to accrual effective 08/1998) OR Evaluable but radiographically nonmeasurable disease with CA-125 more than 50 units/mL on 2 measurements at least 1 week apart

PATIENT CHARACTERISTICS: Age: 18 and over Performance status: ECOG 0-1 Life expectancy: At least 3 months Hematopoietic: Absolute neutrophil count at least 1,500/mm3 Platelet count at least 100,000/mm3 Hepatic: Bilirubin no greater than 1.5 mg/dL SGOT and SGPT no greater than 3 times upper limit of normal Renal: Creatinine no greater than 1.5 mg/dL OR Creatinine clearance at least 60 mL/min Cardiovascular: No myocardial infarction, congestive heart failure, or other significant cardiac disease within the past 6 months No uncontrolled hypertension Other: No significant active infection (e.g., pneumonia, peritonitis, or wound abscess) No uncontrolled metabolic disease (e.g.,

diabetes mellitus
or hypothyroidism) No asthma (even if controlled with medication) No other serious
concurrent illness No dementia or altered mental status that would preclude informed
consent No other malignancy except curatively treated nonmelanomatous skin cancer or
carcinoma in situ of the cervix Not pregnant Negative pregnancy test Fertile patients must
use effective contraception

PRIOR CONCURRENT THERAPY: Biologic therapy: No concurrent immunotherapy Chemotherapy: See
Disease Characteristics No more than 1 prior chemotherapy regimen No other concurrent
chemotherapy Endocrine therapy: Not specified Radiotherapy: No concurrent radiotherapy
Surgery: See Disease Characteristics Other: At least 4 weeks since prior investigational
agents
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00002659
Intervention Type: Drug
Intervention Name: cisplatin-e therapeutic implant
Title: Cisplatin Plus Epinephrine in Treating Patients With Recurrent or Refractory Head and Neck Cancer
Condition: Head and Neck Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS: Histologically confirmed squamous cell carcinoma of the head and
neck that is recurrent or refractory following at least 1 course of therapy Primary or
metastatic tumors involving skin, nodes (palpable and biopsy- proven), subcutaneous tissue,
or muscle allowed No involvement of major artery or any visceral organ Measurable lesions
accessible for direct intratumoral injection with no immediate risk of hemorrhage or
embolization Most troublesome tumor (identified by the investigator) at least 0.5 cc and no
greater than 20 cc Smaller tumors eligible for treatment but not for efficacy assessment An
improvable primary treatment goal (palliative or preventive) for most troublesome tumor
must be identified by the investigator prior to enrollment If multiple tumors qualify as
most troublesome and share the primary physician-selected treatment goal, the largest tumor
is selected Patient may also select a most troublesome tumor and 1 palliative treatment
goal for that tumor (need not match the physician-selected tumor or goal) No fibrotic
lesions (e.g., previously irradiated lesion with no subsequent disease progression) No
tumors involving or threatening to invade the carotid or other major vessel

PATIENT CHARACTERISTICS: Age: 18 and over Performance status: Karnofsky 60%-100% Life
expectancy: At least 6 months Hematopoietic: Absolute granulocyte count greater than
1,000/mm3 Platelet count greater than 75,000/mm3 Hepatic: Not specified Renal: Creatinine

no greater than 1.5 times normal Cardiovascular: No NYHA class III/IV status No history of
arrhythmia that would increase risk of treatment Other: No hypersensitivity to cisplatin,
bovine collagen, epinephrine, or sulfites No significant history of extracranial carotid
vascular disease from atherosclerosis, radiation therapy or previous carotid artery surgery
No uncontrolled local infection at treatment sites No medical or psychiatric condition that
would preclude informed consent No pregnant or nursing women Adequate contraception
required of fertile patients

PRIOR CONCURRENT THERAPY: More than 28 days since any antineoplastic therapy or therapy
with investigational agents Fully recovered from side effects of prior treatment
Overall Status: Unknown status
Phase: Phase 3

NCTID: NCT00002705
Intervention Type: Drug
Intervention Name: topotecan hydrochloride
Title: Topotecan in Treating Children With Refractory Leukemia
Condition: Leukemia
Eligibility Criteria: DISEASE CHARACTERISTICS:

-Histologically or cytologically confirmed leukemia refractory to conventional therapy or
for which no effective curative therapy exists

PATIENT CHARACTERISTICS:

- Age: Under 21
- Performance status: ECOG 0-2
- Life expectancy: At least 8 weeks
- Adequate platelet count and hemoglobin required (transfusion allowed)
- Bilirubin no greater than 1.5 mg/dL
- AST or ALT no greater than 2 times normal
- Creatinine less than 1.5 mg/dL
- Adequate nutritional status, e.g. higher than third percentile weight for height
- Albumin at least 3 g/dL
- No severe uncontrolled infection
- No pregnant women
- Effective contraception required of fertile women

PRIOR CONCURRENT THERAPY:

- At least 3 weeks since systemic chemotherapy (6 weeks since nitrosoureas)

- Recovered at least 3 months since bone marrow transplant (at least 6 months since total-body irradiation)

- No concurrent anticancer therapy

- No concurrent treatment studies

Overall Status: Completed
Phase: Phase 1

NCTID: NCT00002811
Intervention Type: Drug
Intervention Name: liposomal T4N5 lotion
Title: T4N5 Liposome Lotion Compared With Placebo Lotion for Preventing Actinic Keratoses in Patients With Xeroderma Pigmentosum
Condition: Precancerous Condition
Eligibility Criteria: DISEASE CHARACTERISTICS: Diagnosis of xeroderma pigmentosum confirmed by unscheduled DNA synthesis assay At least one histologically confirmed actinic keratosis All actinic keratoses removed prior to treatment No associated syndromes, e.g., Cockayne's syndrome or trichothiodystrophy

PATIENT CHARACTERISTICS: Age: 1.66 to 60 Other: Good general health and mental capacity No illegal drug use No pregnant or nursing women Negative pregnancy test required of fertile women Effective contraception required of fertile women

PRIOR CONCURRENT THERAPY: See Disease Characteristics
Overall Status: Unknown status
Phase: Phase 3

NCTID: NCT00002933
Intervention Type: Drug
Intervention Name: irinotecan hydrochloride
Title: Irinotecan in Treating Patients With Metastatic or Recurrent Colorectal Cancer
Condition: Colorectal Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS: Histologically confirmed metastatic or recurrent adenocarcinoma of the colon or rectum that is incurable by surgery or radiation therapy A metastatic lesion in the liver or lung should be evaluated for definitive surgical treatment before being considered for this study Measurable disease required Elevated CEA, hepatomegaly ascites, pleural effusion, positive nuclear scan or bone scan, or poorly defined pelvic or abdominal mass are NOT considered measurable disease Must have measurable disease outside the radiation port or progression of disease within a previously radiated area Must be eligible for a biopsy of a malignant lesion No ascites that are detectable on physical exam No brain metastasis

PATIENT CHARACTERISTICS: Age: 18 and over Performance status: ECOG 0-2 Life expectancy: Greater than 12 weeks Hematopoietic: WBC at least 4,000/mm3 Granulocyte count at least 1,500/mm3 Platelet count at least 100,000/mm3 Hepatic: Bilirubin no

greater than 1.2 mg/dL
SGOT less than 4 times upper limit of normal Renal: Creatinine no greater than 1.5 mg/dL or
Creatinine clearance at least 60 mL/min Other: No history of any other malignancy except
curatively treated nonmelanoma skin cancer and carcinoma in situ of the cervix No active
infection or other serious medical conditions deemed unacceptable Negative pregnancy test
Effective contraception required of all fertile patients

PRIOR CONCURRENT THERAPY: Biologic therapy: Not specified Chemotherapy: No prior
chemotherapy for advanced disease Endocrine therapy: Not specified Radiotherapy: See
Disease Characteristics At least 3 weeks since prior radiotherapy Surgery: At least 3 weeks
since any surgical procedure
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00002922
Intervention Type: Drug
Intervention Name: paclitaxel
Title: Paclitaxel in Treating Patients With Advanced Head and Neck Cancer
Condition: Head and Neck Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS: Histologically proven squamous cell carcinoma of the head and neck
(including nasopharynx) that is considered incurable with surgery or radiation therapy
Bidimensionally measurable disease Patients whose only site of measurable disease is within
a previous radiation port must have documented progressive disease or biopsy-proven
recurrence after the completion of radiotherapy No uncontrolled CNS metastases

PATIENT CHARACTERISTICS: Age: 18 and over Performance status: ECOG 0 or 1 Hematopoietic:
Absolute neutrophil count at least 1,500/mm3 Platelet count at least 100,000/mm3 Hepatic:
Bilirubin no greater than 1.5 mg/dL Renal: Creatinine no greater than 1.5 mg/dL OR
Creatinine clearance at least 60 mL/min Calcium normal No history of hypercalcemia
Cardiovascular: No history of ventricular arrhythmias or symptomatic bradyarrhythmia Other:
No significant detectable infection Not pregnant or nursing No other active malignancies
Fertile patients must use effective contraception

PRIOR CONCURRENT THERAPY: Biologic therapy: Prior interleukin-2, interferons, and
monoclonal antibodies allowed Recovered from prior therapy Chemotherapy: Prior paclitaxel
infusion no greater than 24 hours for recurrent or metastatic disease required Endocrine
therapy: Not specified Radiotherapy: Recovered from prior radiotherapy Surgery: Recovered
from any prior major surgery
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00002928

Intervention Type: Drug
Intervention Name: paclitaxel
Title: Paclitaxel in Treating Patients With Recurrent or Progressive Advanced Ovarian Cancer
Condition: Ovarian Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS: Histologically confirmed recurrent or progressive epithelial
ovarian cancer defined as: A serial rise in CA 125 over a minimum of 3 samples to a level
greater than 50% of the upper limit of normal OR Measurable or evaluable disease Disease
progression following paclitaxel given by 3 or 24 hour infusion within the past 6 months

PATIENT CHARACTERISTICS: Age: 18 and over Performance status: Karnofsky at least 60% Life
expectancy: Not specified Hematopoietic: AGC at least 1500/uL Platelet count at least
100,000/uL Hepatic: Bilirubin no greater than 1.5 mg/dL Renal: Creatinine no greater than
2.0 mg/dL Other: No active or uncontrolled infections No history of grade 3-4 peripheral
neuropathy of any etiology No previously developed severe hypersensitivity reactions to
paclitaxel Not pregnant or lactating Patients of childbearing potential must use effective
method of contraception

PRIOR CONCURRENT THERAPY: Biologic therapy: Not specified Chemotherapy: Prior platinum
based chemotherapy required Complete recovery from the myelosuppressive effects of prior
chemotherapy for a minimum of 3 weeks At least one prior regimen of paclitaxel by 3 or 24
hour infusion within 6 months prior to study, with no intervening chemotherapy Endocrine
therapy: No hormone therapy within 3 weeks of entry onto protocol Radiotherapy: No prior
radiation therapy to major bone marrow ares within 4 weeks of entry onto protocol Surgery:
Not specified
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00002917
Intervention Type: Drug
Intervention Name: paclitaxel
Title: Paclitaxel in Treating Patients With Early-Stage Bladder Cancer
Condition: Bladder Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS: Histologically proven CIS and/or unresectable/residual superficial
bladder tumor (pTa G1-G3 to pT1 G1-G3) -confirmed by biopsy, bladder mapping, or positive
cytology Cystoscopic examination and bladder mapping must be performed within 6 weeks of
study

PATIENT CHARACTERISTICS: Age: 18 and over Performance Status: Karnofsky of 60 to 100% Life
Expectancy: Not specified Hematopoietic: Hemoglobin greater than 11 g/dL WBC greater than
4500/mm3 Neutrophils greater than 1500/mm3 Platelet count greater than 100,000/mm3 Hepatic:
Bilirubin, AST, and ALT no greater than 2.5 x normal Renal: Creatinine

no greater than 2.5
x normal Cardiovascular: No concurrent cardiovascular disease Other: No active infection
requiring concurrent therapy Not pregnant or nursing No upper renal tract disease No
concurrent malignancy except for basal or squamous cell skin cancer or noninvasive cancer
of the cervix

PRIOR CONCURRENT THERAPY: Biologic therapy: No intravesical BCG within 3 months prior to
study entry Prior BCG therapy is required for CIS patients (if not contraindicated)
Chemotherapy: No prior intravesical chemotherapy within 4 weeks prior to study No prior
systemic anticancer therapy within 4 months prior to study No prior paclitaxel therapy
Endocrine therapy: Not specified Radiotherapy: No prior radiotherapy within 4 months prior
to study Surgery: Not specified Other: No hypersensitivity reactions to products containing
cremophor
Overall Status: Completed
Phase: Phase 1/Phase 2

NCTID: NCT00002935
Intervention Type: Drug
Intervention Name: porfimer sodium
Title: Photodynamic Therapy in Treating Patients With Early Esophageal Cancer
Condition: Esophageal Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS: Histologically confirmed primary, stage 0 carcinoma in situ (CIS)
in conjunction with Barrett's esophagus or severe dysplasia in Barrett's esophagus who are
medically unsuitable for or have refused surgery Previously biopsied Barrett's mucosa with
areas of severe dysplasia and/or CIS

PATIENT CHARACTERISTICS: Age: 18 and over Performance status: Karnofsky greater than 50%
Life expectancy: Not specified Hematopoietic: WBC at least 2,000/mm3 Platelet count at
least 50,000/mm3 Hepatic: No porphyria or hypersensitivity to porphyrins Bilirubin no
greater than 3.0 mg/dL Alkaline phosphatase no greater than 3 times ULN SGOT no greater
than 3 times ULN PT no greater than 1.5 times the upper limit of normal (ULN) Renal:
Creatinine no greater than 3.0 mg/dL Other: No contraindication to endoscopy Not pregnant
or nursing Fertile patients must use effective contraception

PRIOR CONCURRENT THERAPY: Biologic therapy: Not specified Chemotherapy: No concurrent
chemotherapy At least 1 month since prior chemotherapy Endocrine therapy: Not specified
Radiotherapy: No concurrent radiation therapy No concurrent laser therapy At least 1 month
since prior radiation therapy At least 1 month since prior laser therapy Surgery: Not
specified
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00002911
Intervention Type: Drug
Intervention Name: marimastat
Title: Marimastat in Treating Patients With Stage III Non-small Cell Lung Cancer
Condition: Lung Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS: Histologically or cytologically confirmed non-small cell lung
cancer Stage IIIA/B disease No malignant pleural effusions Minimal residual disease after
one or a combination of the following: Incomplete surgical resection i.e., macroscopic
residual disease at completion of surgery Radical radiotherapy with no evidence of disease
progression at entry Documented complete or partial tumor response following at least 2
courses of cytotoxic chemotherapy No evidence of disease progression during or following
prior therapy

PATIENT CHARACTERISTICS: Age: 18 and over Performance status: ECOG 0-2 Hematopoietic:
Absolute neutrophil count greater than 500/mm3 Platelet count greater than 50,000/mm3
Hepatic: Bilirubin less than 2.0 times upper limit of normal (ULN) AST/ALT no greater than
3.0 times ULN Renal: Creatinine no greater than 1.5 times ULN Other: No acute illness
within 1 week of start of study No other illness that would significantly interfere with
study outcome No major medical illness that precludes prolonged marimastat administration
No second malignancy within 5 years except: Adequately treated basal cell carcinoma of the
skin In situ carcinoma of the cervix Not pregnant or nursing Medically approved method of
contraception required of fertile women Willing and able to tolerate and comply with study
requirements

PRIOR CONCURRENT THERAPY: Biologic therapy: Not specified Chemotherapy: See Disease
Characteristics No prior marimastat, batimastat, bleomycin, or busulphan No more than 1
cytotoxic chemotherapy regimen for non-small cell lung cancer Endocrine therapy: Not
specified Radiotherapy: See Disease Characteristics Surgery: See Disease Characteristics
Other: At least 4 weeks since any investigational drug therapies
Overall Status: Completed
Phase: Phase 3

NCTID: NCT00002976
Intervention Type: Drug
Intervention Name: conjugated estrogens
Title: Estrogen Replacement Therapy in Treating Women With Early-Stage Endometrial Cancer
Condition: Endometrial Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS:

- Histologically confirmed grade I, II or III endometrial adenocarcinoma (endometrioid,
villoglandular, mucinous, adenosquamous, papillary serous, clear cell, or not
otherwise specified)

- Must have had total hysterectomy and bilateral salpingo-oophorectomy within past 20 weeks
  - Surgical stage IA, IB, IC, IIA (occult), or IIB (occult) disease
- Must have had normal mammogram, or a negative breast biopsy after an abnormal mammogram, within past year

PATIENT CHARACTERISTICS:

Age:

- Not specified

Performance status:

- Not specified

Life expectancy:

- Not specified

Hematopoietic:

- Not specified

Hepatic:

- Bilirubin no greater than 1.5 times normal
- SGOT no greater than 3 times normal
- No acute liver disease

Renal:

- Not specified

Cardiovascular:

- No prior thromboembolic disease

Other:

- No prior or current carcinoma of the breast
- No other prior invasive malignancy within the past 5 years except nonmelanoma skin cancer

PRIOR CONCURRENT THERAPY:

Biologic therapy:

- Not specified

Chemotherapy:

- Not specified

Endocrine therapy:

- No concurrent hormonal therapy

Radiotherapy:

- Not specified

Surgery:

- See Disease Characteristics

- Recovered from prior surgery

Other:

- No prior cancer treatment that would preclude study therapy

- Concurrent participation on GOG Lap-1 or GOG Lap-2 allowed

Overall Status: Terminated
Phase: Phase 3

NCTID: NCT00002972
Intervention Type: Drug
Intervention Name: paclitaxel
Title: Paclitaxel in Treating Patients With Lung Cancer
Condition: Lung Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS:

- Histologically proven bronchoalveolar carcinoma (BAC) based on these criteria:

  - Absence of primary adenocarcinoma elsewhere

  - Absence of a demonstrable central bronchogenic origin

  - A peripheral location in the lung parenchyma

  - Intact interstitial framework of the lung

  - A histological appearance setting it apart from other tumors, with a characteristic pattern of growth: cuboidal or cylindrical cells lining up the alveolar septa with preservation of basic pulmonary architecture

- Must be unresectable Stage IIIB, IV, or recurrent BAC

- Evidence of multinodular lesions involving the lungs bilaterally or unilaterally (in the latter the lesions must involve more than one lobe)

- At least one target lesion bidimensionally measurable that has not undergone prior irradiation

- No CNS disease

PATIENT CHARACTERISTICS:

Age:

- 18 to 75 (inclusive)

Performance status:

- ECOG 0-2

Life expectancy:

- Greater than 3 months

Hematopoietic:

- ANC at least 1,500/mm^3

Hepatic:

- Bilirubin less than 2 times upper limit of normal
- SGOT, SGPT, and alkaline phosphatase less than 2 times upper limit of normal

Renal:

- Creatinine less than 1.5 times upper limit of normal

Cardiovascular:

- No history of ischemic or congestive heart disease
- No arrhythmia requiring chronic cardiopulmonary medications
- No history of clinically or electrographically documented myocardial infarction

Other:

- No preexisting motor or other serious sensory neurotoxicity
- No active or prior second primary cancer except basal cell carcinoma of the skin or carcinoma in situ of the cervix
- No clinical evidence of uncontrolled infection
- Not pregnant or nursing
- Negative pregnancy test 72 hours prior to start of study medication
- Adequate contraception required of all fertile patients

PRIOR CONCURRENT THERAPY:

Biologic therapy:

- Not specified

Chemotherapy:

- No prior chemotherapy

Endocrine therapy:

- Not specified

Radiotherapy:

- At least 4 weeks since radiotherapy

- Must have at least one bidimensional lesion outside the irradiated fields

Surgery:

- Fully recovered from any prior major surgery

Overall Status: Completed
Phase: Phase 2

NCTID: NCT00002969
Intervention Type: Drug
Intervention Name: paclitaxel
Title: S9714: Paclitaxel in Treating Patients With Stage IIIB or Stage IV Non-small Cell Lung Cancer
Condition: Lung Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS: Histologically proven Stage IIIB or IV bronchioloalveolar non-small cell lung carcinoma -incompletely resected or unresectable - tumors may be multifocal or diffuse -measurable or evaluable disease required No prior brain metastases

PATIENT CHARACTERISTICS: Age: 18 and over Performance Status: SWOG 0-2 Life Expectancy: Not specified Hematopoietic: Absolute granulocyte count at least 1,500/mm3 Platelet count at least 100,000/mm3 Hepatic: Bilirubin no greater than institutional upper limit of normal (ULN) SGOT no greater than 2 times ULN Renal: Creatinine no greater than institutional ULN OR creatinine clearance at least 50 mL/min Other: Not pregnant or nursing Effective contraceptive method used while on study No prior malignancies allowed, except: basal or squamous cell skin cancer in situ cervical cancer Stage I or II cancer which is in remission Any cancer from which patients have been disease free for 5 years

PRIOR CONCURRENT THERAPY: Biologic therapy: No prior biologic therapy for lung cancer Chemotherapy: No prior chemotherapy Endocrine therapy: Not specified Radiotherapy: No prior radiation therapy (including palliative radiotherapy) Surgery: Prior surgery is allowed
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00003010
Intervention Type: Drug
Intervention Name: marimastat
Title: Marimastat or No Further Therapy in Treating Women With Metastatic Breast Cancer That Is Responding or Stable Following Chemotherapy
Condition: Breast Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS: Histologically confirmed adenocarcinoma of the breast with previous manifestations of progressing regional or metastatic cancer Received one prior systemic chemotherapy regimen for the treatment of metastases, which meets all of the following criteria: Included either doxorubicin, a taxane (i.e.,

paclitaxel or docetaxel),
or both 6-8 courses were given If weekly taxane therapy received, at least 12 doses were
given Recovered from all related toxic effects (except alopecia and/or neuropathy) 3-6
weeks have elapsed since last course of chemotherapy was given No more than 40 weeks have
elapsed since the first dose of chemotherapy for metastases No current or prior history of
brain metastases Responding or stable disease since the initiation of systemic chemotherapy
(i.e., no disease progression) required No prior enrollment on ECOG trials for metastatic
disease

PATIENT CHARACTERISTICS: Age: 18 and over Sex: Female Menopausal Status: Not specified
Performance status: ECOG 0 or 1 Hematopoietic: Granulocyte count at least 1,500/mm3
Platelet count at least 100,000/mm3 Hepatic: Bilirubin no greater than 1.5 mg/dL SGOT no
greater 2 times upper limit of normal Renal: Creatinine no greater than 1.5 mg/dL Other:
Not pregnant or nursing Negative pregnancy test required if pre- or peri-menopausal (i.e.,
last menstrual period within one year prior to study) Pre- or peri-menopausal sexually
active women must use effective contraception No other invasive malignancy within last 5
years except curatively treated basal or squamous cell carcinoma of the skin or carcinoma
in situ of the cervix No history of rheumatoid arthritis, osteoarthritis, symptomatic
osteoarthritis requiring therapy, or other inflammatory arthritis At least 5 years since
prior invasive malignancies except: Curatively treated basal cell or squamous cell
carcinoma of the skin Carcinoma in situ of the cervix

PRIOR CONCURRENT THERAPY: Biologic therapy: No concurrent immunotherapy No prior
trastuzumab Chemotherapy: See Disease Characteristics No concurrent chemotherapy No prior
marimastat or batimastat Endocrine therapy: Prior and/or concurrent hormonal therapy for
breast cancer allowed Concurrent hormonal therapy allowed Radiotherapy: No concurrent
radiotherapy Surgery: No prior organ allograft Other: At least 4 weeks since other
investigational agents No concurrent bisphosphonate therapy unless it was initiated prior
to the study No concurrent immunosuppressive therapy Patients receiving anticoagulant
therapy must be carefully monitored
Overall Status: Completed
Phase: Phase 3

NCTID: NCT00003044
Intervention Type: Drug
Intervention Name: cisplatin-e therapeutic implant
Title: Chemotherapy in Treating Patients With Liver Cancer
Condition: Liver Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS: Histologically proven unresectable primary hepatocellular

carcinoma No major vessel involvement Disease must be confined to the liver (no extrahepatic disease) Patients have no more than 3 tumors, with no tumor exceeding 7 cm in diameter, and the sum total tumor volume less than 200 cm3

PATIENT CHARACTERISTICS: Age: 18 and over Performance Status: Karnofsky 40-100% Life Expectancy: At least 4 months Hematopoietic: Hemoglobin at least 10 g/dL Platelet count at least 75,000/mm3 Absolute granulocyte count at least 1,000/mm3 PT within 3 seconds of institutional norm Hepatic: SGPT no greater than 3 times upper limit of normal (ULN) SGOT no greater than 3 times ULN Child-Pugh grade A or B Albumin at least 25 g/L Bilirubin no greater than 2.98 mg/dL Absent or easily controlled ascites not requiring routine or intermittent paracentesis Alkaline phosphatase no greater than 2.5 times ULN Renal: Creatinine no greater than 1.3 times ULN OR Creatinine clearance at least 45 mL/min Cardiovascular: No coronary artery disease No New York Heart Association class III or greater cardiac symptoms Other: Not pregnant or nursing No medical or psychiatric condition compromising informed consent No obesity or tumor location that would limit adequate tumor imaging No history of bleeding from liver tumor(s) or gastroesophageal bleeding No known hypersensitivity to cisplatin, bovine collagen, epinephrine, sulfites or radiographic contrast agents No history of encephalopathy

PRIOR CONCURRENT THERAPY: Biologic therapy: No prior biologic therapy for hepatocellular carcinoma No concurrent immunomodulating agents Chemotherapy: No prior or concurrent chemotherapy for hepatocellular carcinoma No concurrent cytotoxic agents Endocrine therapy: No prior endocrine therapy for hepatocellular carcinoma Radiotherapy: No prior radiotherapy for hepatocellular carcinoma Surgery: Prior surgical resection of the liver allowed Other: No concurrent use of aspirin, nonsteroidal anti-inflammatory agents, anticoagulants including warfarin sodium (Coumadin), and epinephrine containing medications including topical anesthetics such as bupivacaine HCl No prior investigational agents within 4 weeks of study No concurrent use of probenecid or thiazides Concurrent use of analgesics and antiemetics is allowed Concurrent use of topical and other local anesthetics, locoregional nerve blocks, and systemic agents is allowed
Overall Status: Unknown status
Phase: Phase 2

NCTID: NCT00003041
Intervention Type: Drug
Intervention Name: pyrazoloacridine
Title: Pyrazoloacridine in Treating Women With Refractory Metastatic Breast Cancer
Condition: Breast Cancer

Eligibility Criteria: DISEASE CHARACTERISTICS: Histologically confirmed metastatic breast cancer Bidimensionally measurable disease of any of the following types required: Bidimensionally measurable lung lesions on chest X-ray, CT scan, or MRI Palpable and quantifiable lymph nodes at least 2 x 2 cm Abdominal mass at least 2 x 2 cm quantifiable by CT scan Bidimensionally measurable liver metastases at least 2 x 2 cm Palpable hepatomegaly if liver edge is clearly defined and extends at least 5 cm below the costal margin of the xiphoid process Unacceptable as measurable disease: Diffuse lung infiltration or unidimensionally measurable hilar lesions Pelvic mass of indefinite dimension Bone metastases Pleural effusion or ascites No brain metastases Must have failed or progressed on prior therapy or relapsed less than 12 months after therapy discontinuation Hormone receptor status: Not specified

PATIENT CHARACTERISTICS: Age: 16 and over Sex: Female Menopausal status: Not specified Performance status: SWOG 0-2 Life expectancy: At least 6 months Hematopoietic: Granulocyte count at least 1,500/mm3 Platelet count at least 100,000/mm3 Hepatic: SGOT no greater than 2.5 times upper limit of normal Bilirubin no greater than 1.5 mg/dL Renal: Creatinine no greater than 1.5 mg/dL OR Creatinine clearance at least 60 mL/min Cardiovascular: No history of congestive heart failure, myocardial infarction within past 6 months, ventricular arrhythmia, or ischemic heart disease requiring medication If necessary, ejection fraction at least 50% by MUGA Other: Not pregnant or nursing Negative pregnancy test Fertile patients must use effective contraception No other prior malignancies in past 5 years other than basal cell or squamous cell carcinoma of the skin or carcinoma in situ of the cervix No other serious illnesses or active infections No seizure disorder requiring anticonvulsant therapy

PRIOR CONCURRENT THERAPY: Biologic therapy: No concurrent biologic therapy Chemotherapy: See Disease Characteristics No more than 2 prior chemotherapy regimens for metastatic disease One prior adjuvant chemotherapy regimen for metastatic disease allowed At least 4 weeks since prior chemotherapy No other concurrent chemotherapy Endocrine therapy: One prior regimen of hormonal therapy for metastatic disease allowed At least 3 weeks since prior hormonal therapy and recovered No concurrent hormonal or corticosteroid therapy Radiotherapy: At least 4 weeks since prior radiotherapy to less than 25% bone marrow No concurrent radiotherapy Surgery: At least 4 weeks since prior surgery and recovered No concurrent surgery Other: At least 4 weeks since any prior treatment directed at the tumor and recovered No other concurrent anticancer or investigational therapy No concurrent

participation on another therapeutic clinical trial
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00003062
Intervention Type: Drug
Intervention Name: temozolomide
Title: Temozolomide in Patients With Progressive or Recurrent Non-small Cell Lung Cancer
Condition: Lung Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS: Histologically confirmed progressive or recurrent stage IV
non-small cell lung cancer (NSCLC) Patient with brain metastases on CT or MRI scan are
included Symptomatic cases must have had brain radiotherapy at least one month prior to
registration Patients without brain metastases: At least one target lesion Bidimensionally
measurable Not previously irradiated

PATIENT CHARACTERISTICS: Age: Under 70 Performance status: WHO 0-2 Life expectancy: Not
specified Hematopoietic: Absolute neutrophil count greater than 2,000/mm3 WBC greater than
3,500/mm3 Platelet count greater than 100,000/mm3 Hepatic: Bilirubin no greater than 1.46
mg/dL Transaminases less than 2 times upper limit of normal Renal: Creatinine no greater
than 1.70 mg/dL Creatinine clearance greater than 60 mL/min Other: No prior or concurrent
malignancies at other sites with the exception of adequately treated in situ carcinoma of
the cervix or basal and squamous carcinoma of the skin Not pregnant or nursing Negative
pregnancy test 24 hours prior to commencing temozolomide

PRIOR CONCURRENT THERAPY: No other investigational drugs allowed during this study Biologic
therapy: Prior biologic therapy allowed No concurrent biologic therapy allowed No
concurrent growth factor to induce neutrophil increase No concurrent erythropoietin
Chemotherapy: No prior chemotherapy for metastatic disease At least 3 months since any
neoadjuvant and adjuvant treatment, and induction chemotherapy preceding radical
radiotherapy Endocrine therapy: See Protocol Outline Concurrent steroids should be
maintained on the lowest dose possible Radiotherapy: Prior radiotherapy allowed Concurrent
local radiotherapy to nonbrain lesions allowed Concurrent palliative radiation therapy of
bone lesions permitted No concurrent radiation to target lesions No concurrent brain
radiotherapy Surgery: Prior surgery allowed
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00003076
Intervention Type: Drug
Intervention Name: eflornithine
Title: Eflornithine to Prevent Cancer in Patients With Barrett's Esophagus
Condition: Esophageal Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS: Must have a columnar lined

esophagus that meets the following
criteria: Specialized intestinal metaplasia Nondysplastic or low grade dysplasia Extends a
minimum of 1 cm above the gastroesophageal junction

PATIENT CHARACTERISTICS: Age: Over 18 Performance status: Karnofsky 80-100% Life
expectancy: Not specified Hematopoietic: WBC greater than 4,000/mm3 Platelet count greater
than 120,000/mm3 Hemoglobin greater than 12 g/dL Prothrombin time less than 3 seconds
beyond control Partial thromboplastin time less than 10 seconds beyond control Hepatic:
Bilirubin less than 1.5 mg/dL Transaminases less than 1.5 times normal Renal: Creatinine
less than 1.5 mg/dL Urinalysis: less than 1+ protein, 0-3 urinary casts, 0-5 white blood
cells and red blood cells Cardiovascular: No severe dyspnea at rest, orthopnea, edema,
history of congestive heart failure requiring continued treatment, or unstable angina
Neurologic: No severe degenerative neurologic disease Pulmonary: No requirement of
supplemental oxygen for exertion or rest Other: No prior malignancy within 5 years No
active rheumatoid arthritis, lupus or other rheumatologic autoimmune disease (no less than
2 years of quiescence if inactive) No history of abnormal wound healing No history of
esophageal varices or variceal bleeding Not pregnant or nursing Negative pregnancy test
Adequate contraception required of all fertile patients

PRIOR CONCURRENT THERAPY: No regular, scheduled use of antiinflammatory medications,
steroids, or anticoagulants No nutritional supplements other than two multivitamins per day
or four single nutrient vitamin supplements per day
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00003126
Intervention Type: Drug
Intervention Name: Interleukin-2
Title: Interleukin-2 in Treating Patients With Stage III or Stage IV Kidney Cancer
Condition: Kidney Cancer
Eligibility Criteria: Inclusion Criteria

- An Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1.

- Adequate organ function as defined by a white blood cell (WBC) count of 4,000/L; a
platelet count of 100,000/L; a Hemoglobin level of 10 g/dL; a serum creatinine of 1.5
mg/dL or creatinine clearance of 60 mL/min; and a direct bilirubin level of 1.5 mg/dL.

- Forced expiratory volume at 1 second more than 2.0 L or 75% of predicted for height
and age from pre-enrollment pulmonary function testing.

- No history or evidence of cardiac disease on ECG

- No prior systemic treatment for RCC, but patients may have received prior locoregional
radiation therapy to solitary resectable metastases, which must have undergone
surgical resection before enrollment.

- No prior history of invasive malignancy in the past 5 years

- Human immunodeficiency virus (HIV) negative

- Female patients must not be pregnant or planning to become pregnant

Exclusion criteria

â ¢ Age younger than 16
Overall Status: Completed
Phase: Phase 3

NCTID: NCT00003129
Intervention Type: Drug
Intervention Name: valrubicin
Title: Chemotherapy in Treating Patients With Early-Stage Bladder Cancer
Condition: Bladder Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS:

- Histologically confirmed recurrent superficial bladder cancer defined as papillary
transitional cell carcinoma (stage Ta/T1) and/or carcinoma in situ (stage Tis) of the
urinary bladder

  - No evidence of invasion of the underlying muscle (stage T2) at baseline

- Must meet 1 of the following criteria:

  - Failure of at least 2 prior courses of intravesical therapy, 1 of which must have
been a course of BCG

  - Recurrent or persistent disease within 6 months after failing a 6-week course of
BCG followed by maintenance therapy

  - Inability or ineligibility to complete 1 course of intravesical therapy with BCG,
and failure of 2 prior courses of intravesical therapy with an alternative agent

- Diagnosis must have been made no more than 24 months after completion of prior
treatment with intravesical immunotherapy or chemotherapy

- If carcinoma in situ is current or previous diagnosis, the biopsies must be obtained
from at least 4 sites (bladder mapping)

- If prostatic urothelial biopsy discloses carcinoma in situ, transurethral prostatic
resection must be carried out prior to study

- Papillary disease must have undergone complete transurethral resection (TURBT) within

28 days before study

PATIENT CHARACTERISTICS:

Age:

- 18 and over

Performance status:

- ECOG 0-1

Life expectancy:

- Not specified

Hematopoietic:

- WBC greater than 4,000/mm^3
- Platelet count greater than 100,000/mm^3

Hepatic:

- Bilirubin less than 2 times upper limit of normal (ULN)
- SGOT and SGPT less than 3 times ULN

Renal:

- Creatinine no greater than 2.5 mg/dL

Other:

- Normal upper tract (ureter and renal pelvic) evaluation within 6 months
- No known sensitivity to anthracyclines or to Cremophor EL
- HIV negative
- No known AIDS or HIV-1 associated complex
- No other significant concurrent illness
- No other prior malignancy within the past 3 years except superficial bladder cancer, adequately treated basal cell or squamous cell skin cancer, or carcinoma in situ of the cervix
- Not pregnant or nursing
- Fertile patients must use effective contraception

PRIOR CONCURRENT THERAPY:

Biologic therapy:

- See Disease Characteristics
- No concurrent biological response modifier therapy

Chemotherapy:

- See Disease Characteristics

- Prior oral bropirimine for bladder cancer allowed

- No prior AD 32 for bladder cancer

- No other intravenously administered systemic chemotherapy for bladder cancer

- No concurrent chemotherapy for any other malignancy

Endocrine therapy:

- No concurrent hormonal therapy

Radiotherapy:

- No prior radiotherapy

- No concurrent radiotherapy

Surgery:

- See Disease Characteristics

Overall Status: Completed
Phase: Phase 2

NCTID: NCT00003165
Intervention Type: Drug
Intervention Name: doxorubicin-HPMA conjugate
Title: Doxorubicin in Treating Women With Advanced Breast Cancer
Condition: Breast Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS: Histologically or cytologically proven advanced metastatic carcinoma of the breast Bidimensionally measurable disease No brain or leptomeningeal disease

PATIENT CHARACTERISTICS: Age: Over 18 Performance status: WHO 0-2 Life expectancy: At least 3 months Hematopoietic: Hemoglobin at least 10 g/dL Neutrophil count at least 2,000/mm3 Platelet count at least 100,000/mm3 Hepatic: Bilirubin no greater than 11.7 mg/dL AST/ALT no greater than 2 times upper limit of normal (5 times upper limit of normal in presence of liver metastases) Renal: Creatinine no greater than 1.7 mg/dL Cardiovascular: No concurrent treatment for congestive cardiac failure Cardiac function within normal limits by MUGA or ECHO scan, if prior anthracycline therapy Other: Not pregnant or nursing Fertile patients must use effective contraception No concurrent nonmalignant systemic disease No active uncontrolled infection No prior history of malignant disease except: Squamous cell carcinoma of the skin Curatively treated carcinoma in situ of the cervix

PRIOR CONCURRENT THERAPY: Biologic therapy: No concurrent immunological therapy Chemotherapy: At least 1 prior chemotherapy regimen for advanced disease (including adjuvant therapy), but not more than 2 prior regimens At least 4 weeks

since prior
chemotherapy (6 weeks for nitrosourea or mitomycin) and recovered Cumulative dose of prior
epirubicin no greater than 450 mg/m2 Cumulative dose of prior doxorubicin no greater than
240 mg/m2 No concurrent chemotherapy Endocrine therapy: No concurrent hormonal therapy Low
dose steroid therapy allowed if dose established at least 4 weeks prior to study
Radiotherapy: At least 4 weeks since prior radiotherapy and recovered Surgery: Not
specified Other: No concurrent experimental therapy
Overall Status: Unknown status
Phase: Phase 2

NCTID: NCT00003154
Intervention Type: Drug
Intervention Name: aminocamptothecin colloidal dispersion
Title: Chemotherapy in Treating Patients With Advanced Non-small Cell Lung Cancer
Condition: Lung Cancer
Eligibility Criteria: DISEASE CHARACTERISTICS: Histologically confirmed measurable stage IIIB or IV non-small
cell lung cancer No brain metastases

PATIENT CHARACTERISTICS: Age: 18 and over Performance status: ECOG 0-2 Life expectancy: At
least 12 weeks Hematopoietic: WBC at least 3500/mm3 Granulocyte count at least 1,500/mm3
Platelet count at least 100,000/mm3 Hepatic: Bilirubin no greater than 1.5 mg/dL SGOT and
SGPT no greater than 2.5 times upper limit of normal (ULN) Alkaline phosphatase no greater
than 2.5 times ULN Renal: Creatinine no greater than 1.5 mg/dL Creatinine clearance at
least 60 mL/min Calcium and electrolytes normal Other: No other malignancy within past 5
years except curatively treated nonmelanoma skin cancer or carcinoma in situ of the cervix
Not pregnant or nursing No active infections or other serious medical conditions

PRIOR CONCURRENT THERAPY: Biologic therapy: Not specified Chemotherapy: No prior
chemotherapy Endocrine therapy: Not specified Radiotherapy: At least 2 weeks since prior
radiotherapy No prior radiotherapy to site(s) of measurable disease Surgery: At least 3
weeks since any prior surgery
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00000873
Intervention Type: Drug
Intervention Name: Infant Formula
Title: A Study on the Effect of High-Calorie Infant Formula on Growth and Nutrition in HIV-Infected Infants
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Children may be eligible for this study if they:

- Are 1 to 17 days old. (This study has been changed. Originally, infants 1 to 15 days

old were eligible for this study.)

- Weigh 4 or more pounds.

- Were born to an HIV-positive mother.

- Have a caregiver willing to measure and keep records of infant's food intake.

Exclusion Criteria

Children will not be eligible for this study if they:

- Are breast-fed.

- Have certain disorders, including the inability to feed by mouth, or a life-threatening condition.

- Take medication which affects growth.

Overall Status: Completed
Phase: nan

NCTID: NCT00000897
Intervention Type: Drug
Intervention Name: Zidovudine
Title: A Study to Evaluate the Effects of Different Methods of Birth Control on the Drug Actions of Zidovudine (an Anti-HIV Drug) in HIV-Positive Women and to Compare Zidovudine Metabolism in Men and Women
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Men and women may be eligible for this study if they:

- Are HIV positive.

Women may be eligible for this study if they:

- Have regular periods and a normal gynecological exam, (including a Pap smear and mammogram).

- Enter the study between Days 10 and 18 of the first day of their last period.

- Are willing to use either the Pill or Depo-Provera as birth control.

- Have a negative pregnancy test within 14 days prior to study.

Exclusion Criteria

Men and women will not be eligible for this study if they:

- Cannot take ZDV for any reason.

- Have cancer.

- Are taking stavudine.

Women will not be eligible for this study if they:

- Cannot take the Pill or Depo-Provera.

- Are pregnant or nursing.

- Are receiving nelfinavir and want to enroll in Step 2.

- Have a history of chronic high blood pressure, thrombophlebitis, and/or pulmonary emboli if participating in Step 2 of the study.

(This study has been changed so that women with certain criteria are excluded from participating in Step 2.)
Overall Status: Completed
Phase: nan

NCTID: NCT00000909
Intervention Type: Drug
Intervention Name: Aldesleukin
Title: A Study to Evaluate the Effects of Giving IL-2 Alone to HIV-Positive Patients With CD4 Cell Counts of at Least 350 Cells/mm3 Who Do Not Wish to Receive Anti-HIV Therapy
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Patients may be eligible for this study if they:

- Are HIV-positive.

- Have had at least one CD4 cell count greater than or equal to 350 cells/mm3 within 30 days of study entry.

- Are at least 18 years old.

- Agree to abstinence or use of effective methods of birth control 1 month before and during the study.

Exclusion Criteria

Patients will not be eligible for this study if they:

- Have a history of a potentially life-threatening autoimmune or inflammatory disease.

- Abuse alcohol or drugs, or have any serious psychiatric or medical illnesses that would affect their safety or ability to complete the study.

- Have a history of an AIDS-defining illness.

- Have a history of cancer, other than Kaposi's sarcoma.

- Have ever taken IL-2 or any antiretroviral medications.

- Are pregnant.

- Are taking certain medications, including anti-seizure medications.
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00000889
Intervention Type: Drug
Intervention Name: Aldesleukin
Title: A Study to Evaluate the Effects of Giving Interleukin-2 (IL-2) Plus Anti-

HIV Therapy to HIV-Positive Patients With CD4 Cell Counts of at Least 350 Cells/mm3
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

You may be eligible for this study if you:

- Are HIV-positive.

- Have a CD4 cell count greater than or equal to 300 cells/mm3.

- Are at least 18.

- Have been on antiretroviral therapy for at least 7 days prior to study entry.

Exclusion Criteria

You will not be eligible for this study if you:

- Abuse alcohol or drugs, or have any serious psychiatric or medical illnesses that would affect your safety or ability to complete the study.

- Have a history of cancer (other than Kaposi's sarcoma), an AIDS-defining illness, a central nervous system (CNS) abnormality, or an autoimmune/inflammatory disease.

- Are pregnant or breast-feeding.

- Have ever received IL-2.

Overall Status: Completed
Phase: Phase 2

NCTID: NCT00000921
Intervention Type: Drug
Intervention Name: Prednisone
Title: The Effects of Prednisone on HIV Levels and the Immune System
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

You may be eligible for this study if you:

- Are HIV-positive.

- Have a CD4 cell count of 200-600 cells/mm3 within 30 days of study entry. (This study has been changed. You now must have a CD4 cell count of 200-700 cells/mm3 within 45 days of study entry.)

- Have had your viral load measured within 30 days of study entry.

- Have been on stable anti-HIV therapy with at least two anti-HIV agents for at least 12 weeks, and you intend to remain on this therapy during the study.

- Are at least 18 years of age.

- Agree to abstain from sex or use effective methods of birth control during the study and for 30 days after.

Exclusion Criteria

You will not be eligible for this study if you:

- Abuse alcohol or drugs or have a serious psychological condition.

- Are allergic to prednisone or other corticosteroids.

- Have a history of opportunistic (AIDS-related) infections, including cytomegalovirus (CMV), Mycobacterium avium complex (MAC), or Kaposi's sarcoma (KS).

- Have a history of a serious medical condition, including heart problems, tuberculosis (TB), cancer, diabetes, or osteoporosis.

- Are being treated for herpes at study entry.

- Have received certain medications, including blood pressure medication.

- Are pregnant or breast-feeding.

Overall Status: Completed
Phase: Phase 2

NCTID: NCT00000949
Intervention Type: Drug
Intervention Name: Aldesleukin
Title: A Study to Evaluate the Effects of Giving Proleukin (rIL-2) to HIV-Positive Patients With CD4 Counts Greater Than 300 Cells/mm3
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

You may be eligible for this study if you:

- Are HIV-positive.

- Agree to practice abstinence or use effective birth control methods during the study.

- Are on anti-HIV therapy and have a CD4 count of at least 300 cells/mm3.

- Are at least 18 years old.

Exclusion Criteria

You will not be eligible for this study if you:

- Have a history of progressive diseases.

- Have a history of severe autoimmune/inflammatory disease.

- Have Crohn's disease.

- Are taking antiseizure medications or certain other medications.

- Are receiving chemotherapy.

- Are pregnant or breast-feeding.

- Have ever received rIL-2.

Overall Status: Completed
Phase: Phase 3

NCTID: NCT00000929
Intervention Type: Drug
Intervention Name: Nonoxynol-9
Title: A Study of the Effects of Advantage 24 on the Rectum
Condition: HIV Infections
Eligibility Criteria: Exclusion Criteria

Co-existing Condition:

Participants with the following symptoms or conditions are excluded:

- Positive HSV-2 serology (HIV-negative participants only).

- Positive syphilis by Venereal Disease Research Laboratory (VDRL) serology and Fluorescent Treponemal Antibody (FTA) or Microhemagglutination Assay (MHA).

Receptive partners with the following additional symptoms or conditions are excluded:

- Rectal gonorrhea or chlamydia by culture.

- Active rectal inflammation, ulceration, or fissures.

Insertive partners with the following additional symptoms or conditions are excluded:

- Penile or urethral irritation, rashes, or lesions.

- Penile or scrotal piercing.

Concurrent Medication:

Excluded for receptive partners:

-

Anticoagulant, including warfarin and heparin.

Participants with the following prior conditions are excluded:

- Sensitivity or irritative symptoms when using N-9 or when exposed to latex.

- Three or more Herpes Simplex 2 Virus (HSV-2) outbreaks within 12 months prior to screening (HIV-positive participants only).

- One or more HSV-2 outbreaks within 6 months prior to screening (HIV-positive participants only).

Receptive partners with the following additional prior conditions are excluded:

- Diagnosed inflammatory bowel disease, ulcerative colitis, Crohn's disease, or rectal malignancy.

- Diagnosed bleeding disorder, including hemophilia and thrombocytopenia.

- Rectal surgery including fistulectomy.

- Prosthetic heart valve or diagnosis of a valvular abnormality.

- Hemorrhoidectomy within 6 months prior to screening.

- Rectal burning, tenesmus, bleeding, or irritation in the week prior to screening.

- Diarrhea (more than 3 stools per day) in the week prior to screening.

- Use of rectally-inserted sex toys, practiced receptive fisting, or rectal douching in the week prior to screening.

Insertive partners with the following additional prior conditions are excluded:

Urethral burning or discharge in the week prior to screening.

Prior Medication:

Excluded for receptive partners:

Use of laxatives in the week prior to screening.

Participants meet the following criteria:

- HIV-negative or HIV-positive; participant's partner must be the same serostatus.

- Plan to have anal intercourse only with the study partner for the duration of the study. During all episodes in which Advantage 24 is used, one partner is exclusively insertive and the other partner is exclusively receptive.

- Sexual partner of at least 3 months is eligible and agrees to participate.

- Agree to use non-N-9 lubricant and condoms for all episodes of anal intercourse.

- Avoid use of Advantage 24 for purposes other than specified by the protocol.

Receptive partners meet the following additional criteria:

- Plan to have receptive anal intercourse with the study partner with Advantage 24 applied rectally, and using N-9 lubricant and condoms, at the couple's usual frequency (at least 3 times per week).

- Agree to apply the specified amount of Advantage 24 daily to the rectum.

- Avoid use of laxatives, use of rectally-inserted sex toys, receptive fisting, and rectal douching.

Insertive partners meet the following additional criteria:

- Plan to have insertive anal intercourse with the study partner with Advantage 24 applied to the glans of the penis, and using non-N-9 lubricant and condoms, at the couple's usual frequency (at least 3 times per week).

- Agree to apply the specified amount of Advantage 24 daily to the penis.

Overall Status: Completed
Phase: Phase 1

NCTID: NCT00000926
Intervention Type: Drug
Intervention Name: Nonoxynol-9
Title: A Study of Nonoxynol-9 (N-9) and HIV Infection
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Volunteers may be eligible if they:

- Are HIV-negative.

- Are sexually active and expect to have vaginal intercourse at least twice a week during the study.

- Are willing to keep a diary of their sexual behavior and N-9 use.

- Are willing to have regular clinic visits including pelvic exams.

- Are at least 18 years old.

- Are female.

Exclusion Criteria

Volunteers will not be eligible if they:

- Have had a child or an abortion in the past 42 days.

- Are allergic to latex or N-9.

- Have genital sores.

- Have syphilis, chlamydia, gonorrhea, or trichomoniasis.

- Are enrolled in another study for a product like N-9.

- Expect to use another vaginal product other than N-9 during the study.

- Are pregnant.

Overall Status: Completed
Phase: Phase 3

NCTID: NCT00000927
Intervention Type: Drug
Intervention Name: BufferGel
Title: A Study of BufferGel in Women
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

All participants must have:

- HIV-negativity by licensed EIA.

- Willingness and ability to complete a study diary.

- A regular menstrual cycle with a minimum of 18 days between menses.

- Ability to insert BufferGel daily as required by the protocol.

Cohort IA participants must:

- Agree to abstain from sexual intercourse for the duration of the study.

Cohort IB participants must:

- Agree to have vaginal intercourse at least 2 times per week and use non-lubricated condoms for each act of intercourse.

- Have currently (for 3 months or longer) a single sexual partner who is at low-risk for HIV infection.

Exclusion Criteria

Co-existing Condition:

Participants with the following conditions or symptoms are excluded:

- A Grade 3 or higher liver, renal, or hematology abnormality.

- Menopausal.

- Breakthrough menstrual bleeding.

- Any STD or symptoms, as seen on pelvic exam, consistent with an STD or other genital tract infection or trauma including vaginitis, cervicitis, edema, erythema, ecchymosis, petechial hemorrhage, vulvar or cervicovaginal lesions or abrasions, subepithelial hemorrhage, or signs of genital tract infection (other than asymptomatic bacterial vaginosis) from laboratory evaluations.

Concurrent Medication:

Excluded:

- Any vaginal product other than BufferGel, including lubricants and feminine hygiene products.

- Vaginal drying agents.

- Douche.

- Participation in any other microbicide or contraceptive study.

- Treatment for any STD.

Participants with the following prior conditions are excluded:

- IUD, abnormal PAP smear, pregnancy, abortion, or gynecologic

surgery in the last 3
months.

- Any of the following side effects related to Depo-provera use in the past 2 months:

- headaches, dizziness, abdominal pain, fatigue, or nervousness.

Prior Medication:

Excluded:

- A course of antibiotic therapy (other than treatment for malaria) in the last 14 days.

- Any spermicide within the past month.

- Initiation of Depo-provera for contraceptive purposes in the last 6 months.

Risk Behavior:

Excluded:

- Use of intravenous drugs currently or within the past year.

Overall Status: Completed
Phase: Phase 1

NCTID: NCT00000984
Intervention Type: Drug
Intervention Name: CD4 Antigens
Title: A Phase I Study of the Safety and Pharmacokinetics of Recombinant CD4 (rCD4) in Infants and Children Infected With or at Risk for HIV Infection
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Concurrent Medication:

Allowed:

- Prophylactic medication for patients with previous documented episodes of Pneumocystis
carinii pneumonia (PCP).

- Concomitant zidovudine (AZT) or intravenous gamma globulin (IVIG) during maintenance
therapy phase of the study.

AMENDED: As of 10/19/90 only Children 0 to 3 months are being enrolled.

Original design: Patients must be infected with HIV or at risk for HIV infection. They must
be one of the following:

- Asymptomatic.

- Mildly symptomatic but not eligible for and/or decline ACTG protocol 052.

- Markedly symptomatic but not eligible for and/or decline ACTG protocol 051 or cannot
tolerate zidovudine (AZT) therapy.

All patients must have:

- A life expectancy of at least 3 months.

- A legally-qualified guardian with the ability to sign a written informed consent form, which must be obtained prior to treatment. A willingness to abstain from all other experimental therapy for HIV infection during the entire study period.

Exclusion Criteria

Concurrent Medication:

Excluded:

- Zidovudine (AZT).

- Intravenous gamma globulin (IVIG).

- Pentamidine.

- Trimethoprim / sulfamethoxazole (TMP/SMX).

- Corticosteroids.

- Nonsteroidal anti-inflammatory agents (NSAIDS).

- Other known immunomodulatory agents.

- All other experimental therapies.

Patients will be excluded from the study for the following reasons:

- Serious active opportunistic infection or malignancies prior to study entry.

- Defined organ insufficiencies.

Prior Medication:

Excluded within 3 weeks of study entry:

- Zidovudine (AZT).

- Intravenous gamma globulin.

- Cancer chemotherapy.

- Immunomodulatory agents.

- Other experimental therapy.

Patients may not have any of the following diseases or symptoms:

- Serious active opportunistic infection or malignancies prior to study entry.

- Cardiopathy.

- Two or more episodes of prior Pneumocystis carinii pneumonia (PCP).

- Hematologic insufficiency defined as granulocytes = or < 1000 cells/mm3; platelets =

or < 100000 cells/mm3; hemoglobin = or < 8 g/dl.

- Renal insufficiency defined as creatinine > 2 mg/dl; = or > 5 white blood cells or red
blood cells/hpf or = or > 2+ proteinuria in urine.

- Hepatic insufficiency defined as bilirubin = or > 3 x upper limit of normal; SGOT = or
> 10 upper limit of normal.

Overall Status: Completed
Phase: Phase 1

NCTID: NCT00000983
Intervention Type: Drug
Intervention Name: Zidovudine
Title: The Safety of Different Dose Levels of Zidovudine in HIV-Infected Children
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Concurrent Medication:

AMENDED:

- 03-19-91 Prophylaxis for PCP is recommended according to current practice guidelines.
As per published recommendations, primary prophylaxis with TMP / SMX on a M-T-W basis
is encouraged.

Allowed:

- Immunoglobulin therapy as single dose exposure prophylaxis or for children with
hypogammaglobulinemia.

- Trimethoprim / sulfamethoxazole (TMP / SMX) and parenteral or aerosolized pentamidine
for prophylaxis for Pneumocystis carinii pneumonia for children with AIDS and/or CD4+
counts = or < 500 cells/mm3.

- Systemic ketoconazole and acyclovir, or oral nystatin for acute therapy.

- Aerosol ribavirin for short-term treatment of acute respiratory syncytial virus (RSV).

AMENDED:

- 9/17/90 enrollment is limited to children < 6 years of age.

- Original design:

- Patients must have the following:

- Parent or guardian available to give written informed consent.

- Laboratory evidence of HIV infection.

- Children < 15 months of age, with CD4+ cell count > 500 cells/mm3, who are thought to
have acquired HIV through perinatal transmission and whose only laboratory evidence of

HIV infection is a positive antibody test, must also have one or more of the laboratory criteria described in Disease Status AND one or more of the disease criteria that are required of children > 15 months old with CD4+ cell counts > 500 cells/mm3.

Prior Medication:

Allowed:

- Aerosol ribavirin.

Exclusion Criteria

Co-existing Condition:

Patients with the following conditions or symptoms are excluded:

Previous AIDS-defining opportunistic infection or neoplasms as specified by the CDC surveillance criteria for AIDS.

- Previous unexplained recurrent, serious bacterial infections (two or more within a 2-year period) including sepsis, meningitis, pneumonia, abscess of an internal organ, and bone/joint infections caused by Haemophilus, Streptococcus, or other pyogenic bacteria.

- Qualifying for entrance criteria to zidovudine (AZT) + or - gammaglobulin (ACTG 051).

- Encephalopathy.

- Failure to thrive (defined as a child who crosses two percentile lines on the growth chart or child who is < fifth percentile and does not follow curve) and/or oral candidiasis for at least 2 months despite appropriate topical therapy.

- Lymphocytic interstitial pneumonitis (LIP) with steroid dependency or requiring supplemental oxygen.

- Preexisting malignancies.

Concurrent Medication:

AMENDED:

- 03-19-91 Prophylaxis with antiviral or antifungals agents, except for PCP prophylaxis is prohibited.

- Drugs that are metabolized by hepatic glucuronidation should be used with caution.

Excluded:

- Prophylaxis for oral candidiasis or otitis media or other

infections (sinusitis,
urinary tract infections).

- Immunoglobulin therapy not specifically allowed.

- Ketoconazole, acyclovir, or nystatin for prophylaxis.

- Drugs that are metabolized by hepatic glucuronidation and might alter metabolism of
zidovudine (AZT).

Patients with the following are excluded:

- Previous AIDS-defining opportunistic infection or neoplasms as specified by the CDC
surveillance criteria for AIDS.

- Previous unexplained recurrent, serious bacterial infections (two or more within a
2-year period) including sepsis, meningitis, pneumonia, abscess of an internal organ,
and bone/joint infections caused by Haemophilus, Streptococcus, or other pyogenic
bacteria.

- Qualifying for entrance criteria to zidovudine (AZT) + or - gammaglobulin (ACTG 051).

- Encephalopathy.

- Failure to thrive (defined as a child who crosses two percentile lines on the growth
chart or child who is < fifth percentile and does not follow curve) and/or oral
candidiasis for at least 2 months despite appropriate topical therapy.

- Lymphocytic interstitial pneumonitis (LIP) with steroid dependency or requiring
supplemental oxygen.

- Preexisting malignancies.

Prior Medication:

Excluded within 2 weeks of study entry:

- Any other experimental therapy or drugs that cause prolonged neutropenia or
significant nephrotoxicity.

Excluded within 1 month of study entry:

- Antiretroviral agents.

- Immunomodulating agents including immunoglobulin, interferon, isoprinosine, and IL-2.

Excluded within 2 months of study entry:

- Systemic ribavirin for retroviral therapy.

Prior Treatment:

Excluded within 1 month of study entry:

- Lymphocyte or red blood cell transfusions.

Active alcohol or drug abuse.
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00000963
Intervention Type: Drug
Intervention Name: Didanosine
Title: A Study of Dideoxyinosine (ddI) in HIV-Infected Children Who Have Not Had Success With Zidovudine or Who Cannot Take Zidovudine
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Concurrent Medication:

Allowed:

- Prophylaxis treatment for Pneumocystis carinii pneumonia (PCP).

- Immunoglobulin.

- Maintenance therapy with amphotericin B (l mg/kg) up to 5 days/week.

Concurrent Treatment:

Allowed:

- Blood transfusions.

Prior Medication:

Allowed:

- Prophylaxis treatment for Pneumocystis carinii pneumonia (PCP).

Patients enrolled in ACTG 128 and ACTG 138 must meet study end points or meet protocol definitions for being permanently off zidovudine (AZT) before enrolling in this study.

- Patients currently enrolled in ACTG 051 who have not reached the study end points but who meet the entry criteria for ACTG 144 may be co-enrolled in ACTG 144.

- Patient or guardian available to give written informed consent.

Exclusion Criteria

Co-existing Condition:

Patients with the following conditions or symptoms are excluded.

- Hypersensitivity to didanosine (ddI).

- Symptomatic cardiomyopathy.

- Seizures that are not well controlled by ongoing anticonvulsant therapy.

- Symptomatic pancreatitis.

- Grade 1 or higher peripheral neuropathy.

- Active malignancy requiring chemotherapy.

Concurrent Medication:

Excluded:

- Zidovudine (AZT), other antiretroviral agents, biological modifiers, and investigational medications.

Avoid:

- Drugs with potential to cause peripheral neuropathy or pancreatitis.

Patients with the following are excluded:

- Active malignancy requiring concomitant chemotherapy.

Prior Medication:

Excluded:

- Antiretroviral agents other than zidovudine (AZT) or dideoxycytidine (ddC) within 4 weeks of study entry.

- Immunomodulating agents such as interferons, isoprinosine, or interleukin-2 within 2 weeks of entry.

- Any other experimental therapy within 1 week of entry.

- Drugs that have or will cause prolonged neutropenia, significant pancreatitis, significant nephrotoxicity, or peripheral neuropathy within 1 week of entry.

Overall Status: Completed
Phase: Phase 2

NCTID: NCT00000965
Intervention Type: Drug
Intervention Name: Zidovudine
Title: The Effects of Zidovudine on the Blood of HIV-Infected Patients
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Concurrent Medication:

Allowed:

- FDA-approved anti-pneumocystis and antifungal prophylactic or suppressive regimens.

- Acyclovir for up to 3 weeks intermittently.

Patients must:

- Meet current guidelines for receiving prescription zidovudine.

- Have written informed consent from both subject and parent or guardian if under 18. Be capable of understanding and giving informed consent. Women and minorities are actively encouraged to participate.

Exclusion Criteria

Co-existing Condition:

Patients with the following conditions or symptoms are excluded:

- Malabsorption syndrome (3 or more loose stools/day for at least 4 weeks associated with unintentional weight loss of greater than 10 percent of body weight).

Concurrent Medication:

Excluded:

- Probenecid or non-FDA approved investigational drugs.

- Systemic chemotherapy.

- Other antiviral agents, licensed or investigational, including ganciclovir, foscarnet, ribavirin, didanosine (ddI), dideoxycytidine (ddC), and dideoxydidehydrothymidine (D4T).

Chronic acyclovir.

-

Patients with the following are excluded:

- Active bacterial, fungal, or viral infection requiring systemic therapy not specifically allowed.

- Significant, chronic medical conditions that could impair compliance with study treatment.

Prior Medication:

Excluded:

- Zidovudine (AZT).

- Systemic chemotherapy within previous 6 months.

- Acyclovir within 30 days of study entry.

Risk Behavior:

Excluded:

- Unable to take oral medication reliably.

- Alcohol or drug abuse that could impair compliance with study treatment.

Overall Status: Completed

Phase: nan

NCTID: NCT00000962
Intervention Type: Drug
Intervention Name: Nevirapine
Title: The Safety and Effectiveness of BI-RG-587 in HIV-Infected Patients
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Concurrent Medication:

Allowed:

- Pentamidine or dapsone prophylaxis for Pneumocystis carinii pneumonia (PCP) in patients with a CD4+ cell count = or < 200 cells/mm3.

- Antifungal prophylaxis with oral fluconazole or ketoconazole.

- Antiviral prophylaxis with a maximum of 1 gram of oral acyclovir per day.

- Acute therapy for intercurrent infections so long as that therapy is not an excluded medication of an excluded opportunistic infection.

Patients must have:

- Positive HIV antibody test results by ELISA.

- Average of CD4+ cell count at 60 and at 21 days prior to study beginning = or < 400 cells/mm3.

- Seven of 10 patients in each treatment arm must have p24 antigen levels = or > 70 pg/ml (> 50 pg/ml at U. of Mass. site only) or be plasma viremic.

- Preserved hematologic, hepatic, and renal function as defined by required lab values.

- Ambulatory performance score of = or > 70 Karnofsky.

- Ability to voluntarily provide written informed consent prior to treatment.

- Willingness and ability to follow protocol requirements.

Exclusion Criteria

Co-existing Condition:

Patients with the following symptoms or conditions are excluded:

- Active cytomegalovirus disease.

- Toxoplasmic encephalitis requiring suppressive therapy.

- Mycobacteriosis requiring maintenance chemotherapy.

- Visceral Kaposi's sarcoma requiring chemotherapy and/or irradiation.

- Malignancy other than Kaposi's sarcoma or limited cutaneous basal

cell carcinoma.

- More than mild diarrhea (defined as more than transient or > 4 loose stools per day).

Concurrent Medication:

The following medications / substances may NOT be ingested up to one hour before or 4 hours
after a Nevirapine dose:

- Antacids (particularly those containing calcium carbonate).

- Cimetidine.

- Carafate.

- Cholestyramine resin.

- Alcohol and alcohol-containing substances.

- Benzodiazepines (diazepam, triazolam).

Excluded:

- Any approved or investigational antiretroviral, immunosuppressive, or cytotoxic drugs.

- Glucocorticoids and steroid hormones (including oral contraceptives).

- Dicumarol, warfarin, and other anticoagulant medications.

- Nitroglycerin.

- Digitoxin.

- Valproic acid.

- Tolbutamide.

- Doxycycline.

- Chloramphenicol.

- Isoniazid.

- Any sulfonamide medications.

Patients with the following are excluded:

- History of clinically important disease other than HIV infection defined by the
investigator as possibly putting the patient at risk during study participation.

- Conditions listed in Exclusion Co-Existing Conditions and symptoms.

- Having received any approved or investigational antiretroviral, immunosuppressive, or
cytotoxic drugs or any other experimental drug with 4 weeks of study entry.

- A positive zidovudine (AZT) detection assay performed 7 days prior

to drug dosing will
exclude patients from study participation.

Prior Medication:

Excluded within 4 weeks of study entry:

- Any approved or investigational antiretroviral, immunosuppressive or cytotoxic drugs.

- Glucocorticoids and steroid hormones (including oral contraceptives).

- Dicumarol, warfarin, and other anticoagulant drugs.

- Nitroglycerin. Digitoxin.

- Valproic acid.

- Tolbutamide.

- Doxycycline.

- Chloramphenicol.

- Isoniazid.

- Antiepileptics (phenobarbital and other barbiturates).

- Trimethoprim / sulfamethoxazole (Bactrim).

Risk Behavior:

Excluded:

- Patients whose use of alcohol or drugs is sufficient to impair compliance with
protocol requirements.

Overall Status: Completed
Phase: Phase 1

NCTID: NCT00000990
Intervention Type: Drug
Intervention Name: Zidovudine
Title: The Safety and Effectiveness of Zidovudine in the Treatment of HIV-Infected Children With Mild to Moderate Symptoms
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Concurrent Medication:

Allowed:

- Prophylaxis for Pneumocystis carinii pneumonia (PCP) in children with AIDS or CD4 cell
count = or < 500 cells/mm3.

Children must demonstrate the following clinical and laboratory findings:

- Laboratory evidence of HIV infection as demonstrated by either a positive viral
culture or detectable serum p24 antigen or = or > two positive tests for HIV antibody,

which must be determined by a federally licensed ELISA test and confirmed by Western blot.

- Children < 15 months of age, who are thought to have acquired HIV through perinatal transmission and whose only laboratory evidence of HIV infection is a positive antibody test, must also have one or more of the following laboratory criteria indicative of immunologic abnormality:

- hypergammaglobulinemia (IgG or IgA) defined as greater than the upper limit of normal for age-adjusted normals; absolute depression in the CD4+ cells to = or < 500 cells/mm3; decreased helper/suppressor ratio < 1.0; depressed in vitro mitogen response to at least one antigen/mitogen.

- Absence of serious bacterial infections as defined in Exclusion Criteria requiring therapy at the time of entry.

- Hemophiliacs are included.

Exclusion Criteria

Co-existing Condition:

Children will be excluded for the following reasons:

- Recurrent or life-threatening toxicity. Several allergic reactions such as exfoliative erythroderma, anaphylaxis, or vascular collapse. The presence of one or more of the indicator diseases of AIDS, such as opportunistic infections, malignancy, recurrent bacterial infections, or encephalopathy. Development of two or more episodes of recurrent varicella zoster infection or chronic zoster defined as = or > 30 days duration. Development of AIDS related complex, with failure to thrive, persistent or recurrent oral candidiasis, plus at least one of the following:

- Diarrhea that is either persistent or recurrent, lymphadenopathy at two or more noncontiguous sites, organomegaly, nephropathy manifested by nephrotic syndrome without evidence of renal failure, two or more episodes of herpes stomatitis or one or more episodes of herpes zoster within a 1 year period; plus at least one of the following:

- hypergammaglobulinemia, depression in the CD4+ cells to = or < 500/mm3, decreased helper/suppressor ratio < 1.0, depressed in vitro mitogen response to at least one antigen/mitogen.

Concurrent Medication:

Excluded:

- Hepatotoxic drugs.

- Steroids for lymphocytic interstitial pneumonitis (LIP).

- Prophylaxis for oral candidiasis, or otitis media.

- Immunoglobulin therapy.

- Chronic use of drugs that are metabolized by hepatic glucuronidation.

Concurrent Treatment:

Excluded:

- Supplemental oxygen treatment for lymphocytic interstitial pneumonitis (LIP).

Children will be excluded from the study for the following reasons:

- AIDS-defining opportunistic infection or neoplasm.

- Unexplained recurrent, serious bacterial infections (= or > 2 within a 2-year period)
  including sepsis, meningitis, pneumonia, abscess of an internal organ, and bone/joint
  infections caused by Haemophilus, Streptococcus, or other pyogenic bacteria.

- Encephalopathy.

- One or both of the following:

- Failure to thrive, defined as a child who crosses two percentile lines on the growth
  chart or a child who is less than the fifth percentile and does not follow the curve;
  and/or persistent (= or > 2 months) oral candidiasis despite appropriate topical
  therapy.

- Children with lymphocytic interstitial pneumonitis (LIP) who are steroid dependent or
  requiring supplemental oxygen or who have a pretreatment PaO2 < 70 mmHg.

- Children who qualify for the entrance criteria to open-label zidovudine (AZT) or AZT
  plus or minus gammaglobulin.

Prior Medication:

Excluded:

- Rifampin or rifampin derivatives.

- Antiretroviral agents.

- Zidovudine (AZT).

- Excluded within 2 weeks of study entry:

- Other experimental therapy.

- Drugs which cause prolonged neutropenia or significant nephrotoxicity.

- Excluded within 4 weeks of study entry:

- Immunomodulating agents including immunoglobulin, interferon, isoprinosine, and IL-2.

Prior Treatment:

Excluded within 4 weeks of study entry:

- Lymphocyte transfusions.

Active alcohol or drug abuse.
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00000988
Intervention Type: Drug
Intervention Name: Stavudine
Title: A Study of BMY-27857 in Patients With AIDS or AIDS Related Complex
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Concurrent Medication:

Allowed:

- Aerosolized pentamidine for Pneumocystis carinii pneumonia prophylaxis.

- TMP/SMX as an alternative prophylactic agent, 1 DS tablet orally per day.

- Acute therapy with oral acyclovir for herpes simplex infections for no more than 7
days, providing d4t is suspended Symptomatic therapy such as analgesics,
antihistamines, antiemetics, antidiarrheal agents, or other supportive therapy may be
administered for toxicities as deemed necessary by the principal investigator. For
therapy of fever, aspirin rather than acetaminophen should be used.

Concurrent Treatment:

Allowed:

- Transfusion of up to 2 units of packed red blood cells every 3 weeks for grade 3 or
grade 4 anemia (see Recommendations for Grading of Acute and Subacute Toxic Effects
(Adults)) until patient returns to baseline from grade 3 or to baseline or grade 1
from grade 4.

Patient must have:

- AIDS or AIDS related complex (CDC Group IVA or CDC Group IVC-2 with thrush or oral
leukoplakia).

- Ability to provide informed consent.

- Availability to follow-up for at least 6 months.

- Absence of active, AIDS-defining opportunistic infection on study entry.

Exclusion Criteria

Co-existing Condition:

Patients with the following are excluded:

- Active, AIDS-defining opportunistic infection.

- Intractable diarrhea.

- History or propensity for seizure disorders requiring anticonvulsants for control.

- Any other clinical condition which in the opinion of the investigator would make the patient unsuitable or unable to comply with the dosing requirements.

Concurrent Medication:

Excluded:

- Systemic therapy with this or any other antiretroviral drug (including AL-721, ddI, ddC, interferon, immunomodulating drugs) or investigational drug.

- Ribavirin.

- Cytotoxic anticancer therapy.

- Therapy with any agent known as a potent inducer or inhibitor of drug-metabolizing enzymes, such as rifampin or barbiturates.

- Systemic maintenance or chemoprophylaxis for opportunistic infections.

- Trimethoprim / sulfamethoxazole for Pneumocystis carinii infections.

- Acute therapy with ketoconazole for thrush.

- Neurotoxic agents listed in the protocol.

Patients with the following are excluded:

- Previous intolerance to zidovudine (AZT) as demonstrated by transfusion dependent anemia (transfusion required every 3 weeks or less and AZT-related depression of neutrophils to < 500 cells/mm3).

- Life expectancy < 6 months.

Prior Medication:

Excluded:

- Any other prior therapy which in the opinion of the investigator would make the patient unsuitable or unable to comply with the dosing requirements.

Excluded within 2 weeks of study entry:

- Therapy with any agent known as a potent inducer or inhibitor of drug-metabolizing enzymes, such as rifampin or barbiturates.

Excluded within 1 month of study entry:

- Systemic therapy with this or any other antiretroviral drug (including AL-721, interferon, immunomodulating drugs, ddI, ddC) or any investigational drug.

Excluded within 3 months of study entry:

- Ribavirin.

- Cytotoxic anticancer therapy.

Prior Treatment:

Excluded:

- Any prior therapy which in the opinion of the investigator would make the patient unsuitable or unable to comply with the dosing requirements.

Preference:

- Tolerating zidovudine (AZT) at time of study entry.

Active alcohol or drug abuse sufficient, in the investigator's opinion, to prevent adequate compliance with study therapy.
Overall Status: Completed
Phase: Phase 1

NCTID: NCT00001007
Intervention Type: Drug
Intervention Name: Zidovudine
Title: A Study of Zidovudine in Infants Exposed to the HIV Before or Soon After Birth
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Infant gestation period must have been = or > 36 weeks and birthweight must = or > 2000 grams. Active infection must not be present at the time of entry into the study although an HIV culture or P24 serum antigen determination must be obtained prior to study entry. The child must have a life expectancy greater than 3 months. Parents or guardian must be available to give informed consent.

Prior Medication:

Allowed on a case-by-case basis:

- Some essential supportive therapies including antibiotics.

Exclusion Criteria

Co-existing Condition:

Patients with the following conditions or symptoms are excluded:

- Any of the following laboratory findings within 2 weeks of study entry.

- A total bilirubin > 2 times age-adjusted upper limit of normal.

- Liver transaminase values > 3 x upper limit of normal.

- Serum creatinine > 1.5 x upper limit of normal.

- Total granulocyte count < 1500 cells/mm3.

- Hemoglobin < 10 g/dl or hemoglobinopathy.

- A urine toxicology screen positive for any drug or chemical.

- Infants must not have hemoglobinopathy or active infection at entry.

Prior Medication:

Excluded within 2 months of study entry:

- Antiretroviral agents.

- Excluded within 4 weeks of study entry:

- Immunomodulating agents including steroids, interferon, isoprinosine, and interleukin.

- Immunoglobulin.

- Excluded within 2 weeks of study entry:

- Any other experimental therapy, drugs which cause prolonged neutropenia or significant
  nephrotoxicity, or rifampin / rifampin derivatives.

- Some essential supportive therapies including antibiotics may have infrequent or
  transient effects. These drugs will be considered on a case-by-case basis.

Prior Treatment:

Excluded within 2 weeks of study entry:

- Red blood cells or whole blood transfusion.

- Excluded within 4 weeks of study entry:

- Lymphocyte transfusions for immune reconstitution.

Infants may not be entered into the study during the first 2 weeks of life if their mother

received methadone therapy during the last trimester of her pregnancy or used any known
illicit drug. A maternal urine toxicology screen may be optionally performed prior to entry
of the child, and children whose mothers have a screen which is positive for any drugs or
chemicals may not be enrolled within 2 weeks of the positive screen.
Overall Status: Completed
Phase: Phase 1

NCTID: NCT00001015
Intervention Type: Drug
Intervention Name: Ribavirin
Title: A Study of Ribavirin in the Treatment of Patients With AIDS and AIDS-Related Problems
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Concurrent Medication:

Allowed:

- Short-course therapy (7 days) with oral acyclovir.

- Short-course therapy (7 days) with ketoconazole.

- Topical medications.

- Aerosolized pentamidine for prophylactic purposes.

Concurrent Treatment:

Allowed:

- Blood transfusions for hemoglobin toxicity.

Patients must have two positive HIV p24 antigen tests with titers = or > 70 picograms at
least 72 hours apart and within 1 month prior to entry, the last of which must be within 2
weeks of starting therapy.

Prior Medication:

Allowed:

- Zidovudine (AZT), without cessation of therapy required due to intolerance.

- AZT therapy must be discontinued at least 30 days prior to study entry.

Exclusion Criteria

Co-existing Condition:

Patients with the following are excluded:

- Active opportunistic infection, symptomatic visceral Kaposi's sarcoma (KS) or
progression of KS within the month prior to entry into the study, neoplasms other than
KS, basal cell carcinoma of the skin, or in situ carcinoma of the cervix. Significant

diarrhea, defined as = or > 3 liquid stools per day within the past week.

Concurrent Medication:

Excluded:

- Ongoing systemic therapy and/or prophylaxis for an AIDS-defining opportunistic infection.
- Antineoplastic therapy.
- Other experimental medications.
- Systemic chemoprophylaxis for Pneumocystis carinii pneumonia.
- Chronic (> 7 days) oral acyclovir therapy.

Concurrent Treatment:

Excluded:

- Blood transfusions unless they are for = or > grade 3 hemoglobin toxicity.

Patients with the following are excluded:

- Active opportunistic infection, symptomatic visceral Kaposi's sarcoma (KS) or progression of KS within the month prior to entry into the study, neoplasms other than KS, basal cell carcinoma of the skin, or in situ carcinoma of the cervix. Significant diarrhea, defined as = or > 3 liquid stools per day within the past week.

Prior Medication:

Excluded within 30 days of study entry:

- Antiretroviral agents including zidovudine (AZT).
- Biologic modifiers.
- Systemic corticosteroids.

Prior Treatment:

Excluded within 2 months of study entry:

- Blood transfusion except for those who have taken zidovudine (AZT) who may not have received a transfusion within the previous month.

Active drug or alcohol abuse.
Overall Status: Completed
Phase: Phase 1

NCTID: NCT00000997
Intervention Type: Drug
Intervention Name: Zalcitabine
Title: A Study of Dideoxycytidine in HIV-Infected Patients
Condition: HIV Infections

Eligibility Criteria: Inclusion Criteria

Prior Medication:

Allowed:

- Oral nonabsorbable antifungal agents.

Exclusion Criteria

- Active drug or alcohol abuse.

Co-existing Condition:

- Patients with fever > 102 degrees F at study entry will be excluded.

- Patients with fever > 102 degrees F at study entry will be excluded.

Prior Medication: Excluded:

- Chronic systemic medications.

- Any other experimental drug within 2 weeks of study entry.

- Drugs with known nephrotoxic or hepatotoxic effects within 2 weeks of study entry.

- Drugs known to cause neutropenia within 2 weeks of study entry.

- Rifampin or rifampin derivatives, phenytoin, or barbiturates within 2 weeks of study entry.

- Any other medication except oral nonabsorbable antifungal agents within 72 hours of study entry.

All medications, including aspirin, must be approved by investigator. All medications, including aspirin, must be approved by investigator.

Patients must demonstrate the following clinical and laboratory findings:

- AIDS, AIDS related complex (ARC), or persistent generalized lymphadenopathy as defined by the CDC classification.

- No ascites.

- Off all medications except oral antifungal, nonabsorbable agents for 72 hours prior to study entry.

Overall Status: Completed
Phase: nan

NCTID: NCT00000994
Intervention Type: Drug
Intervention Name: Zidovudine
Title: A Study of AZT in HIV-Infected Patients With AIDS-Related Kaposi's Sarcoma
Condition: HIV Infections

Eligibility Criteria: Inclusion Criteria

Concurrent Medication:

Allowed:

- Acute treatment for mucocutaneous candidiasis, localized cutaneous herpes simplex, or localized or disseminated zoster infections.

Concurrent Treatment:

Allowed:

- Blood transfusion for treatment of Grade 3 hemoglobin toxicity if the patient's cardiovascular status is compromised or if the hemoglobin fails to show signs of recovery following withdrawal from the study drug. Toxicity grades according to NIAID Recommendations for Grading Acute and Subacute Toxic Effects (Adults).

Patients must have:

- HIV-related, biopsy-proven Kaposi's sarcoma mucocutaneous lesions without constitutional symptoms.

Exclusion Criteria

Co-existing Condition:

Patients with the following conditions will be excluded:

- Symptomatic, visceral Kaposi's sarcoma.

- Lymphedema.

- HIV neurologic disease as determined by a standard neurologic examination and neuropsychological questionnaire.

Concurrent Medication:

Excluded:

- Aspirin or acetaminophen on a regular basis or for longer than 72 hours without approval of investigator.

- Cimetidine.

- Flurazepam.

- Indomethacin.

- Ranitidine.

- Probenecid.

- Drugs causing anemia, neutropenia, or significant risk of nephrotoxicity.

- Prophylaxis or chronic suppression of herpes simplex.

- Treatment of herpes simplex virus cutaneous disease more often than once a month for 5
- 7 days.

Concurrent Treatment:

Excluded:

- Radiation therapy for treatment of Kaposi's sarcoma lesions.

The following patients will be excluded from the study:

- Patients with a history of any AIDS-defining opportunistic infection.

- Patients with any of the following constitutional symptoms with no etiology
established:

- Temperature more than 38 degrees and/or drenching night sweats for more than 1 month;
watery diarrhea for 2 or more weeks; weight loss of more than 10 percent.

- Patients with a history of other systemic malignancies or lymphomas.

Prior Medication:

Excluded:

- Systemic antineoplastic chemotherapy.

- Zidovudine (AZT).

- Excluded within 30 days of study entry:

- Antiretroviral agents.

- Immunomodulating agents.

- Prophylaxis for Pneumocystis carinii pneumonia.

- Prophylaxis for herpes simplex virus infections.

- Any other experimental therapy.

Prior Treatment:

Excluded within 30 days of study entry:

- Any experimental therapy.

- Active substance abuse.

Overall Status: Completed
Phase: Phase 3

NCTID: NCT00001006
Intervention Type: Drug
Intervention Name: AS-101
Title: A Study of AS-101 in Patients With AIDS or AIDS Related Complex (ARC)
Condition: HIV Infections

Eligibility Criteria: Inclusion Criteria

Concurrent Medication:

Allowed:

- Inhaled pentamidine for Pneumocystis carinii pneumonia (PCP) prophylaxis.
- Ketoconazole.
- Standard outpatient therapy for infections developing during the trial.
- Oral acyclovir for up to 7 days.

Patients must have:

- Antibody to HIV by ELISA.
- AIDS or AIDS related complex (ARC).
- T4 cell count < 400 cells/mm3 on 2 determinations at least 72 hours apart.

Prior Medication:

Allowed:

- Inhaled pentamidine for Pneumocystis carinii pneumonia (PCP) prophylaxis.
- Ketoconazole.
- Oral acyclovir for up to 7 days.

Exclusion Criteria

Co-existing Condition:

Patients with the following conditions or symptoms are excluded:

- Active opportunistic infection or malignancy requiring concurrent treatment.
- Serious medical problems, such as diabetes, renal disease, ASHD, or hypertension, which would complicate interpretation of treatment results.
- Transfusion requirements exceeding 2 transfusions per month in order to achieve hemoglobin > 9 g/dl.

Concurrent Medication:

Excluded:

- Treatment for active opportunistic infection or malignancy.
- Systemic antiviral preparations.
- Immunosuppressive agents.
- Immunostimulation therapy.

- Specific therapy for Kaposi's sarcoma or other malignancies.

Concurrent Treatment:

Excluded:

- More than 2 units of red blood cell transfusions per month in order to achieve hemoglobin > 8 g/dl.

Patients unlikely or unable, for reasons such as distance from the hospital or psychological considerations, to comply with the requirements of the protocol, especially in regard to regular attendance for treatment, are excluded.

Prior Medication:

Excluded:

- Systemic antiviral preparations.
- Isoprinosine.
- Excluded with 1 month of study entry:
- Immunosuppressive agents.
- Immunomodulators.

Prior Treatment:

Excluded:

- Immunostimulation therapy, such as BCG vaccine.

Active drug or alcohol abuse.

Overall Status: Completed
Phase: Phase 1

NCTID: NCT00001000
Intervention Type: Drug
Intervention Name: Ampligen
Title: A Study of Atvogen in Healthy Volunteers and HIV-Infected Patients Who Have No Symptoms of Infection
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Patients' general good health should be determined by screening history, physical examination, and laboratory tests including CBC with differential, erythrocyte sedimentation rate, urinalysis, SMA-24, and drug screen within the established limits of normal for the hospital laboratory.

Exclusion Criteria

Co-existing Condition:

The following subjects will be excluded from the study:

- Smokers.

- Volunteers who have ingested alcohol 48 hours prior to the study.

- Volunteers with clinically apparent viral disease or other illnesses, including allergies, within 2 weeks prior to the study or conditions which predispose them to chronic immune stimulation.

Concurrent Medication:

Excluded:

- All medications.

The following subjects will be excluded from the study:

- Smokers.

- Volunteers who have ingested alcohol 48 hours prior to the study.

- Volunteers with clinically apparent viral disease or other illnesses, including allergies, within 2 weeks prior to the study or conditions which predispose them to chronic immune stimulation.

Prior Medication:

Excluded within 2 weeks of study entry:

- All medications.

Recent history of drug or alcohol abuse.
Overall Status: Completed
Phase: nan

NCTID: NCT00000993
Intervention Type: Drug
Intervention Name: Zidovudine
Title: A Study of Zidovudine in the Prevention of HIV Infection in Individuals Exposed to the Virus
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Participant must be HIV-negative at entry and source must be HIV-positive. The source should be documented to be infected with HIV by one of the following criteria:

- Clinical diagnosis of AIDS or ARC.

- Positive test for HIV antibody (both ELISA and Western blot) or presence of HIV p24 antigen in serum.

- Participant may be enrolled if the source of exposure is suspected of being infected with HIV (member of risk group, some type of symptom of HIV infection), but the source must be confirmed to be infected with HIV for the participant to remain in the study.

- Significant exposure within 5 days prior to beginning therapy,

defined as one of the
following:

- Research laboratory workers or auxiliary personnel who, during the course of their
work, were exposed to high titers of virus on abraded skin or mucous membranes or were
accidentally inoculated with high titers of cell-associated or free virus through an
exposed wound or puncture.

- Organ transplant recipients from HIV-positive donor.

- Recipients of blood or blood products from HIV-positive donor.

- Women who have been artificially inseminated with semen from HIV-positive donor.

- Other sources of exposure considered appropriate by the principal investigator and the
sponsor.

- Persons with poor health (such as renal, hepatic, or bone marrow insufficiency) will
be evaluated on a case-by-case basis.

Exclusion Criteria

Prior Medication:

Excluded within 4 weeks of study entry:

- Treatment with any potentially myelosuppressive drug.

- Nephrotoxic agents.

- Other experimental therapy.

Prior Treatment:

Excluded within 1 month of study entry:

- Blood transfusion with evidence of compromised blood marrow function.

Patients may not have any of the following:

- History of a malignancy other than cutaneous basal cell or cervical carcinomas.

- Significant, chronic underlying medical illness which, in the physician's judgment,
would impair study completion.

- Liver dysfunction with bilirubin > 5 x ULN, alkaline phosphatase > 5 x upper limit of
normal, or SGPT > 5 x upper limit of normal.

- Compromised bone marrow function with hemoglobin < 11 g/dl or blood transfusion within
the last month, granulocytes < 1500 cells/mm3, or platelets < 100000/mm3.

When possible, no other concomitant medication will be administered

during the treatment
period.

Prior diagnosis of HIV infection by one of the following criteria:

- HIV antibody positive by ELISA or Western blot assays.

- HIV p24 antigen positive.

- Clinical symptoms which lead to a diagnosis by a licensed physician of AIDS / AIDS
related complex (ARC) / AIDS dementia.

Active drug or alcohol abuse sufficient in the investigators' opinion to prevent compliance
with the study regimen.
Overall Status: Completed
Phase: nan

NCTID: NCT00000999
Intervention Type: Drug
Intervention Name: Zidovudine
Title: The Safety and Effectiveness of Zidovudine (AZT) in the Treatment of HIV Infection in Patients With AIDS and Advanced ARC
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Concurrent Medication:

Allowed:

- For fever control and mild analgesia, modest doses of aspirin or nonprescription doses
of ibuprofen may be used with caution; prolonged (> 72 hours) administration is not
advised without dose supervision.

Patients must have a documented history of positive HIV antibody by ELISA, or positive
result by ELISA at study entry and be in one of the following categories:

- AIDS patients recovered from one or more episodes of categorically confirmed
Pneumocystis carinii pneumonia (PCP) who were previously enrolled in the zidovudine
(AZT) treatment IND protocol.

- Patients who qualify for AZT under the labeling:

- (a) patients with a prior episode of cytologically confirmed PCP; (b) patients with a
prior episode of any other AIDS defining opportunistic infection and < 200 T4 cells;
(c) patients with advanced AIDS related complex (ARC) as defined by the clinical
diagnosis of mucocutaneous candidiasis and/or unexplained weight loss (= or > 15 lbs
or > 10 percent of total body weight within the previous 3 months) and < 200 T4 cells
and one or more of the following symptoms:

- (1) fever > 100 degrees F without infectious cause of > 3 weeks duration; (2) clinical

diagnosis of hairy leukoplakia; (3) herpes zoster infection within 3 months of entry;
(4) unexplained diarrhea after 3 samples eliminating ova, parasites, cryptosporidia,
and Mycobacterium avium-intracellulare.

Note:

- Kaposi's sarcoma without any of the symptoms listed above, regardless of total T4
lymphocyte count, does not constitute an indication for AZT treatment under the
labeling.

Exclusion Criteria

Co-existing Condition:

- Patients whose symptoms do not fit into the categories described in Disease Status and
General Inclusion Criteria are excluded.

Concurrent Medication: Excluded:

- Acetaminophen.

Overall Status: Completed
Phase: Phase 1

NCTID: NCT00001011
Intervention Type: Drug
Intervention Name: Zidovudine
Title: The Safety and Effectiveness of Zidovudine in the Treatment of Patients With Early AIDS Related Complex
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

- Patients must have a positive antibody to HIV confirmed by a federally licensed ELISA
test kit.

- The CD4 cell count must be 201 - 799 cells/mm3 measured on two separate occasions
within 60 days at least 72 hours apart prior to study entry (at least 1 of 2 counts
and the mean must be < 800 cells/mm3, and at least 1 of 2 counts and the mean must be
> 200 cells/mm3). The last count must be within 14 days of study entry.

Concurrent Medication:

Allowed:

- Acetaminophen and acetaminophen products but use should be minimized. Continuous use
for > 72 hours is discouraged.

- Aerosolized pentamidine.

Prior Medication:

Allowed:

- Chemoprophylaxis for Pneumocystis carinii pneumonia with

aerosolized pentamidine of
300 mg every 4 weeks through the Respirgard II nebulizer if patient has CD4(+) count <
200 cells/mm3 measured on 2 determinations at least 48 hours apart.

Exclusion Criteria

Concurrent Medication:

Excluded:

- Other antiretroviral agents, biologic modifiers or corticosteroids.
- Other experimental medications.
- Systemic chemoprophylaxis of Pneumocystic carinii pneumonia (PCP) - aerosolized
pentamidine is allowed.

Prior Medication:

Excluded:

- Zidovudine (AZT).
- Other antiretroviral agents.
- Excluded within 30 days of study entry:
- Biologic modifiers or corticosteroids.
- Excluded within 60 days of study entry:
- Ribavirin.

Prior Treatment:

Excluded within 30 days of study entry:

- Blood transfusions.

Patients may not have any of the following diseases or symptoms:

- Active oral candidiasis at entry.
- An opportunistic infection or malignancy fulfilling the definition of AIDS (CDC
Surveillance Case Definition for Acquired Immunodeficiency Syndrome).
- Temperature > 38.5 degrees C persisting for > 14 consecutive days or > 15 days in a
30-day interval present at entry.
- Chronic diarrhea defined as = or > 3 liquid stools per day, persisting for > 14 days
without a definable cause during the past 2 years.
- HIV neurologic disease as manifested by motor abnormalities including impaired rapid
eye movements or ataxia; motor weakness in the lower extremities; sensory deficit
consistent with a peripheral neuropathy; bladder or bowel incontinence.

- Concurrent neoplasms other than basal cell carcinoma of the skin or in situ carcinoma of the cervix.

- Subjects with hemophilia should be evaluated and treated under the hemophilia protocols, if available at that ACTG.

Patients may not have any of the following diseases or symptoms:

- Active oral candidiasis at entry.

- An opportunistic infection or malignancy fulfilling the definition of AIDS (CDC Surveillance Case Definition for Acquired Immunodeficiency Syndrome).

- Temperature > 38.5 degrees C persisting for > 14 consecutive days or > 15 days in a 30-day interval present at entry.

- Chronic diarrhea defined as = or > 3 liquid stools per day, persisting for > 14 days without a definable cause during the past 2 years.

- HIV neurologic disease as manifested by motor abnormalities including impaired rapid eye movements or ataxia; motor weakness in the lower extremities; sensory deficit consistent with a peripheral neuropathy; bladder or bowel incontinence.

- Concurrent neoplasms other than basal cell carcinoma of the skin or in situ carcinoma of the cervix.

- Subjects with hemophilia should be evaluated and treated under the hemophilia protocols, if available at that ACTG.

Active drug or alcohol abuse.
Overall Status: Completed
Phase: Phase 3

NCTID: NCT00001009
Intervention Type: Drug
Intervention Name: Dextran sulfate
Title: A Study of Dextran Sulfate in HIV-Infected Patients and in Patients With AIDS or AIDS Related Complex (ARC)
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Concurrent Medication:

Allowed:

- Aerosolized pentamidine for prophylaxis of Pneumocystis carinii pneumonia (PCP).

- Acetaminophen.

- Ketoconazole.

Consistently positive serum HIV p24 antigen = or > 70 picograms/ml, defined by the Abbott HIV antigen test, on two occasions, each within 1 month prior to entry, separated by at least 72 hours, the last of which must be within 2 weeks of starting therapy. Positive antibody to HIV with a federally licensed ELISA test kit.

Exclusion Criteria

Patients with any negative HIV p24 antigen test within 1 month of entry are excluded.
Hemophiliacs are excluded.

Prior Medication:

Excluded within 4 weeks of study entry:

- Biologic response modifiers.

- Zidovudine (AZT) or other antiretroviral agents.

- Other investigational drugs.

- Excluded within 12 weeks of study entry:

- Ribavirin.

- Excluded:

- Ongoing therapy and/or prophylaxis for an AIDS-defining opportunistic infection.

- Anticoagulant drugs.

- Systemic corticosteroids.

- Aspirin.

- Dextran sulfate.

- Sedatives.

- Barbiturates.

Prior Treatment:

Excluded within 2 weeks of study entry:

- Transfusion.

Severe diarrhea:

- = or > 5 loose or watery stools per day. Significant malabsorption:

- > 10 percent weight loss within past 3 months with serum carotene < 75 IU/ml or vitamin A < 75 IU/ml. Transfusion dependent:

- Requiring 2 units of blood > once a month. Active opportunistic infection. Symptomatic visceral Kaposi's sarcoma (KS), progression of KS within 1 month of entry, or concurrent neoplasms other than KS. Basal cell carcinoma of the

skin or in situ
carcinoma of the cervix. Hemorrhagic diseases such as hemophilia A or B or von
Willebrand disease.

Active drug or alcohol abuse sufficient in the investigator's opinion to prevent adequate
compliance with study therapy.
Overall Status: Completed
Phase: Phase 1

NCTID: NCT00001012
Intervention Type: Drug
Intervention Name: AL 721
Title: A Study of AL721 in HIV-Infected Patients With Swollen Lymph Nodes
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

- Persistent generalized lymphadenopathy (PGL) (CDC-Group III), defined as palpable
lymphadenopathy (nodes of 1 cm or greater) at two or more noncontiguous extrainguinal
sites persisting for > 3 months in the absence of an illness other than HIV infection
to account for the findings.

- AIDS related complex (ARC), defined as the presence of at least one of the following
findings within 12 months prior to entry and the absence of a concurrent illness or
condition other than HIV infection to explain the findings:

- Any findings which define CDC-Group IV A.

- History of any one of the findings that define CDC-Group IV C2.

- Patients with any of the ARC symptoms can also have PGL and be enrolled in the
protocol as ARC patients.

- A positive antibody to HIV by any federally licensed ELISA test kit within 30 days of
entry.

Concurrent Medication: Allowed:

- Topical or oral antifungal, antiviral, or antibiotic agents to treat oral candidiasis,
herpes simplex, herpes zoster, or bacterial infections that develop during the course
of the study.

Exclusion Criteria

- Exclude hemophiliacs.

- Active substance abuse.

- Alcohol consumption should be kept to a minimum.

Co-existing Condition:

Patients with the following will be excluded:

- Hemophilia.

- History or presence of an AIDS-defining opportunistic infection or malignancy.

- AIDS related complex (ARC) patients with prior (within the last 12 months) or current history of diarrhea defined as = or > 3 liquid stools per day persisting for longer than 1 month.

- Significant malabsorption:

- Greater than 10 percent weight loss within past 3 months with serum carotene < 75 IU/ml or vitamin A < 75 IU/ml.

- Significant cardiac, liver, renal, or neurologic disorder.

- Active ARC-defining secondary infection (oral candidiasis, oral hairy leukoplakia, multidermatomal herpes zoster, recurrent nontyphoidal Salmonella bacteremia or Nocardiosis) undergoing therapy or prophylaxis within 7 days of study entry.

- Active tuberculosis under treatment.

- Concurrent neoplasm other than basal cell carcinoma of the skin or in situ carcinoma of the cervix.

Concurrent Medication:

Excluded:

- Any medication that will interfere with the assessment of AL-721, including nutritional supplements, vitamins, laxatives, and over-the-counter products containing lecithin.

- Chemoprophylaxis for Pneumocystis carinii (PCP), candida, herpes simplex, herpes zoster infections, or bacterial infections.

- Intravenous topical or oral antifungal, antiviral, or antibiotic agents to treat oral candidiasis, herpes simplex, herpes zoster, or bacterial infections that develop during the course of the study.

- Systemic chemotherapy.

Prior Medication:

Excluded within 30 days of study entry:

- Any investigational drug.

- Biologic response modifiers.

- Corticosteroids.

- Chemotherapeutic agents.

- Excluded within 90 days of study entry:

- Any antiretroviral agent or AL-721.

Overall Status: Completed
Phase: Phase 1

NCTID: NCT00001071
Intervention Type: Drug
Intervention Name: Filgrastim
Title: A Study of Stem Cells and Filgrastim
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Concurrent Medication:

Allowed:

- PCP prophylaxis.

- Antiretroviral therapy in patients with CD4 counts <= 500 cells/mm3.

- Narcotic analgesics for grade 3/4 bone pain toxicity.

Patients must have:

- HIV infection.

- HIV infected patients with CD4 count > 500 cells/mm3 must be asymptomatic. Patients with CD4 count 200-500 cells/mm3 may be either asymptomatic or symptomatic but must not have AIDS. Patients with CD4 count < 200 cells/mm3 may or may not have AIDS-defining conditions.

- No antiretroviral therapy within the past 30 days in patients with asymptomatic disease and CD4 count > 500 cells/mm3.

- Stable antiretroviral therapy for the past 60 days if CD4 count <= 500 cells/mm3.

- Suitable venous access.

Prior Medication:

Allowed:

- Prior antiretroviral therapy.

Exclusion Criteria

Co-existing Condition:

Patients with the following symptoms or conditions are excluded:

- Current malignancy.

- Any medication condition that interferes with study evaluation.

- Known hypersensitivity to E. coli-derived proteins (e.g., insulin,

human growth
hormones).

Concurrent Medication:

Excluded:

- Acute treatment for serious opportunistic infection.

- Systemic cytotoxic chemotherapy.

Concurrent Treatment:

Excluded:

- Systemic radiation therapy.

Patients with the following prior conditions are excluded:

- Prior malignancy.

- Leukapheresis or lymphopheresis within the past 180 days.

- Significant active CNS disease or seizures within the past year.

Prior Medication:

Excluded:

- G-CSF or GM-CSF within the past 6 months.

- Investigational antiretrovirals within the past 30 days.

- Treatment for opportunistic infection within the past 14 days.

Active alcohol or substance abuse.
Overall Status: Completed
Phase: nan

NCTID: NCT00001068
Intervention Type: Drug
Intervention Name: Lamivudine
Title: A Study of Disease Progression and Anti-HIV Treatments
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Patients must have:

- Prior participation on protocol ACTG 175.

PER AMENDMENT 8/27/96:

- Patients must be on study/on treatment at the time the protocol study treatment is
extended.
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00001070
Intervention Type: Drug
Intervention Name: Oral Vitamin C
Title: The Safety and Effectiveness of Different Doses of Vitamin C in HIV-Infected Patients
Condition: HIV Infections

Eligibility Criteria: nan
Overall Status: Withdrawn
Phase: nan

NCTID: NCT00001064
Intervention Type: Drug
Intervention Name: Allogenic Dendritic Cells
Title: A Pilot Study of Immunization With HIV-1 Antigen Pulsed Allogenic Dendritic Cells in HIV-Infected Asymptomatic Patients With CD4+ T Cells > 350 Cells/mm3
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Patients must have:

- HLA A2+.
- Same cell type as donor sibling.
- CD4 count > 350 cells/mm3.
- HIV asymptomatic status.
- No HIV antivirals during study.
- Normal labs and chest x-ray.

Donor siblings must have:

- HLA A2+.
- HIV negativity.
- Ability to donate cells on multiple occasions.
- Negative status for hepatitis B and C.

Exclusion Criteria

Concurrent Medication:

Excluded:

- Antiviral therapy (unless CD4 count declines to < 350 cells/mm3).

Prior Medication:

Excluded:

- Antiviral therapy within 90 days prior to study entry.

Overall Status: Terminated
Phase: nan

NCTID: NCT00001105
Intervention Type: Drug
Intervention Name: F105 Monoclonal Antibody (Human)
Title: The Safety and Effectiveness of Human Monoclonal Antibody, F105, in the Treatment of HIV
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Concurrent Medication:

PART B ONLY. Allowed:

- Concomitant AZT or other antiretroviral drugs if patient is on a stable dose of such therapy within 3 months prior to study entry.

Patients must have:

- Documented HIV-1 infection.

- CD4 count 200 - 500 cells/mm3 (Part A) or <= 400 cells/mm3 (Part B, per amendment).

- No diagnosis of AIDS (Part A only, per amendment).

- Life expectancy of at least 6 months.

Part B patients only (per amendment):

- Primary (viral) isolates sensitive to F105 antibody using the yield reduction assay currently under development by ACTG, determined within 15-90 days prior to study entry.

- Plasma viremia by qualitative plasma culture.

- NO active opportunistic infection within 6 weeks prior to drawing of first isolate.

- NO AIDS-related malignancy other than minimal Kaposi's sarcoma.

Prior Medication:

Allowed:

- Prior AZT or other nucleoside antiviral agents.

Exclusion Criteria

Co-existing Condition:

Patients with the following symptoms or conditions are excluded:

- Evidence of active renal disease as manifested by sediment containing red or white cell casts.

Concurrent Treatment:

Excluded:

- Red cell transfusions administered to maintain hemoglobin at acceptable level or alleviate symptoms of anemia.

Prior Medication:

Excluded within 6 weeks prior to study entry:

- Intravenous gamma globulin.

- Chemotherapy.

- Corticosteroids.

- Other experimental therapy.

EXCLUDED IN ALL PATIENTS:

- Immunosuppressive treatments, cytokine therapy, or biologic response modifiers not included in this study, including interferons or adjuvant treatment for chronic and severe fungal infections such as cryptococcal meningitis.

- Intravenous gamma globulin.

- Chemotherapy.

- Corticosteroids.

- Other experimental therapy.

- G-CSF, GM-CSF, or erythropoietin.

EXCLUDED IN PART A ONLY:

- Drugs known to enhance or block metabolism of other drugs.

EXCLUDED IN PART B ONLY:

- AZT or other antiretroviral drugs IF INITIATED during or within 1 month after completion of study.

Active alcohol or drug abuse that may compromise ability to comply with study requirements.
Overall Status: Completed
Phase: Phase 1

NCTID: NCT00001104
Intervention Type: Drug
Intervention Name: Zidovudine
Title: A Study of Zidovudine in HIV-Infected Patients Who Have Hemophilia
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Concurrent Medication:

Allowed with caution for Study A:

- Hepatotoxic drugs.

Patients in Study A must have:

- Hemophilia with no symptoms for AIDS. Most patients will have well-established factor 8 or 9 deficiency. However, patients with other coagulation diseases, such as factor 5 deficiency, and von Willebrand disease, will also be acceptable for the study.

Wives in Study B are included even if they are known to be seropositive or are not sexually active at the time the study starts.

Prior Medication:

Allowed for Study A:

- Patients who were on the Phase I ZDV study, ACTG 017, or are on ACTG 062 may enter after waiting 3 weeks.

Exclusion Criteria

Co-existing Condition:

Patients in Study A with the following symptoms or conditions are excluded:

- AIDS-defining illness.

- Severe ARC.

- Severe or prolonged toxicity.

Concurrent Medication:

Excluded for Study A:

- Isoniazid or rifampin.

- Treatment for Pneumocystis carinii pneumonia (PCP), oral candidiasis, and localized cutaneous herpes simplex or zoster infections.

- Probenecid.

- Aspirin on a regular basis, or for more than 72 hours without contacting the investigator.

- Drugs causing neutropenia or significant risk of nephrotoxicity.

Patients in Study A with the following prior conditions are excluded:

- AIDS-defining opportunistic infection or malignancy.

- Unexplained temperature greater than 38 C for more than 5 consecutive days or more than 10 days in any 30-day period in the 2 years prior to entry.

- Unexplained diarrhea defined as three or more liquid stools per day, persisting more than 7 days within 2 years prior to entry.

- Unintentional weight loss of greater than 10 lbs. or more than 10 percent of usual body weight within 2 years prior to study entry.

- Oral hairy leukoplakia at any time prior to entry.

- Oral candidiasis unrelated to the use of antibiotic therapy for more than 2 weeks within 2 years prior to entry or within the past 3 months.

- Herpes zoster within 2 years prior to entry into the study.

Prior Medication:

Excluded for Study A:

- Antiretroviral agents, including ZDV, ribavirin, HPA-23, rifampin, AL721 within 8 weeks of study entry.

- Significant course of immunomodulating agents such as steroids (greater than 1 week), isoprinosine, thymic factors within 3 months of study entry.

- Any other experimental therapy within 3 months of study entry.

Discouraged but not forbidden for Study B:

- Sexual contact with infected husband.

Overall Status: Completed
Phase: Phase 3

NCTID: NCT00001118
Intervention Type: Drug
Intervention Name: Enfuvirtide
Title: Study of a New Anti-HIV Drug, T-20, in HIV-Infected Children
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Children may be eligible for this study if they:

- Are 3 to 12 years old (consent of parent or guardian required).

- Are HIV-positive.

- Are receiving combination anti-HIV therapy. He/she must have been taking this combination for at least 16 weeks, and it must include either 2 NRTIs alone or 2 NRTIs plus either an NNRTI or a PI. (This study has been changed. This no longer has to be a child's first anti-HIV drug combination.)

- Have a viral load greater than 10,000 copies/ml while taking this anti-HIV drug combination.

- Have never received treatment with a PI or an NNRTI. (One or two doses are allowed.)

- Have never taken at least 1 NRTI.

Exclusion Criteria

Children will not be eligible for this study if they:

- Are receiving treatment for an opportunistic (AIDS-related) or serious bacterial infection at the time of study entry.

- Are receiving chemotherapy for cancer.

- Have certain serious diseases (other than HIV) or conditions.

- Have received or are currently receiving certain medications.

- Are pregnant.

Overall Status: Completed
Phase: Phase 1

NCTID: NCT00001116
Intervention Type: Drug
Intervention Name: Tumor Necrosis Factor soluble receptor-immunoadhesin complex
Title: A Study to Evaluate the Ability of TNFR:Fc to Decrease the Amount of IL-6 (Interleukin-6) and TNF-alpha (Tumor Necrosis Factor) in HIV-Infected Patients
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

You may be eligible for this study if you:

- Are HIV-positive.

- Are enrolled in ACTG 328.

- Agree to practice abstinence or use barrier methods of birth control during the study.

- Are at least 18 years old.

Exclusion Criteria

You will not be eligible for this study if you:

- Have any active opportunistic (HIV-associated) infections.

- Have any medical condition or psychological issue that would interfere with study
requirements.

- Are pregnant or breast-feeding.

- Are receiving any experimental drug other than IL-2.

- Are receiving certain other medications.
Overall Status: Completed
Phase: nan

NCTID: NCT00001132
Intervention Type: Drug
Intervention Name: Abacavir sulfate
Title: Effectiveness of the Early Addition of Abacavir to an Anti-HIV Drug Combination
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Patients may be eligible for this study if they:

- Are HIV-positive.

- Have been taking anti-HIV therapy that includes at least 3 anti-HIV drugs and is an
acceptable anti-HIV drug combination for 60 to 104 days before study treatment.
Patients must not have changed any of the drugs in the 28 days before study entry.
(This study has been changed by extending the number of days that anti-HIV therapy has
been received.)

- Have a viral load greater than 500 but less than or equal to 10,000 copies/ml and have
had a significant decrease in viral load between 49 and 84 days after starting this

anti-HIV therapy. (This study has been changed by extending the length of time of viral load decrease.)

- Are at least 13 years old (consent of parent or guardian required if under 18).

- Agree to practice abstinence or use barrier method of birth control (such as condoms) during the study and for 3 months after.

Exclusion Criteria

Patients will not be eligible for this study if they:

- Have ever taken ABC.

- Have received anti-HIV therapy for more than 104 days in the past. (This study has been changed by extending the number of days that anti-HIV therapy has been received.)

- Have a fever for 7 days in the 30 days before study entry.

- Have cancer, including Kaposi's sarcoma, that requires chemotherapy.

- Have an active infection that requires treatment in the 21 days before study entry.

- Have any opportunistic (AIDS-related) infection or disease that requires a change in medication in the 14 days before study entry.

- Have any medical condition or history of an illness that the doctor feels would place them at risk or make them unable to complete the study.

- Are taking drugs that affect the immune system or any experimental anti-HIV drugs, except for their current drug combination.

- Are taking St. John's wort. (This study has been changed. Previously, patients taking St. John's wort were eligible.)

- Have received a vaccine in the 21 days before study entry.

- Are pregnant or breast-feeding.

Overall Status: Completed
Phase: Phase 2

NCTID: NCT00001282
Intervention Type: Drug
Intervention Name: Zidovudine (AZT) & Interleukin-2 (IL2)
Title: A Phase I/II Study of the Combination of Azidothymidine and Interleukin-2 (IL-2) in the Treatment of HIV-Infected Patients
Condition: HIV Infection
Eligibility Criteria: Laboratory values Grade 0 or 1.

Hemoglobin greater than 9 g/dl; neutrophil count greater than 1,000 cells/mm(3) permitted for patients with CD4 counts under 200 cells/mm(3).

No therapy with corticosteroids, chemotherapy, or experimental therapy other than IL-2 in the prior 4 weeks.

Willing and able to take AZT. Therapy with dideoxyinosine or dideoxycytidine will not be permitted.

Any approved anti-retroviral drug can be administered, either alone or in combination.

Delavirdine (U90152S), 400 mg tid, permitted as an antiretroviral agent, either alone or in combination with currently approved antiretroviral agents.

Patients must not have a malignancy other than Kaposi sarcoma.

Patient must not have concurrent opportunistic infection other than oropharyngeal candidiasis or HSV. Patients may have CD4 counts less than 200 cells/mm(3) with a concurrent opportunistic infection, but the patient must be responding to at least 2 weeks of therapy or no effective therapy can be available.

Patients must not abuse substances.

Patients must not have significant cardiac, pulmonary, rheumatologic, autoimmune, or CNS disease.

Home - patient must be enrolled and in good standing on a current NIAID protocol involving the use of IL-2 therapy. The patient must already have undergone at least one year of treatment on the protocol during with IL-2 therapy has been given, including at least 2 well-tolerated outpatient cycles of scIL-2 at a stable dose.

Home - The patient must have a history of generally tolerable side effects while receiving IL-2 that did not require frequent medical interventions, intravenous fluid replacement, and/or IL-2 dose reductions. Conditions generally not suitable for home scIL-2 administration would include (but are not limited to) an unusually heavy requirement for narcotic usage during a cycle, significant urticaria (hives) or other allergic conditions, and any history of possible airway compromise due to throat swelling.

Home - Patient must not have experienced any serious (grade 3 or higher) clinical or laboratory abnormalities of medical significance during days 0-5 of the last 2 outpatient scIL-2 cycles.

Home -The patient must have a strong relationship with a private physician or health-care provider at home who has demonstrated close involvement in the patient's care to date and who would be willing to help supervise a patient's care during each home scIL-2 cycle. Because of the need to identify a single health-care provider at home

who will agree to be
available to render care (if needed) during a patient's scIL-2 cycle, patients who
currently receive their home care from rotating staff members in a general clinic setting
may not be eligible for home scIL-2 administration. A signed written statement
acknowledging willingness to participate in monitoring must be received by the clinic 8
study team from the private physician or health-care provider prior to the first home
scIL-2 cycle. In addition, communication must occur between your clinic 8-study team and
the designated physician or health-care provider prior to each subsequent cycle to confirm
that individual's continued willingness to serve as on-site provider for any serious
medical conditions that might develop during a cycle.

Home - The patient must live at a home address with easy access to a telephone and must
have demonstrated reliability in responding to telephone calls from clinic 8 staff members.
The patient must also be able to provide the study team with reliable contact information
for a close family member or friend who will agree to serve in the capacity of a
"care-giver" during each cycle: i.e. someone who will be able to render non-medical
assistance to the patient and be able to check on their condition daily in the event that
emergency medical assistance needs to be summoned. It will become the patient's
responsibility to ensure that the local "care-giver" communicates their willingness to
serve in this capacity by telephoning the clinic 8-study team prior to each cycle.

Home -The patient must have "reasonable" (i.e. rapid and close) access at home to emergency
medical services and a nearby medical facility in the event of a medical crisis. The
suitability of the at-home situation will be assessed on a case-by-case basis by the clinic
8-study team.

Home - The patient must have demonstrated reliability and consistency in sterile technique,
the reconstitution of IL-2 vials, and the administration of scIL-2 injections.

Home - The patient must be receiving outpatient scIL-2 cycles at least once every 6 months
as part of their normal protocol participation, except at the discretion of the study team.

Home - The patient must have access to a reliable home weight scale and be able to weigh
themselves accurately on a daily basis for the purposes of safety monitoring.
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00001298

Intervention Type: Drug
Intervention Name: carboxypeptidase-G2
Title: A Trial of Carboxypeptidase-G2 (CPDG2) and Thymidine for the Management of Patients With Methotrexate Toxicity and Renal Dysfunction
Condition: Kidney Diseases
Eligibility Criteria: Patients of any age at risk for life-threatening toxicity following MTX administration
secondary to delayed drug excretion as defined by:

Plasma MTX concentration at least 10 micromoles/liter more than 42 hours after the start of
the MTX infusion; OR

Creatinine at least 1.5 times the upper limit of normal or creatinine clearance less than
60 ml/sqm/min and delayed MTX excretion documented by plasma MTX concentration measurements
(at least 2 standard deviations above the mean) at least 12 hours following MTX
administration.
Overall Status: Completed
Phase: Phase 1

NCTID: NCT00001357
Intervention Type: Drug
Intervention Name: Interleukin-2
Title: Subcutaneously Administered Interleukin-2 Therapy in HIV-Infected Patients
Condition: HIV Infection
Eligibility Criteria: 18 years of age or older with positive HIV-1 ELISA and Western blot.

CD4+ cell counts greater than or equal to 350 cells/mm(3).

No prior IL-2 therapy.

No antiretroviral therapy for 6 weeks prior to study entry.

Willingness to remain off antiretrovirals for 12 months or until a protocol defined
recommendation or required change is determined.

No therapy with systemic corticosteroids, chemotherapy, or experimental therapy in the 4
weeks prior to entry on study.

SGOT less than or equal to 150 microliter/l; Hgb greater than 10 gm/dl; Granulocyte count
less than or equal to 1,000/mm(3); T. bilirubin less than or equal to 2.0 mg/dl; Serum
creatinine less than or equal to 2.0 mg/dl; Proteinuria less than or equal to 1+; platelet
count greater than 75,000.

No history of AIDS-defining opportunistic infection, or malignancy other than mucocutaneous
Kaposi sarcoma.

No significant cardiac, pulmonary, kidney, rheumatologic, gastrointestinal, psychiatric, or
neurological disease.

No pregnancy or breastfeeding.

No avascular necrosis of the bone.

Patient must be fully informed of the known benefits of antiretroviral therapy.

HOME PATIENTS:

Patient must be enrolled and in good standing on a current NIAID protocol involving the use of IL-2 therapy. The patient must already have undergone at least one year of treatment on the protocol during which IL-2 therapy has been given, including at least 2 well-tolerated outpatient cycles of scIL-2 at a stable dose.

The patient must have a history of generally tolerable side effects while receiving IL-2 that did not require frequent medical interventions, intravenous fluid replacement, and/or IL-2 dose reductions. Conditions generally not suitable for home scIL-2 administration would include (but are not limited to) an unusually heavy requirement for narcotic usage during a cycle, significant urticaria (hives) or other allergic conditions, and any history of possible airway compromise due to throat swelling.

Patient must not have experienced any serious (grade 3 or higher) clinical or laboratory abnormalities of medical significance during days 0-5 of the last 2 outpatient scIL-2 cycles.

The patient must have a strong relationship with a private physician or health-care provider at home who has demonstrated close involvement in the patient's care to date and who would be willing to help supervise a patient's care during each home scIL-2 cycle. Because of the need to identify a single health-care provider at home who will agree to be available to render care (if needed) during a patient's scIL-2 cycle, patients who currently receive their home care from rotating staff members in a general clinic setting may not be eligible for home scIL-2 administration. A signed written statement acknowledging willingness to participate in monitoring must be received by the clinic 8 study team from the private physician or health-care provider prior to the first home scIL-2 cycle. In addition, communication must occur between your clinic 8-study team and the designated physician or health-care provider prior to each subsequent cycle to confirm that individual's continued willingness to serve as on-site provider for any serious medical conditions that might develop during a cycle.

The patient must live at a home address with easy access to a telephone and must have demonstrated reliability in responding to telephone calls from clinic 8 staff members. The patient must also be able to provide the study team with reliable

contact information for a
close family member or friend who will agree to serve in the capacity of a "care-giver"
during each cycle: i.e., someone who will be able to render non-medical assistance to the
patient and be able to check on their condition daily in the event that emergency medical
assistance needs to be summoned. It will become the patient's responsibility to ensure that
the local "care-giver" communicates their willingness to serve in this capacity by
telephoning the clinic 8-study team prior to each cycle.

The patient must have "reasonable" (i.e., rapid and close) access at home to emergency
medical services and a nearby medical facility in the event of a medical crisis. The
suitability of the at-home situation will be assessed on a case-by-case basis by the clinic
8-study team.

The patient must have demonstrated reliability and consistency in sterile technique, the
reconstitution of IL-2 vials, and the preparation and administration of scIL-2 injections.

The patient must be receiving outpatient scIL-2 cycles at least once every 6 months as part
of their normal protocol participation, except at the discretion of the study team.

The patient must have access to a reliable home weight scale and be able to weigh
themselves accurately on a daily basis for the purposes of safety monitoring.
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00001474
Intervention Type: Drug
Intervention Name: Interleukin-2
Title: Pharmacodynamics of Intermittent IL-2 Infusions in HIV Seropositive Patients
Condition: HIV Infection
Eligibility Criteria: Patients must meet all the following to be eligible for study entry:

Documented HIV infection (ELISA and Western blot positive).

18 years or older.

Karnofsky performance status greater than or equal to 70.

CD4 cell count between 200 and 500 cells/mm(3).

Negative urine or serum pregnancy test within 7 days prior to study entry for women of
childbearing potential.

Patients must be receiving a stable FDA approved antiretroviral regimen for at least 2
weeks prior to study entry.

SGOT less than or equal to 150 u/l.

Total bilirubin less than or equal to 2.0 mg/dl.

Serum creatinine less than or equal to 2.0 mg/dl.

Proteinuria less than or equal to 1+.

Granulocyte count greater than or equal to 1,000/mm(3).

Hemoglobin greater than or equal to 10 gm/dl and platelet count greater than or equal to
75,000.

Patients should have a companion who is willing to monitor the outpatient infusions of
IL-2.

Patient must sign an informed consent conforming to FDA and institutional guidelines.

No prior IL-2 therapy.

No malignancy other than mucocutaneous Kaposi sarcoma.

No history of prior AIDS-defining opportunistic infection.

No current history of alcohol or substance abuse, or dependence that in the opinion of the
screening team may affect patient safety or compliance.

No patients exhibiting psychiatric or cognitive disturbance or illness, which in the
assessment of the protocol team may affect patient safety or compliance.

No clinically significant cardiac, thyroid, pulmonary, kidney or CNS impairment.

No hypertension requiring anti-hypersensitive therapy.

No use of systemic corticosteroids, chemotherapy, or experimental therapy in the prior 4
weeks.

No pregnant or lactating patients.

No patients who are likely to require treatment with G-CSF, GM-CSF, or interferons.

No patients with a history of Crohn's disease or autoimmune diseases with potentially
life-threatening complications.

No patients with avascular necrosis of the bone.

Home - patient must be enrolled and in good standing on a current NIAID protocol involving
the use of IL-2 therapy. The patient must already have undergone at least one year of
treatment on the protocol during with IL-2 therapy has been given, including at least 2
well-tolerated outpatient cycles of scIL-2 at a stable dose.

Home - The patient must have a history of generally tolerable side effects while receiving

IL-2 that did not require frequent medical interventions, intravenous fluid replacement, and/or IL-2 dose reductions. Conditions generally not suitable for home scIL-2 administration would include (but are not limited to) an unusually heavy requirement for narcotic usage during a cycle, significant urticaria (hives) or other allergic conditions, and any history of possible airway compromise due to throat swelling.

Home - Patient must not have experienced any serious (grade 3 or higher) clinical or laboratory abnormalities of medical significance during days 0-5 of the last 2 outpatient scIL-2 cycles.

Home -The patient must have a strong relationship with a private physician or health-care provider at home who has demonstrated close involvement in the patient's care to date and who would be willing to help supervise a patient's care during each home scIL-2 cycle. Because of the need to identify a single health-care provider at home who will agree to be available to render care (if needed) during a patient's scIL-2 cycle, patients who currently receive their home care from rotating staff members in a general clinic setting may not be eligible for home scIL-2 administration. A signed written statement acknowledging willingness to participate in monitoring must be received by the clinic 8 study team from the private physician or health-care provider prior to the first home scIL-2 cycle. In addition, communication must occur between your clinic 8-study team and the designated physician or health-care provider prior to each subsequent cycle to confirm that individual's continued willingness to serve as on-site provider for any serious medical conditions that might develop during a cycle.

Home - The patient must live at a home address with easy access to a telephone and must have demonstrated reliability in responding to telephone calls from clinic 8 staff members. The patient must also be able to provide the study team with reliable contact information for a close family member or friend who will agree to serve in the capacity of a "care-giver" during each cycle: i.e. someone who will be able to render non-medical assistance to the patient and be able to check on their condition daily in the event that emergency medical assistance needs to be summoned. It will become the patient's responsibility to ensure that the local "care-giver" communicates their willingness to serve in this capacity by telephoning the clinic 8-study team prior to each cycle.

Home -The patient must have "reasonable" (i.e. rapid and close) access at home to emergency medical services and a nearby medical facility in the event of a medical

crisis. The
suitability of the at-home situation will be assessed on a case-by-case basis by the clinic
8-study team.

Home - The patient must have demonstrated reliability and consistency in sterile technique,
the reconstitution of IL-2 vials, and the administration of scIL-2 injections.

Home - The patient must be receiving outpatient scIL-2 cycles at least once every 6 months
as part of their normal protocol participation, except at the discretion of the study team.

Home - The patient must have access to a reliable home weight scale and be able to weigh
themselves accurately on a daily basis for the purposes of safety monitoring.
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00001567
Intervention Type: Drug
Intervention Name: Roferon-A
Title: A Phase II Efficacy Study of Roferon-A in Hairy Cell Leukemia
Condition: Hairy Cell Leukemia
Eligibility Criteria: Age 18-70.

Patients must have morphologically identifiable hairy cells in peripheral blood and bone
marrow, or tissue biopsies with at least one of the following: 1) Positive stain for the
tartrate-resistant acid phosphatase 2) Electron microscopy compatible with hairy cells.

Patients must be ambulatory with an expected survival greater than 16 weeks and be willing
and able to give written informed consent.

Patients must have a disease that is assessable, defined by: 1) Pancytopenia 2) Bone marrow
leukemic infiltrate 3) Lymphadenopathy, splenomegaly, or hepatomegaly.

Patients must not require palliative chemotherapy, immunotherapy or hormonal therapy other
than the treatment prescribed in this protocol.

Patients must be tested for Hepatitis B surface antigen within one week of entry into this
study.

No pregnant or lactating women. No fertile men and women, unless using effective
contraception.

No patients with unstable angina. Patients with Class III or IV cardiovascular disease may
be entered only after medical clearance by a cardiology consultant.

No patients with severe intercurrent infection or patients having had surgery within the
past four weeks unless fully recovered.

No patients with impaired renal function (serum creatinine greater than 1.8).

No patients with impaired hepatic function (total bilirubin greater than 1.4).

No patients with serum calcium greater than 12 mg/dl.

No patients with a performance status less than or equal to 60% on the Karnofsky scale.

No patients who have had any prior (leukocyte or fibroblast) interferon therapy.

No patients unable to carry out the treatment program.

No patients less than 20,000 per cu mm platelets and clinical bleeding disorder; both must
be present for patient to be excluded.
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00001696
Intervention Type: Drug
Intervention Name: Genistein
Title: A Pharmacokinetic Study of Genistein, a Tyrosine Kinase Inhibitor
Condition: Cancer
Eligibility Criteria: Must be 18 years old or greater.

ECOG performance status of 0-1.

Individuals without a history of cancer are eligible, as are those with a history of
cancer. Individuals with a history of cancer (excluding non-melanomatous skin cancer) will
need to submit their pathology slides for review in the Laboratory of Pathology, NCI.

Must be able to understand and give informed consent.

Life expectancy greater than 6 months.

Hgb greater than or equal to 8.0gm/dl, platelets greater than or equal to
100,000/microliters, ANC greater than or equal to 1000/microliters, creatinine less than or
equal to 2.0/mg/dl, SGPT and SGOT less than or equal to 147 and 168 U/L, total bilirubin
less than or equal to 2 mg/dl (patients with a higher level of bilirubin due to a familial
defect in bilirubin metabolism will be considered on an individual basis).

No history of breast cancer.

No pregnant or breast feeding subjects.

Must not be HIV positive.

No history of venous thrombosis within the past year.

No medical conditions, which, in the opinion of the investigators would jeopardize either
the patient or the integrity of the data obtained.

No patients who are currently receiving active therapy for neoplastic disorders. However,
patients with prostate cancer who are on an LHRH agonist (e.g., Lupron or Zoladex), or who
have undergone surgical castration, are eligible for study.

No patients who are on estrogen therapy.

No patients taking hormonal forms of contraception.

No patients with a known soy intolerance.
Overall Status: Completed
Phase: Phase 1

NCTID: NCT00001766
Intervention Type: Drug
Intervention Name: Amprenavir, Efavirenz, Abacavir, Nelfinavir, Ritonavir
Title: Drug Interactions Among Anti-HIV Agents
Condition: HIV Infection
Eligibility Criteria: INCLUSION

Adults (greater than 18 years) infected with HIV-1.

Plasma viral burden greater than 500 RNA copies/ml by bDNA method at screening visit while
receiving a protease inhibitor as a part of combination therapy.

Treatment with a protease inhibitor or inhibitor(s) for the preceding 20 weeks with no
protease inhibitor drug change or dose interruption for greater than 3 days in the most
recent 12 weeks.

Laboratory values at screen:

hemoglobin greater than 9 g/dl;

granulocyte count greater than 900 cells/microL;

platelet count greater than 80,000 cells/microL;

AST (SGOT) less than 151 U/L;

Creatine less than 2 mg/dL.

Willingness to avoid becoming pregnant or causing a pregnancy by use of effective methods
which include surgical sterilization and barrier methods such as condoms and/or diaphragms.
Hormonal methods of birth control are not acceptable unless barrier methods are also used
because drug interactions may render their concentrations subtherapeutic.

Willing and able to provide written informed consent.

Negative serum or urine pregnancy test on the day of enrollment.

No intolerance of ritonavir or nelfinavir.

EXCLUSION

Treatment with systemic corticosteroids at greater than physiologic

replacement doses,
interleukins, interferons, radiation therapy or cytotoxic chemotherapeutic agents within 30
days of study drug administration or an anticipated need for radiation or chemotherapy
treatment within the next 48 weeks (with the exception of local treatment for Kaposi's
sarcoma).

Subjects suffering from serious medical conditions such as diabetes, congestive heart
failure, cardiomyopathy, or other cardiac dysfunction, which, in the opinion of the
investigator, would compromise the safety of the patient.

Current or anticipated therapy with other agents with documented activity against HIV-1 in
vitro (other than stable maintenance dosing of foscarnet begun prior to screening).

Prior exposure to abacavir, amprenavir or efavirenz.

Concomitant therapy at entry with corticosteroids in other than replacement doses,
chemotherapy, or investigational agents.

Active, untreated opportunistic infection or other major illness that would, in the opinion
of the investigator, increase the risk that adverse events might pose to the patient or
might render the patient too ill to return for study visits.

Lymphoma not diagnosed within 5 years of study enrollment.

Significant substance abuse or psychiatric illness that might interfere with assessment or
compliance.

Refusal to employ adequate means of birth control (non-hormonal methods); efavirenz is
potentially teratofenic and conception must be avoided.

Malabsorption or other gastrointestinal dysfunction which, in the opinion of the
investigator, might interfere with drug absorption or render the patient unable to take
oral medication.

History of serious rash (erythema multiforme or Stevens-Johnson syndrome) caused by
nevirapine or delavirdine.

Treatment with phenobarbital, rifampin, rifabutin, midazolam, astemizole, cisapride, or
triazolam unless subject is safely able to discontinue the drug(s) prior to receipt of
study medications.

Pregnancy or lactation.
Overall Status: Completed
Phase: Phase 1

NCTID: NCT00001818
Intervention Type: Drug

Intervention Name: Hydroxyurea
Title: Combination Drug Treatment of Pediatric HIV Infection
Condition: HIV Infection
Eligibility Criteria: Patients must have a diagnosis of HIV-1 infection as defined by the Centers for Disease
Control.

All patients must have availability of a parent or legal guardian able and willing to give
informed consent and comply with the requirements of the study.

Post menarchal adolescent females must have a negative urine pregnancy test within 14 days
prior to initiation of study therapy and consent to urine pregnancy testing at every visit
for the remainder of the study. If sexually active, must also be willing to use a barrier
method of contraception or willing to remain sexually abstinent during the course of the
study.

Sexually active males must agree to practice barrier contraception for the duration of the
study.

Patients must have a plasma HIV-RNA viral load of greater than or equal to 10,000 copies/ml
(4.0 log10) on 2 occasions at least 1 week apart at study entry.

Patients must be between the ages of 3 years to 21 years old and able to swallow capsules.

Patients must have an age-adjusted normal serum creatinine or a creatinine clearance
greater than or equal to 60 ml/min/1.73 m(2).

Patients must have an absolute granulocyte count greater than 1,500/mm(3), hemoglobin
greater than 8 gm/dL, and platelet count greater than 75,000/mm(3).

Patients must have an SGOT/SGPT/GGT less than 2.5 times normal unless considered to be
attributable to underlying HIV disease.

Patients must have a serum amylase less than 1.5 times the upper limit of normal. If
abnormal, a fractionated pancreatic amylase less than 45 U/L.

Immunomodulating agents such as corticosteroids for LIP, IVIG, erythropoietin, and anti-D
will be allowed.

Must not be critically ill or clinically unstable.

Must not have a history or a prior malignancy requiring active treatment within the last 2
years.

Must not have a prior history of hydroxyurea use.

Must not have the presence of an active infection requiring acute intervention at the time
of entry.

Patients receiving treatment for an infection that requires prolonged treatment must have been stable on therapy for at least 7 days prior to study entry.

Prophylaxis for PCP as well as maintenance anti-mycobacterial therapy, antifungal, and anti-viral therapy at the time of study will be allowed.

Must not currently use G-CSF or GM-CSF to maintain an adequate neutrophil count.

No evidence of active peripheral neuropathy.

No history of peripheral neuropathy of Grade III or greater severity associated with the use of antiretroviral agents.

No patients with a previous history of pancreatitis attributed to ddI.

No previous history of pancreatitis requiring total parental nutrition within 2 years of study enrollment.

Patients will be excluded if unable to tolerate antiretroviral therapy with stavudine, didanosine or efavirenz due to allergic symptoms felt to be related to these antiretroviral therapeutic agents.

Patients must not have a history of erythema multiforme or Stevens Johnson Syndrome attributable to stauvudine, didanosine or nonnucleoside RTI.

No patients with multiple circumscribed active retinal lesions characterized by alterations in retinal pigmentary epithelium consistent with didanosine toxicity.

No antiretroviral therapy within two weeks of study entry.
Overall Status: Completed
Phase: Phase 1

NCTID: NCT00001857
Intervention Type: Drug
Intervention Name: BG9588
Title: Study Comparing the Safety of BG9588 (Anti-CD40L Antibody) Against Standard Treatment in Kidney Transplantation
Condition: Kidney Transplantation
Eligibility Criteria: Must be a candidate for a renal transplant from a living related, living non-related, or cadaveric donor.

Must be willing and able to give written informed consent.

Aged between 18 and 65 years, inclusive. Subjects over the age of 65 may be considered on an individual basis based on medical suitability.

Female subjects must be post-menopausal or surgically sterile, or using an acceptable method of contraception (oral contraceptives, Norplant, Depo-Provera, and barrier devices are acceptable; condoms used alone are not acceptable).

WBC count must be greater than or equal to 3000/mm(2).

No history of malignancy (except non-metastatic cutaneous squamous or basal cell carcinomas that have been completely excised without evidence of recurrence for at least 1 year).

No active systemic bacterial, fungal or viral infections (including active zoster or herpetic lesions).

No serological evidence of HIV, HCV, or HbsAg.

No active peptic ulcer disease.

No condition or circumstance that could potentially interfere with the evaluation of BG9588.

No contraindication to monoclonal antibody therapies.

No history of Major Thromboembolic event (e.g. stroke, pulmonary embolus).

For the first 5 patients, no patient with a PRA greater than 20%.

No previous participation in the study.

No use of any investigational agent or device within 4 weeks prior to first dose of study drug.

No Cold Ischemia Time of donor kidney greater than 36 hours.

No uncontrolled non-heart-beating donor status.

No positive T-cell Crossmatch.
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00001967
Intervention Type: Drug
Intervention Name: HAART
Title: Intermittent Versus Continuous Medication in the Treatment of HIV
Condition: HIV Infection
Eligibility Criteria: INCLUSION CRITERIA:

Documentation of HIV-1 infection by licensed ELISA test kit and confirmed by a second method (e.g. Western Blot).

Absolute CD4+ T-cell count of greater than or equal to 300/mm(3) within 30 days before randomization (For patients who are status post-splenectomy, also CD4+ T-cell greater than 20%). For patients in cohort 2, the lowest documented CD4+ T-cell count must be greater than or equal to 200 cells/mm(3).

Receiving HAART (at least 2 NRTIs and an NNRTI or a PI) with at least 1 viral load test below the limit of detection (at least less than 500 copies/ml) greater than or equal to 3 months for cohort 1 and 4 and greater than or equal to 6 months for cohorts 2, 3 and 5

before screening.

A confirmatory viral load of less than 50 copies/ml prior to enrollment.

Age at least 18 years.

For women of childbearing potential, a negative pregnancy test (serum or urine) is required
within 14 days prior to randomization.

Laboratory values (within 30 days prior to randomization):

AST no more than 5 times the upper limit of normal (ULN);

Total or direct bilirubin no more than 2 times the ULN unless there is a pattern consistent
with Gilbert's syndrome or the patient is receiving indinavir;

Creatinine no more than 2.0 mg/dL;

Platelet count at least 50,000 microliters.

Willingness to provide blood samples for storage that may be used in future studies of HIV
infection and/or immunopathogenesis.

EXCLUSION CRITERIA:

Concurrent malignancy, or any other disease state, requiring cytotoxic chemotherapy .

Symptomatic for significant HIV-related illnesses, such as opportunistic infections and
malignancies other than mucocutaneous Kaposi's sarcoma .

Use of experimental antiretrovirals less than or equal to 6 months prior to enrollment. An
exception may be made for hydroxyurea according to the judgment of the Principal
Investigator.

For cohort 1 and the extension of cohort 2, current use of IL-2 or history of use of IL-2 .
Cohorts 2, 3, 4 and 5, patients must not be currently receiving cycles of IL-2.

For the extension of cohort 2, participation in previous STI studies or off HAART for
greater than 2 weeks consecutively in the last year.

Pregnancy or breastfeeding during the study period.

Significant cardiac, pulmonary, kidney, rheumatologic, gastrointestinal, or CNS disease as
detectable on routine history, physical examination, or screening laboratory studies are
excluded. If an abnormality is a contraindication to a specific drug, an alternative drug
within the same class may be used.

Psychiatric illness that, in the opinion of the PI, might interfere with study compliance.

Active substance abuse or history of prior substance abuse that may

interfere with protocol
compliance or compromise patient safety.

Refusal to practice safe sex or use precautions against pregnancy (effective birth control
or abstinence).

Known history or laboratory evidence of chronic hepatitis B infection including surface
antigen positivity .

Patients not receiving salvage HAART, i.e. no evidence of clinical resistance to licensed
antiretrovirals.

Patients in cohort 1 cannot be receiving nevirapine at the time of enrollment.

Patients receiving nevirapine or abacavir at time of enrollment.

Expanded access medications are not allowed at time of enrollment nor while on study.
Overall Status: Completed
Phase: Phase 4

NCTID: NCT00002011
Intervention Type: Drug
Intervention Name: Methoxsalen
Title: The Therakos UVAR Photopheresis System in the Treatment of AIDS-Related Complex
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Patients must have the following:

- Diagnosis of AIDS-related complex (ARC).

- Veins that can provide adequate access.

- Negative drug screen for drugs of abuse and zidovudine (AZT).

- Be willing to adhere to the protocol and sign a patient informed consent prior to
study entry.

- Live within adequate commuting distance to the treatment center.

- Not be on any other investigational drug/device.

- Be 18 - 80 years old but minimum age requirements may be affected by state regulations
or specific medical conditions.

Exclusion Criteria

Co-existing Condition:

Patients with the following conditions or symptoms are excluded:

- Inability to tolerate extracorporeal volume loss during the leukocyte-enrichment
phase.

- Photosensitive disease, such as porphyria or systemic lupus

erythematosus. Care must
be taken in selecting patients who require drugs (either systemically or topically)
during the course of the study with photosensitizing potential such as phenothiazines,
tetracyclines, sulfonamides or chlorothiazide.

- Renal insufficiency with creatinine > 3 mg/dl.

- Symptoms of toxic effects (World Health Organization Criteria) resulting from previous
therapy.

- Severe emotional, behavioral or psychiatric problems that in the opinion of the
investigator would result in poor compliance with the treatment regimen.

- Idiosyncratic or hypersensitivity reactions to 8-MOP compounds.

- History of or active Pneumocystis carinii pneumonia, other opportunistic infection or
neoplasms (Kaposi's sarcoma), or wasting syndrome.

- Active hepatitis.

- Aphakia because of the significantly increased risk of retinal damage due to absence
of lenses.

Concurrent Medication:

Excluded:

- Zidovudine (AZT).

- Photosensitizing drugs should not be administered prior to photopheresis treatment.

- Other investigational drugs.

Concurrent Treatment:

Excluded:

- Other treatment using an investigational device.

Patients with the following are excluded:

- Inability to tolerate extracorporeal volume loss during the leukocyte-enrichment
phase.

- Photosensitive disease.

- Symptoms of toxic effects (World Health Organization Criteria) resulting from previous
therapy.

- Severe emotional, behavioral or psychiatric problems that in the opinion of the
investigator would result in poor compliance with the treatment regimen.

- Idiosyncratic or hypersensitivity reactions to 8-MOP compounds.

- Actively involved in drug abuse.

- Aphakia because of the significantly increased risk of retinal damage due to absence of lenses.

Prior Medication:

Excluded:

- Zidovudine (AZT).

Actively involved in drug abuse.
Overall Status: Completed
Phase: nan

NCTID: NCT00002023
Intervention Type: Drug
Intervention Name: Zidovudine
Title: An Oral Dose-Ranging Finding Study in Patients With HIV Disease, CDC Classification Groups IIB, III, and IV-C2
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Patients must have HIV reactivity.

- Patients must belong to one of the following three groups according to the CDC classification:

- IIB - including only those patients with autoimmune thrombocytopenia (platelet count = or < 100000 platelets/mm3).

- OR Lymphopenia (lymphocyte count = or < 1000 cells/mm3).

- OR Helper cell lymphopenia (helper cells < the mean of normals).

- OR CDC classification III or IV-C2.

- Patients with = or < involuntary 10 percent weight loss in the last 6 months.

- ECOG performance status 0 or 1.

- Weigh 70 kg + or - 15 kg in order to standardize the g/kg dosing.

- Positive antibody for HIV by an ELISA test kit. If the ELISA is negative, then eligibility will be confirmed by second confirmatory test, i.e., immunoblot.

Exclusion Criteria

Co-existing Condition:

Patients with the following are excluded:

- AIDS or the CDC classification stage IV except stage IV-C2.

- HIV antibody negative by immunoblot.

- Persistent fevers of > 38.5 degrees C.

- Persistent diarrhea undiagnosed > 1 month.

- Involuntary weight loss of > 10 percent in the 6 months prior to study entry.

- ECOG performance status of 2, 3, or 4.

- Class IV-C2 with prior history of:

- Multidermal herpes zoster.

- Oral candidiasis on more than one occasion.

- Tuberculosis.

Concurrent Medication:

Excluded:

- Other antiretroviral agents.

- Active immunomodulating agents.

- Any other experimental therapy.

- Drugs which cause anemia or neutropenia.

- Drugs which are glucuronidated and may interfere with the metabolism of AZT, i.e.,
acetaminophen > 5 days.

- Acyclovir systemically administered > 5 days.

- Any other experimental agents.

Patients with the following are excluded:

- AIDS or the CDC classification stage IV except stage IV-C2.

- HIV antibody negative by immunoblot.

- Persistent fevers of > 38.5 degrees C.

- Persistent diarrhea undiagnosed > 1 month.

- Involuntary weight loss of > 10 percent in the 6 months prior to study entry.

- ECOG performance status of 2, 3, or 4.

- Class IV-C2 with prior history of:

- Multidermal herpes zoster.

- Oral candidiasis on more than one occasion.

- Tuberculosis.

Prior Medication:

Excluded within 3 months of study entry:

- Other antiretroviral agents. Active immunomodulating agents.

- Excluded within 2 weeks of study entry:

- Drugs which cause anemia or neutropenia.

- Drugs which are glucuronidated and may interfere with the metabolism of zidovudine
(AZT), i.e., acetaminophen > 5 days.

- Acyclovir systemically administered > 5 days.

- Any other experimental agents.

Known active drug abuse.
Overall Status: Completed
Phase: nan

NCTID: NCT00002012
Intervention Type: Drug
Intervention Name: Interferon alfa-n3
Title: Double-Blind, Randomized, Placebo-Controlled Study of Low Dose Oral Interferon Alfa-n3 (Human Leukocyte Derived) in ARC Patients
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Concurrent Medication:

Allowed:

- Zidovudine (AZT).

Patients must have:

- Diagnosis of AIDS related complex (ARC).

- Given written informed consent.

- Been receiving a dose of = or < 600 mg/day of zidovudine (AZT) at least 90 days prior
to study entry IF they are currently taking AZT.

Prior Medication:

Allowed:

- Zidovudine (AZT) at a dose = or < 600 mg/day at least 90 days prior to study entry.

Exclusion Criteria

Co-existing Condition:

Patients with the following conditions or symptoms are excluded:

- History of AIDS-defining condition or evidence of AIDS dementia.

- Evidence of chronic hepatitis with severe liver dysfunction, or other active
gastrointestinal, renal, respiratory, endocrine, hematologic, cardiovascular or
psychiatric disorder that would limit the subject's ability to complete the 12 weeks
of the study period.

Concurrent Medication:

Excluded:

- Ketoconazole.

- Trimethoprim / sulfamethoxazole (TMP/SMX).

- Experimental medications.

Patients with the following are excluded:

- Absolute CD4 count of < 100 or > 350 cells/mm3.

- Any disease or disorder listed in Patient Exclusion Co-existing Conditions.

- Unlikely or unable to comply with the requirements of the protocol.

- Unwilling or unable to give informed consent.

- Development of antibodies to interferon during prior interferon therapy that occurred
  > 3 months prior to study entry.

Prior Medication:

Excluded within 45 days of study entry:

- Immunomodulators (e.g., BCG vaccine, isoprinosine).

- Chemotherapy.

- Steroids.

- Excluded within 3 months of study entry:

- Interferon therapy. Active IV drug abuse.

Overall Status: Completed
Phase: nan

NCTID: NCT00002028
Intervention Type: Drug
Intervention Name: Didanosine
Title: A Treatment IND (Investigational New Drug) Protocol for the Use of Videx (2',3'-Dideoxyinosine, ddI) in Patients With Acquired Immunodeficiency Syndrome (AIDS) or AIDS- Related Complex (ARC) Who Are Intolerant to Zidovudine (Retrovir)
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Concurrent Medication:

Allowed:

- Concomitant medications for the treatment of AIDS or ARC (including aerosolized
  pentamidine).

- Phenytoin, but with caution.

- Note:

- Extreme caution should be exercised in the use of ddI in any patient receiving concomitant therapies, particularly those receiving other nucleosides (e.g. ganciclovir), drugs with toxicities similar to those observed with ddI (list included under concomitant medications section of protocol), and other drugs with significant toxicities, including many drugs used for treatment of major opportunistic infections.

Patients must:

- Have a diagnosis of AIDS or be symptomatic, HIV positive, and have a CD4 cell count < 200 cells/mm3.

Be intolerant to zidovudine (AZT) therapy. Not be suitable for study entry into the phase II didanosine (ddI) study by reason of inclusion or exclusion criteria or by reason of geographic location.

Be able to provide signed informed consent (parent/guardian as appropriate). Be available for monthly follow-up while taking ddI. Meet baseline lab criteria within 14 days prior to initial drug dosing.

Note:

- Extreme caution should be exercised in the use of ddI in any patient receiving concomitant therapies, particularly those receiving other nucleosides (e.g., ganciclovir), drugs with toxicities similar to those observed with ddI (list included under concomitant medications section of protocol), and other drugs with significant toxicities, including many drugs used for treatment of major opportunistic infections.

Caution should also be exercised in a patient having intractable diarrhea or patients following a low-sodium diet. Physicians caring for patients must perform clinical and laboratory evaluations every 7 - 10 days for the first 2 months of ddI therapy. All high-risk patients (for example, patients with preexisting disorders of body systems known to be adversely affected by ddI, particularly those with a history of peripheral neuropathy, pancreatitis, seizure disorder, cardiac abnormalities, gout, and significant elevations of liver function test results), must have clinical and laboratory evaluations performed every 10 days and results submitted to Bristol-Myers Squibb on the case report forms provided.

Prior Medication:

Allowed:

- Anti-emetic medication.

- Required:

- Zidovudine (AZT).

Exclusion Criteria

Co-existing Condition:

Patients with the following conditions or symptoms are excluded:

- Malignancy likely to require chemotherapy in the first 3 months of ddI treatment.

- Acute pancreatitis.

- A poorly controlled seizure disorder.

- Grade B or greater peripheral neuropathy.

Concurrent Medication:

Excluded:

- Zidovudine (AZT).

- Chemotherapy in the first 3 months of ddI treatment.

Patients with the following are excluded:

- Malignancy likely to require systemic chemotherapy in the first 3 months of ddI
  treatment.

- Acute pancreatitis.

- A poorly controlled seizure disorder.

- Grade B or greater peripheral neuropathy.

Prior Medication:

Excluded within 15 days of study entry:

- Any antiretroviral drug except zidovudine (AZT).

Overall Status: Completed
Phase: nan

NCTID: NCT00002018
Intervention Type: Drug
Intervention Name: Interferon alfa-n3
Title: Double-Blind, Randomized, Dose Ranging Study of Alferon LDO (Low Dose Oral Interferon Alfa-n3 (Human Leukocyte Derived)) in HIV+ Subjects
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Concurrent Medication:

Allowed:

- Zidovudine (AZT).

- Didanosine (ddI)

Patients must have:

- Seropositivity to HIV-1 by ELISA and Western blot.

- At least 1 of the HIV-related clinical symptoms or opportunistic infections listed in protocol.

- Written informed consent.

- If already on zidovudine (AZT) or didanosine (ddI), must have been on this therapy for at least 75 of the 90 days prior to study entry.

Prior Medication:

Allowed:

- Zidovudine (AZT).

- Didanosine (ddI)

Exclusion Criteria

Co-existing Condition:

Patients with the following conditions or symptoms are excluded:

- Major active opportunistic infection requiring active care within 2 weeks of study entry.

- Evidence of chronic hepatitis with severe liver dysfunction:

- albumin < 2 g/dl and SGOT or SGPT > 5 x upper limit of normal prothrombin time > 1.5 x upper limit of normal).

- Other active gastrointestinal, renal, respiratory, endocrine, hematologic, cardiovascular, neurologic, or psychiatric disorder.

- Transfusion dependency defined as requiring > 1 unit of packed red blood cells (RBC) per month within 3 months prior to study entry.

Concurrent Medication:

Excluded:

- Experimental medications other than didanosine (ddI).

- Chronic prophylactic use of any topical or systemic fungal medication such as ketoconazole, fluconazole, or clotrimazole.

- Chronic prophylactic use of any topical or systemic anti-viral medication such as acyclovir or ganciclovir except zidovudine (AZT) or didanosine (ddI).

Patients with the following are excluded:

- Asymptomatic at study entry.

- Presence of antibodies to interferon due to prior therapy.

- Hospitalization within 2 weeks of study entry.

- Transfusion dependency.

- Unwilling or unable to give informed consent.

- Evidence of any concurrent organ dysfunction listed in Exclusion Co-Existing Conditions.

- Unlikely or unable to comply with the requirements of the protocol.

Prior Medication:

Excluded within 6 weeks of study entry:

- Interferons.

- Excluded within 45 days of study entry:

- Immunosuppressive agents.

- Chemotherapy.

- Steroids.

- Immunomodulators.

- Isoprinosine.

- BCG vaccine.

Prior Treatment:

Excluded within 2 weeks of study entry:

- Hospitalization.

Active intravenous (IV) drug abuse.
Overall Status: Completed
Phase: nan

NCTID: NCT00002004
Intervention Type: Drug
Intervention Name: CD4 Antigens
Title: A Phase I Study of the Safety and Pharmacokinetics of Recombinant CD4 (rCD4) in Patients With AIDS and AIDS-Related Complex
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Patients must have:

- HIV-1 seropositivity.

- Diagnosis of AIDS or AIDS related complex (ARC).

- Failure to tolerate or respond to zidovudine (AZT) or decided to decline AZT therapy.

- The ability to sign a written informed consent form prior to

treatment.

- A willingness to abstain from all other experimental therapy for HIV infection during the entire study period.

- A life expectancy of at least 3 months.

Exclusion Criteria

Co-existing Condition:

Patients with the following conditions or symptoms are excluded:

- Serious active opportunistic infections.

- Malignancies other than Kaposi's sarcoma.

Concurrent Medication:

Excluded:

- Zidovudine (AZT).

- Corticosteroids.

- Nonsteroidal anti-inflammatory agents (NSAI).

- Other experimental therapy.

Patients with the following are excluded:

- Serious active opportunistic infections.

- Malignancies other than Kaposi's sarcoma.

Prior Medication:

Excluded within 3 weeks of study entry:

- Zidovudine (AZT).

- Chemotherapy.

- Immunomodulators.

- Other experimental therapy.

Overall Status: Completed
Phase: Phase 1

NCTID: NCT00001998
Intervention Type: Drug
Intervention Name: Nystatin
Title: Pharmacokinetics of Nystatin LF I.V. in Patients With Acquired Immune Deficiency Syndrome-Related Complex (ARC)
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Patients must have the following:

- Positive HIV antibody test.

- Diagnosis of AIDS-related complex (ARC).

- CD4+ cell count between 100 and 300 cells/mm3.
- Estimated life expectancy of at least 6 months.
- Normal neurological status.

Exclusion Criteria

Co-existing Condition:

Patients with the following conditions or symptoms are excluded:

- Active opportunistic infection requiring ongoing therapy except patients being treated topically for oral thrush.

Patients with the following are excluded:

- Active opportunistic infection.
- Known hypersensitivity to polyene antibiotics.
- Unwillingness to sign an informed consent or to be in compliance of protocol requirements.

Prior Medication:

Excluded within 72 hours of study entry:

- Biologic response modifier agents.
- Corticosteroids.
- Cytotoxic chemotherapeutic agents.
- Potential nephrotoxins.
- Potential neutropenic agents.
- Rifampin or rifampin derivatives.
- Systemic anti-infectives.
- Phenytoin or barbiturates (inducers of microsomal enzymes).
- All systemic medications.

Prior Treatment:

Excluded within 72 hours prior to study entry:

- Radiation therapy.

Active alcohol or drug abuse unless they have been off drugs and/or alcohol for two weeks prior to start of study.

Overall Status: Completed
Phase: nan

NCTID: NCT00002017
Intervention Type: Drug
Intervention Name: Interleukin-2, Polyethylene Glycolated
Title: Immunomodulation of HIV-1 Infected Individuals With PEG-Interleukin-2

Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Concurrent Medication:

Allowed:

- Zidovudine (AZT).

- Necessary topical agents such as nystatin, clotrimazole, and acyclovir.

- Aerosolized pentamidine for Pneumocystis carinii pneumonia (PCP) prophylaxis.

- Oral antibiotics for PCP prophylaxis if hematologically stable for = or > 30 days prior to study entry.

- Necessary systemic agents for the treatment of other chronic disorders, such as diabetes or asthma.

Patients must have:

- HIV-1 seropositivity.

- Asymptomatic.

- No opportunistic infection for 8 weeks prior to study entry.

- Been on azidothymidine (AZT) (= or > 500 mg/day) for at least 8 weeks prior to beginning interleukin-2 (IL-2), with stable CD4 cell counts.

Prior Medication:

Allowed:

- Zidovudine (AZT).

Exclusion Criteria

Co-existing Condition:

Patients with the following conditions or symptoms are excluded:

- Active, life-threatening opportunistic infection (OI) with bacterial, viral, fungal, or protozoan pathogens.

- Fever = or > 101 F. within 10 days prior to study entry.

- Significant central nervous system (CNS) disease including AIDS dementia, psychiatric disability, or seizure disorder.

- Significant cardiac disease (New York Heart Association Stage III or IV).

- Significant pulmonary disease (Forced Expiratory Volume < 75 percent.

- Weight loss = or > 10 percent within last 3 months.

Concurrent Medication:

Excluded:

- Systemic therapy for opportunistic infection (OI).

Patients with the following are excluded:

- Presence of antibody to interleukin-2 (IL-2).

- Diseases or symptoms listed in Exclusion Co-Existing Conditions.

Prior Medication:

Excluded within 12 weeks prior to study entry:

- Other immunomodulators.

- Corticosteroids.

- Other experimental therapy.

- Anti-neoplastic chemotherapy.

Active drug or alcohol abuse.
Overall Status: Completed
Phase: nan

NCTID: NCT00002020
Intervention Type: Drug
Intervention Name: Zidovudine
Title: Trial of an Alternative Dosing Regimen of Oral Retrovir in Patients With AIDS or Advanced ARC
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Concurrent Medication:

Allowed:

- Prophylaxis or treatment for Pneumocystis carinii pneumonia (PCP) consisting of either
trimethoprim / sulfamethoxazole, aerosolized pentamidine, pyrimethamine / sulfadoxine, or
dapsone allowed at the discretion of the investigator.

Patients with the following are excluded:

- Any immediately life-threatening infection or medical condition present at the time of
study entry.

- Any active opportunistic or other infection requiring chronic therapy at the time of
study entry. Patients with PCP may be randomized to study medication following a
minimum 7-day course of therapy resulting in stabilization of their disease. Patients
with stabilized disease must have a fever < 39 C for at least 48 hours, pO2 (on room
air) = or > 60 mm, and an Arterial/alveolar gradient = or < 30 mm.

- Diagnosis of AIDS Dementia Complex.

- Received more than 4 weeks of antiretroviral therapy or who previously discontinued antiretroviral therapy due to drug related toxicity.

- Diseases and conditions listed in Exclusion Co-existing Conditions.

Patients must have the following:

- Seropositive for HIV infection documented by any federally licensed ELISA and confirmed by Western blot.

- Advanced HIV disease or AIDS-related complex.

- Ability to give informed consent.

Exclusion Criteria

Co-existing Condition:

Patients with the following conditions or symptoms are excluded:

- AIDS with malignant disease likely to require cytotoxic chemotherapy.

- Diagnosis of AIDS Dementia Complex.

- Impaired renal function (Creatinine clearance < 50 ml/min/1.73m2 or serum creatinine = or > 2 mg/dl).

- Impaired hepatic function (ALT = or > 5 x upper limit of normal).

- Fever > 39 C at entry.

Concurrent Medication:

Excluded:

- Any other experimental therapy.

- Drugs which cause significant bone marrow suppression.

- Cytolytic chemotherapy.

- Drugs which cause significant nephrotoxicity or hepatotoxicity.

Concurrent Treatment:

Excluded:

- Radiation therapy (with the exception of electron beam therapy to an area < 100 cm2).

Prior Medication:

Excluded within 2 weeks of study entry:

- Any other experimental therapy. Drugs which cause significant bone marrow suppression.
Cytolytic chemotherapy. Drugs which cause significant nephrotoxicity or hepatotoxicity.

Excluded within 4 weeks of entry:

- Immunomodulating agents, including pharmacological doses of steroids for more than 10 days (except for management of severe PCP in which case duration should not exceed 21 days). Interferon. Isoprinosine. IL-2.

Excluded within 8 weeks of entry:

-

Antiretroviral agents including:

- Ribavirin. Dideoxycytidine (ddC). Dideoxyadenosine (ddA). Didanosine (ddI). Foscarnet. Dextran Sulfate. AL-721. Retrovir (Zidovudine, AZT) for greater than 4 weeks or within 90 days of study entry, or patients who originally discontinued Retrovir due to drug-related toxicity. Drugs metabolized by hepatic glucuronidation may alter the metabolism of Retrovir and should not be used chronically.

Prior Treatment:

Excluded:

- Radiation therapy (with the exception of electron beam therapy to an area < 100 cm2) within 2 weeks of study entry.

Known active drug or alcohol abuse.
Overall Status: Completed
Phase: nan

NCTID: NCT00002005
Intervention Type: Drug
Intervention Name: CD4 Antigens
Title: A Phase I Study of Recombinant CD4(rCD4) in Patients With AIDS and AIDS-Related Complex
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Patients must have:

- HIV-1 seropositivity.

- Diagnosis of AIDS or AIDS related complex (ARC).

- Failure to tolerate or respond to zidovudine (AZT) or decided to decline AZT therapy.

- The ability to sign a written informed consent form prior to treatment.

- A willingness to abstain from all other experimental therapy for HIV infection during the entire study period.

- A life expectancy of at least 3 months.

Exclusion Criteria

Co-existing Condition:

Patients with the following conditions or symptoms are excluded:

- Serious active opportunistic infections.
- Malignancies other than Kaposi's sarcoma.

Concurrent Medication:

Excluded:

- Zidovudine (AZT).
- Corticosteroids.
- Nonsteroidal anti-inflammatory agents (NSAI).
- Other experimental therapy.

Patients with the following are excluded:

- Serious active opportunistic infections.
- Malignancies other than Kaposi's sarcoma.

Prior Medication:

Excluded within 3 weeks of study entry:

- Zidovudine (AZT).
- Chemotherapy.
- Immunomodulators.
- Other experimental therapy.

Overall Status: Completed
Phase: nan

NCTID: NCT00002036
Intervention Type: Drug
Intervention Name: Anti-HIV Immune Serum Globulin (Human)
Title: Phase I Safety Study of Anti-HIV Immune Serum Globulin (Human)
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Patients must have:

- Proof of HIV infection.
- Diagnosis of asymptomatic HIV infection or early AIDS related complex (ARC) with no zidovudine (AZT) or other anti-HIV therapy. OR a diagnosis of AIDS and = or > 3 months of AZT therapy.

Exclusion Criteria

Co-existing Condition:

Patients with the following conditions or symptoms are excluded:

- HIV-induced neurological disease.

- IgA negative.

Concurrent Medication:

Excluded:

- Immunomodulating agents.
- Steroids.
- Interferons.

Patients with the following are excluded:

- Active substance abuse.
- Use of immunomodulating drugs such as steroids or interferons.
- HIV-induced neurological disease.
- IgA negative.

Required with a diagnosis of AIDS:

- = or > 3 months of zidovudine (AZT) therapy.

Active substance abuse.
Overall Status: Completed
Phase: Phase 1

NCTID: NCT00002050
Intervention Type: Drug
Intervention Name: Thymopentin
Title: A Study of Thymopentin Effects on HIV-1 Infectivity of Blood Mononuclear Cells and Semen in HIV Infected Patients
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Concurrent Medication:

Allowed:

- Aerosolized pentamidine.

Patients must have the following:

- Seropositive for HIV-1 (ELISA assay) confirmed by Western blot.
- HIV-1 p24 antigen must be detected in supernatant fluids from co-cultures of patients' PBMC on two separate occasions.
- Voluntarily sign consent.
- Patients with HIV "wasting syndrome" are allowed.

Prior Medication:

Allowed:

- Aerosolized pentamidine.

Exclusion Criteria

Co-existing Condition:

Patients with the following are excluded:

- AIDS as defined by the CDC.
- Significant hepatic disease.
- Thrombocytopenia.
- Hypersensitivity to thymopentin.
- Hemophilia A or B or other hematologic disorders requiring current or previous administration of blood products.
- Abnormal chest x-ray (indicative of active disease (opportunistic infection)) within 30 days prior to study entry.

Patients with the following are excluded:

- AIDS as defined by the CDC.
- Significant hepatic disease.
- Thrombocytopenia.
- Hypersensitivity to thymopentin.
- Hemophilia A or B or other hematologic disorders requiring current or previous administration of blood products.
- Abnormal chest x-ray (indicative of active disease (opportunistic infection)) within 30 days prior to study entry.

Prior Medication:

Excluded within 30 days of study entry:

- Immunomodulatory or experimental therapy.
- Excluded within 90 days of study entry:
- Zidovudine (AZT).

Intravenous drug abuse.
Overall Status: Completed
Phase: nan

NCTID: NCT00002060
Intervention Type: Drug
Intervention Name: Inosine pranobex
Title: A Multi-Center Randomized Double-Blind Placebo-Controlled Study To Investigate the Effect of Isoprinosine in Patients With AIDS Related Complex (ARC)
Condition: HIV Infections
Eligibility Criteria: Exclusion Criteria

Concurrent Medication:

Excluded:

- Cardiac glycosides.

Patients with the following are excluded:

- AIDS.

- Presenting with chronic candida infection-colo/rectal, oral/pharyngeal, cutaneous (finger/toenails) - for = or > 3 months who have not responded to therapy.

- Critical illness.

- Hemophilia.

Prior Medication:

Excluded within 1 month of study entry:

- Steroids.

- Cytotoxic immunosuppressive agents.

- Radiotherapy and/or systemic antiviral medication.

- Immunomodulators (including Isoprinosine).

Prior Treatment:

Excluded within 1 month of study entry:

- Radiotherapy.

History of gout, uric acid urolithiasis, uric acid nephrolithiasis, or renal dysfunction.

- Lymphoid malignancy.

Homosexual male patients with AIDS related complex (ARC).

Current IV drug abuse.
Overall Status: Completed
Phase: nan

NCTID: NCT00002059
Intervention Type: Drug
Intervention Name: Inosine pranobex
Title: A Double-Blind Placebo Controlled Study To Determine the Optimal Immunopharmacological Dose Level of Isoprinosine in Immunodepressed Volunteers
Condition: HIV Infections
Eligibility Criteria: Exclusion Criteria

Co-existing Condition:

Patients with the following are excluded:

- Opportunistic infections or Kaposi's sarcoma.

- Critical illness.

- History of gout, urolithiasis, nephrolithiasis, renal dysfunction, and severe gastric

ulcer.

Concurrent Medication:

Excluded:

- Steroids.

- Cytotoxic immunosuppressive agents.

Concurrent Treatment:

Excluded:

- Radiotherapy.

The following are excluded:

- Opportunistic infections or Kaposi's sarcoma.

- Critically ill patients.

- Patients receiving steroids, cytotoxic immunosuppressive agents, and/or radiotherapy.

- Patients who have received any other immunotherapy.

- Patients with a history of gout, urolithiasis, nephrolithiasis, renal dysfunction, and
severe gastric ulcer.

Prior Medication:

Excluded:

- Any other immunotherapy.

Patients who fall into the group which is at risk of developing cutaneous sarcoma and/or
opportunistic diseases but at present have no signs or symptoms of these diseases.
Overall Status: Completed
Phase: nan

NCTID: NCT00002046
Intervention Type: Drug
Intervention Name: Zidovudine
Title: A Dose-Frequency Trial of Oral Retrovir in Patients With AIDS or Severe ARC
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Concurrent Treatment:

Allowed:

- Electron beam therapy to an area of less than 100 cm2.

Patients with the following are excluded:

- Any immediately life-threatening infection or medical condition present at the time of
study entry.

- Any active opportunistic or other infection requiring chronic therapy present at the time of study entry.

- Patients with Pneumocystis carinii pneumonia (PCP) may be randomized to study medication following a minimum 7-day course of therapy resulting in stabilization of their disease. Patients with stabilized disease must have fever < 39 degrees C for at least 48 hours; oxygen (on room air)

  = or > 60 mm, and arterial / alveolar gradient = or < 30 mm.

- Kaposi's sarcoma, lymphoma, or other tumor likely to require cytotoxic chemotherapy.

Seropositive for HIV antibody documented by any federally licensed ELISA.

Patients must have ability to give informed consent and advanced HIV disease defined as:

- History of Pneumocystis carinii pneumonia (PCP) with histologic verification within 4 months of study entry.

OR History of other opportunistic infection included in the CDC surveillance definition of AIDS (stage IV-C-1), diagnosed within 4 months of entry, but not requiring chronic suppressive therapy, and a CD4+ cell count < 200 cells/mm3.

OR AIDS related complex (ARC) only those patients with a CD4+ count < 200 cells/mm3 and documentation of at least two signs or symptoms from the list below. One sign or symptom must be weight loss or candidiasis as described.

- Unexplained weight loss > 10 percent or = or > 15 lbs within the previous 4 months; with low weight at entry.

- History of mucocutaneous oral candidiasis (by culture or potassium hydroxide KOH smear).

- Fever > 38 degrees C, without documented infectious cause present, persisting > 1 month.

- Oral hairy leukoplakia.

- Unexplained night sweats, persisting > 1 month.

- Herpes zoster infection within 3 months of entry.

- Chronic diarrhea of unknown infectious etiology persisting > 1 month after 3 samples have been done eliminating ova, parasites, Cryptosporidia, Mycobacterium avium intracellulare, cytomegalovirus (CMV), and other pathogens associated with diarrheal disease in AIDS patients.

Negative Venereal Disease Research Laboratory (VDRL) or Rapid Plasma Reagent (RPR) or, if positive and verified by Fluorescent Treponemal Antibody Absorption (FTAABS), documented history of treatment for syphilis. If FTAABS is positive, but treatment history is not available, the patient may be entered 3 or more days following the initiation of appropriate chemotherapy.

Exclusion Criteria

Co-existing Condition:

Patients with the following are excluded:

- Chronic herpes virus infection.
- Fever > 39 degrees C at study entry.
- Known hypersensitivity to lactate and/or gelatin.
- Kaposi's sarcoma, lymphoma, or other tumor likely to require cytotoxic chemotherapy.
- Impaired renal function.
- AIDS dementia complex.

Concurrent Medication:

Excluded:

- Drugs which cause significant bone marrow suppression.
- Rifampin or rifampin derivatives.
- Drugs which cause significant nephrotoxicity or hepatotoxicity.
- Antiretroviral agents, including ribavirin, dideoxycytidine, dideoxyadenosine, didanosine, foscarnet, dextran sulfate, and AL-721.
- Acyclovir therapy of more than 21 days duration.

Concurrent Treatment:

Excluded:

- Radiation therapy (with the exception of electron beam therapy to an area of less than 100 cm2).
- Experimental therapy.
- Cytolytic chemotherapy.

Prior Medication:

Excluded:

- Acyclovir therapy of more than 21 days duration.

- Zidovudine (AZT).

- Excluded within 2 weeks of study entry:

- Drugs which cause significant bone marrow suppression.

- Rifampin or rifampin derivatives.

- Drugs which cause significant nephrotoxicity or hepatotoxicity.

- Immunomodulating agents, including pharmacologic doses of steroids for > 10 days.

- Excluded within 4 weeks of study entry:

- Interferon.

- Isoprinosine.

- IL-2.

- Excluded within 8 weeks of study entry:

- Antiretroviral agents, including ribavirin, dideoxycytidine, dideoxyadenosine, didanosine, foscarnet, dextran sulfate, and AL-721.

Prior Treatment:

Excluded:

- Radiation therapy (with the exception of electron beam therapy to an area of less than 100 cm2).

- Experimental therapy.

- Cytolytic chemotherapy.

Active drug or alcohol abuse.
Overall Status: Completed
Phase: nan

NCTID: NCT00002031
Intervention Type: Drug
Intervention Name: Dinitrochlorobenzene
Title: Evaluation of the Epidermal Langerhans Cell Population in AIDS / ARC Patients by the Topical Application of a Potent Contact Allergen (1-Chloro-2,4-Dinitro-Chlorobenzene) (DNCB)
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Patients must have the following:

- Stage III or IV HIV infection.

- Provide informed consent.

Exclusion Criteria

Co-existing Condition:

Patients with the following conditions or symptoms are excluded:

- Kaposi's sarcoma lesions in the proposed treatment sites.

- Liable to require radiation or chemotherapy during the course of the study.

- Not likely to survive the length of the study.

- Obvious ultra-violet-irradiated skin damage in the treatment areas and anyone with recent UV exposure or likely to have such exposure (e.g.:

- holiday tans obtained in Hawaii, members of UV box tanning salons, etc.) Allergy to lidocaine.

Concurrent Medication:

Excluded:

- Other Immunomodulators.

Concurrent Treatment:

Excluded:

- Radiation.

Patients with the following are excluded:

- Kaposi's sarcoma lesions in the proposed treatment sites.

- Liable to require radiation or chemotherapy during the course of the study.

- Not likely to survive the length of the study.

- Obvious ultra-violet-irradiated skin damage in the treatment areas.

- Allergy to lidocaine.

Prior Medication:

Excluded:

- Prior DNCB therapy.

Overall Status: Completed
Phase: nan

NCTID: NCT00002051
Intervention Type: Drug
Intervention Name: Thymopentin
Title: Double Blind Study of Thymopentin Effects on Patients With HIV-1 Infection
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Concurrent Treatment:

Allowed:

- Aerosolized pentamidine.

Prior Medication:

Allowed:

- Aerosolized pentamidine.

Exclusion Criteria

Co-existing Condition:

Patients with the following are excluded:

- AIDS as defined by the CDC (except for those with HIV "wasting syndrome").

- Significant hepatic disease.

- Thrombocytopenia (< 75000 platelets/mm3).

- Abnormal chest x-ray (indicative of active disease (opportunistic infection)) within 30 days prior to entry.

- Hemophilia A or B or other hematologic disorders requiring current or previous administration of blood products.

- Known hypersensitivity to thymopentin.

Prior Medication:

Excluded within 30 days of study entry:

- Immunomodulatory or experimental therapy.

- Excluded within 90 days of study entry:

- Zidovudine (AZT).

Patients must not have:

- AIDS as defined by the CDC (except for those with HIV "wasting syndrome").

- Significant hepatic disease.

- Thrombocytopenia (< 75000 platelets/mm3).

Patients with the following conditions are included:

- Seropositive for HIV-1 (ELISA assay) confirmed by Western blot.

- HIV-1 p24 antigen must be detected in supernatant fluids from co-cultures of patient's peripheral blood monocytes (PBMC) on two separate occasions.

- HIV "wasting syndrome".

- Must voluntarily sign consent.

History of intravenous drug abuse.
Overall Status: Completed
Phase: nan

NCTID: NCT00002049
Intervention Type: Drug

Intervention Name: Thymopentin
Title: Double Blind Study of Thymopentin Effects on HIV-1 Infectivity of Blood Mononuclear Cells and Semen in HIV Infected Patients
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Concurrent Medication:

Allowed:

- Aerosolized pentamidine.

Patients must have the following:

- Seropositive for HIV-1 (ELISA assay) confirmed by Western blot. HIV-1 p24 antigen must be detected in supernatant fluids from co-cultures of patients' peripheral blood monocytes (PBMC) on two separate occasions. Voluntarily sign consent.

Patients with HIV "wasting syndrome" are included.

Prior Medication:

Allowed:

- Aerosolized pentamidine.

Exclusion Criteria

Co-existing Condition:

Patients with the following are excluded:

- AIDS as defined by the CDC (except for those with HIV "wasting syndrome").
- Significant hepatic disease.
- Thrombocytopenia.
- Hypersensitivity to thymopentin.
- Hemophilia A or B or other hematologic disorders requiring current or previous administration of blood products.
- Abnormal chest x-ray (indicative of active disease (opportunistic infection)) within 30 days prior to study entry.

Patients with the following are excluded:

- AIDS as defined by the CDC (except for those with HIV "wasting syndrome").
- Significant hepatic disease.
- Thrombocytopenia.
- Hypersensitivity to thymopentin.
- Hemophilia A or B or other hematologic disorders requiring current or previous

administration of blood products.

- Abnormal chest x-ray (indicative of active disease (opportunistic infection)) within
  30 days prior to study entry.

Prior Medication:

Excluded within 30 days of study entry:

- Immunomodulatory or experimental therapy.

- Excluded within 90 days of study entry:

- Zidovudine (AZT).

Intravenous drug abuse.
Overall Status: Completed
Phase: nan

NCTID: NCT00002045
Intervention Type: Drug
Intervention Name: Zidovudine
Title: A Prospective Double-Blind Study of Retrovir in Early HIV Infection
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Concurrent Treatment:

Allowed:

- Electron beam therapy to an area of less than 100 cm2.

Patient must have signs and symptoms of HIV infection confined to those of stages WRII-V or
CDC groups III IV-A, IV-C-2 (except recurrent Salmonella bacteremia, nocardiosis, or
disseminated/extrapulmonary Mycobacterium tuberculosis), and IV-E (except diffuse
interstitial lymphoid pneumonitis).

- Patient must be able to give informed consent.

Exclusion Criteria

Co-existing Condition:

Patients with the following are excluded:

- Evidence of nervous system dysfunction caused by factors other than HIV infection,
  including chronic alcohol or drug abuse.

- Present or prior known AIDS-defining opportunistic infections, lymphomas, or
  malignancies based on CDC criteria.

- Present or prior known systemic opportunistic diseases most recently included in the
  expanded CDC definition of AIDS:

- extrapulmonary or disseminated Mycobacterium tuberculosis infections, recurrent
  nontyphoidal Salmonella septicemia, coccidioidomycosis, diffuse

interstitial lymphoid
pneumonitis.

- Evidence of compromised bone marrow function defined by specified lab values.

- Evidence of HIV neurologic disease.

- Evidence of HIV-associated "wasting syndrome".

- Hypersensitivity to zidovudine (AZT).

Concurrent Medication:

Excluded:

- Cytotoxic chemotherapeutic agents.

- Steroids.

- Interferon or immunomodulating agents.

- Any antiretroviral drug including, but not limited to zidovudine (AZT), ribavirin,
HPA23, AL 721, or phosphonoformate.

Patients with the following are excluded:

- Evidence of nervous system dysfunction caused by factors other than HIV infection,
including chronic alcohol or drug abuse. Present or prior known AIDS-defining
opportunistic infections, lymphomas, or malignancies based on CDC criteria. Present or
prior known systemic opportunistic diseases most recently included in the expanded CDC
definition of AIDS:

- extrapulmonary or disseminated Mycobacterium tuberculosis infections, recurrent
nontyphoidal Salmonella septicemia, coccidioidomycosis, diffuse interstitial lymphoid
pneumonitis.

- Evidence of compromised bone marrow function defined by specified lab values. Evidence
of HIV neurologic disease.

- Evidence of HIV-associated wasting syndrome.

- Hypersensitivity to retrovir.

Prior Medication:

Excluded within 4 weeks of study entry:

- Interferon.

- Immunomodulating agents.

- Myelosuppressive drugs.

- Nephrotoxic agents.

- Other experimental chemotherapy.

Prior Treatment:

Excluded:

- Treatment with radiation therapy (with the exception of electron beam therapy to an area of less than 100 cm2).

Chronic alcohol or drug abuse.
Overall Status: Completed
Phase: nan

NCTID: NCT00000391
Intervention Type: Drug
Intervention Name: Peptide T
Title: A Phase I Trial of Intranasal Peptide T: Safety, Toxicity, and Pharmacokinetics in Human Immunodeficiency Virus-1 (HIV-1) Infected Patients.
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria:

- Patients must have:

HIV infection. Ability to give informed consent. Ability to participate in an outpatient study.

- Allowed: Short course antimicrobials.

- Not breast-feeding

- Abstinence or agree to use barrier methods of birth control / contraception during the study

- Not pregnant

- Negative pregnancy test

- CD4 100 to 500 cells/mm3 (100 - 200 - 300 - 400 - 500).

- Creatinine > 1.6 mg/dl

- Hemoglobin >= 12 g/dl

- Platelet Count >= 100000 /mm3

Exclusion Criteria:

- Excluded: Asymptomatic HIV seropositive or lymphadenopathy syndrome diagnoses only (CDC criteria).

- Patients with the following conditions are excluded: Evidence of life-threatening opportunistic infection at time of entry into trial. Clinical evidence of active central nervous system disease secondary to immune dysregulation associated with HIV infection. Previous history of major psychiatric illness prior to 1977 or the time of initial exposure to HIV, if that is known. Evidence of clinically significant major

psychiatric disturbance other than depression.

- Excluded within 4 weeks of study entry: Suramin. Antiretroviral agents. Anticancer treatments. Psychoactive agents.

- Excluded: Antivirals or immunomodulators.

- Excluded within 4 weeks of study entry: Radiation.

- Evidence of active substance abuse during 30 days prior to entry into trial. All behavior that can put patient at risk for reinfection with HIV: sexual contact with others known to have HIV infection, unsafe sexual practices, or sharing of needles or other intravenous equipment.

- Breast-feeding

- Positive pregnancy test

- Pregnant

- No abstinence or no agreement to use barrier methods of birth control / contraception during the study

Overall Status: Completed
Phase: Phase 1

NCTID: NCT00000438
Intervention Type: Drug
Intervention Name: naltrexone (Revia)
Title: Naltrexone Treatment for Alcoholism
Condition: Alcoholism
Eligibility Criteria: Inclusion Criteria:

- Meets criteria for alcohol dependence.

- Committed to alcohol abstinence as a treatment goal.

- Individuals will be required to identify two family members or close friends who are knowledgeable about their location, drinking behavior, and psychosocial status.

Exclusion Criteria:

- Meets criteria for any other psychoactive substance use disorder (excluding nicotine and caffeine).

- Meets criteria for a major psychiatric disorder and are in need of or currently undergoing pharmacotherapy.

- Females who are pregnant, lactating, or not using a reliable method of contraception.

- Currently experiencing a serious medical condition that would place them at risk or interfere with study participation.

- Experiencing acute hepatitis or liver failure or whose liver

function test is more
than 3 times normal.

- Have a history of severe allergies, multiple adverse drug reactions or known allergy
to naltrexone.

- Vocabulary below the 5th grade reading level.

- Abnormal MRI scan.

- HIV infection due to the neurological sequelae.

- Significant central nervous system diseases.

- Seizure disorder or history of closed head trauma.

- Neuroendocrine disorders.

- Treatment with opiates within the last six months.

Overall Status: Completed
Phase: Phase 4

NCTID: NCT00000455
Intervention Type: Drug
Intervention Name: naltrexone
Title: Naltrexone for Early Problem Drinkers
Condition: Alcoholism
Eligibility Criteria: Inclusion Criteria:

- Limited to early problem drinkers (i.e., those with no more than mild alcohol
dependence).

- Have an average weekly alcohol consumption of greater than or equal to 24 standard
drinks for men and 18 standard drinks for women.

- Able to read English at the eighth grade or higher level and show no evidence of
significant cognitive impairment.

- Willing to provide a collateral informant for interviews regarding the patient's
drinking during the study.

- A woman of child-bearing potential must be non-lactating, practicing a reliable method
of birth control, and have a negative pregnancy test prior to initiation of treatment.

- Willing to provide a signed informed consent to participate in the study.

Exclusion Criteria:

- Have a current clinically significant physical disease or abnormality.

- Have a serious psychiatric illness.

- Have a current diagnosis of drug dependence (other than nicotine dependence) or a
lifetime diagnosis of opioid dependence.

- A current diagnosis of alcohol dependence that is moderate or greater in severity or a history of alcohol withdrawal, or recurrent use of alcohol to alleviate alcohol withdrawal symptoms.

- Used opioids or other psychoactive medications regularly in the month prior to study enrollment.

- History of hypersensitivity to naltrexone (Revia).

Overall Status: Completed
Phase: Phase 4

NCTID: NCT00000445
Intervention Type: Drug
Intervention Name: naltrexone (Revia)
Title: Use of Naltrexone in a Clinical Setting
Condition: Alcoholism
Eligibility Criteria: Inclusion Criteria:

- Meets criteria for alcohol dependence (within the past 3 months).

- Meets criteria for another substance use disorder (except narcotic dependence) but must identify alcohol as the primary substance of abuse.

- Must be able to provide an informed consent.

- Consent to random assignment and be willing to commit to possible medication treatment and research follow-up.

- Must be eligible for treatment at the Dorchester Alcohol and Drug Commission.

Exclusion Criteria:

- Meets criteria for opiate dependence.

- Clinically significant medical problems such as collagen-vascular disease, cardiovascular, renal, gastrointestinal or endocrine problem that would impair participation or limit medication ingestion.

- Hepatocellular disease.

- Women who are pregnant, nursing, or not practicing an effective means of birth control.

- Currently being prescribed naltrexone.

- Known sensitivity or allergy to naltrexone.

Overall Status: Completed
Phase: Phase 4

NCTID: NCT00000442
Intervention Type: Drug
Intervention Name: naltrexone (Revia)
Title: Naltrexone for Relapse Prevention
Condition: Alcoholism

Eligibility Criteria: Inclusion Criteria:

- Meets criteria for alcohol dependence.

- Abstinent from alcohol for a period of at least 3 days prior to beginning of study.

- Able to read English and complete study evaluations.

- Females who are postmenopausal, have had surgical sterilization, or use reliable means of birth control.

Exclusion Criteria:

- Meets criteria for dependence on a psychoactive substance other than alcohol and nicotine and/or cannabis.

- Prior history of opioid dependence.

- Regular use of psychoactive drugs including anxiolytics and antidepressants.

- Prior treatment with naltrexone.

- Current use of disulfiram.

- Psychotic or otherwise severely psychiatrically disabled (e.g., suicidal, current mania).

- Significant underlying medical conditions such as hepatic, cerebral, renal, thyroid, or cardiac disease.

- Abstinent longer than 28 days prior to randomization.

Overall Status: Completed
Phase: Phase 4

NCTID: NCT00000443
Intervention Type: Drug
Intervention Name: ondansetron (Zofran)
Title: Ondansetron Treatment for Alcoholism
Condition: Alcoholism
Eligibility Criteria: Inclusion Criteria:

- Meet criteria for alcohol dependence.

- Subjects with early onset alcoholism must also have a diagnosis of antisocial personality disorder.

- Understand the requirements of the study and be able to complete the questionnaires and rating scales.

Exclusion Criteria:

- Current diagnosis of substance dependence or self-report of having used narcotics (opiates, cocaine, amphetamine-like substances, and hallucinogens) in the 30 day period prior to study.

- Positive urine drug screen test for narcotics, barbiturates, or benzodiazepines.

- Receiving current psychotropic medications.

- Current history of other psychiatric disorders excluding nicotine dependence.

- Hepatocellular disease.

- Pregnant females.

Overall Status: Completed
Phase: Phase 2

NCTID: NCT00000650
Intervention Type: Drug
Intervention Name: Ditiocarb sodium
Title: An Assessment of the In Vivo Biological Effects of Diethyldithiocarbamate (DTC) in HIV-Infected Patients
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Patients must:

- Have HIV infection.

- Be asymptomatic (group 1) or have AIDS (group 2).

- Be able to understand and follow instructions.

Concurrent Medication:

Allowed:

GROUP 2:

- Anti-HIV therapy.

- Systemic prophylaxis or maintenance therapy for any AIDS-defining opportunistic infection excluding agents considered immunomodulators or immunosuppressants.

- Topical nystatin.

- Clotrimazole troches.

- Acyclovir.

- Dapsone.

- Trimethoprim / sulfamethoxazole (T/S).

- Fluconazole.

- Ketoconazole.

- Aerosolized pentamidine.

Exclusion Criteria

Co-existing Condition:

Patients with the following conditions or symptoms are excluded:

ALL PATIENTS:

- Known hypersensitivity to disulfiram or diethyldithiocarbamate (DTC).

- Transfusion dependence.

GROUP 1 PATIENTS ONLY:

- Oral candidiasis documented by morphology or by a response to antifungal therapy.

- Oral hairy leukoplakia.

- Occurrence of herpes zoster in a single dermatomal distribution.

- Recurrent seborrheic dermatitis.

- Unintentional weight loss in excess of 10 pounds or 10 percent of usual body weight within 2 years prior to study.

- Unexplained temperature above 38 degrees C on more than 5 consecutive days or on more than 10 days in any 30 days within 2 years of expected study entry.

- Unexplained diarrhea defined by two or more stools/day for at least 14 days during a 120-day interval.

- Evidence of clinically significant cardiac, respiratory, hepatic, gastrointestinal, endocrine, hematologic, psychiatric, neurologic, renal, or dermatologic disease as demonstrated by history, physical, and laboratory evaluation.

GROUP 2 PATIENTS ONLY:

- Concurrent neoplasms other than Kaposi's sarcoma or basal cell carcinoma of the skin.

- Diagnosis of an acute opportunistic infection within 3 weeks of study entry or had treatment initiated for an opportunistic infection within 3 weeks of study entry.

Concurrent Medication:

Excluded:

ALL PATIENTS:

- Recombinant erythropoietin.

GROUP 1:

- Antiretroviral medications.

GROUP 2:

- Immunomodulators or immunosuppressants.

Concurrent Treatment:

Excluded:

- Requirement for blood transfusions more than once a month.

Patients with the following prior conditions are excluded:

GROUP 1 PATIENTS ONLY:

- Oral candidiasis documented by morphology or by a response to antifungal therapy.

- Oral hairy leukoplakia.

- Occurrence of herpes zoster in a single dermatomal distribution.

- Recurrent seborrheic dermatitis.

- Unintentional weight loss in excess of 10 pounds or 10 percent of usual body weight within 2 years prior to study.

- Unexplained temperature above 38 degrees C on more than 5 consecutive days or on more than 10 days in any 30-day period within 2 years of expected study entry.

- Unexplained diarrhea defined by two or more stools/day for at least 14 days during a 120-day interval.

- Evidence of clinically significant cardiac, respiratory, hepatic, gastrointestinal, endocrine, hematologic, psychiatric, neurologic, renal, or dermatologic disease as demonstrated by history, physical, and laboratory evaluation.

GROUP 2 PATIENTS ONLY:

- Diagnosis of an acute opportunistic infection within 3 weeks of study entry or had treatment initiated for an opportunistic infection within 3 weeks of study entry.

Prior Medication:

Excluded:

ALL PATIENTS:

- Corticosteroids, cytotoxic agents, or immunomodulating agents within 30 days prior to study entry.

- Chronic Antabuse (disulfiram) therapy.

GROUP 1 ONLY:

- Antiretrovial medications within 1 week prior to study entry.

Prior Treatment:

Excluded:

- Transfusion within 7 days of study entry.

- Radiation therapy within 30 days prior to study entry.

Unable to refrain from the use of alcohol for the duration of the study.
Overall Status: Completed
Phase: nan

NCTID: NCT00000653
Intervention Type: Drug
Intervention Name: Zalcitabine
Title: A Trial of Two Doses of 2',3'-Dideoxycytidine (ddC) in the Treatment of Children With Symptomatic HIV Infection Who Are Intolerant of AZT and/or Who Show Progressive Disease While on AZT
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Concurrent Medication:

Allowed:

- Procrit.

- Amphotericin B (1 mg/kg up to 5 days/week).

- Prophylaxis treatment as per ACTG recommendations for Pneumocystis carinii pneumonia.

- Acyclovir (up to 1000 mg/day PO; for > 1000 mg/day PO or for any IV dose, suggest
interrupting ddC).

- Ketoconazole (up to 10 mg/kg/day).

- Nystatin.

- Aspirin, acetaminophen, sedatives, and barbiturates (for up to 72 hours).

- Isoniazid (INH), if there is no evidence of peripheral neuropathy at entry. Children
should receive pyridoxine, 25

- 50 mg/day to avoid possible INH-associated neuropathy.

- Trimethoprim / sulfamethoxazole (T/S).

- Immunoglobulin therapy.

- Aerosolized pentamidine.

- Drugs with little nephro-, hepato-, cytotoxicity that the patient has been taking and
tolerating well for an ongoing condition.

Concurrent Treatment:

Allowed:

- Immunoglobulin therapy.

- Nutritional support (for children with wasting syndrome and/or malnutritional)

including hyperalimentation (TPN) of dietary supplements.

AMENDED:

- Patients enrolled in ACTG 051 may participate in ACTG 138 if they show intolerance to AZT or show disease progression after 6 months of AZT therapy and meet entry criteria for the study.

ORIGINAL design:

- Patients enrolled in ACTG protocols 051 or 128 must meet study end points or meet protocol definitions for being permanently off zidovudine (AZT) before enrolling in this protocol.

Patients must have the following:

- Absence of acute opportunistic infection at time of entry.

- However, if patient is successfully treated for opportunistic infection and has remained stable for 2 weeks after treatment, the patient is then allowed to enter the study. Children receiving maintenance therapy for > 4 weeks are eligible.

- Parent or guardian available to give written informed consent.

Allowed at time of study entry:

- Prophylaxis treatment as per ACTG recommendations, for Pneumocystis carinii pneumonia (PCP).

- Immunoglobulin therapy.

Prior Medication:

AMENDED:

- AZT or ddI up until study entry, other antiretrovirals up until 4 weeks of study entry

Allowed:

- Zidovudine (AZT) within 4 weeks of entry.

- Dideoxyinosine (ddI) within 43 weeks of entry if no peripheral neuropathy has been observed while receiving ddI.

- Other toxicities observed while on ddI must resolve to level 2 or better before patient can begin treatment with ddC.

- Vitamin, folate, iron supplements.

Exclusion Criteria

Co-existing Condition:

AMENDED:

- 04-25-91 Additional excluded symptoms and conditions:

- Symptomatic cardiomyopathy.

- Seizures which are not well controlled by ongoing anticonvulsant therapy.

- Active malignancy requiring concomitant chemotherapy.

- Symptomatic pancreatitis.

- Grade I or greater peripheral neuropathy.

- Receiving concomitant zidovudine (AZT).

- Patients with the following conditions or symptoms are excluded:

- Acute bacterial infections requiring IV or oral antibiotic treatment at time of entry.

- Known hypersensitivity to dideoxycytidine (ddC).

Concurrent Medication:

Excluded:

- Other antiviral agents, biological modifiers, and investigational medications.

- Drugs with potential to cause peripheral neuropathy, including chloramphenicol, iodoquinol, phenytoin, ethionamide, gold, ribavirin, vincristine, cisplatin, dapsone, disulfiram, glutethimide, hydralazine, metronidazole, nitrofurantoin.

Patients with the following are excluded:

- Acute bacterial infections requiring IV or oral antibiotic treatment at time of entry.

- Known hypersensitivity to dideoxycytidine (ddC).

- Active opportunistic infection requiring treatment with an excluded concomitant medication.

Prior Medication:

Excluded:

- Antiretroviral agents (other than zidovudine (AZT) or didanosine (ddI)) within 4 weeks of entry.

- Immunomodulating agents such as interferons, isoprinosine, or interleukin-2 within 2 weeks of entry.

- Any other experimental therapy, drugs that cause prolonged neutropenia, significant nephrotoxicity, or peripheral neuropathy within 1 week of entry.

Overall Status: Completed
Phase: Phase 2

NCTID: NCT00000646
Intervention Type: Drug
Intervention Name: Pentoxifylline
Title: Pentoxifylline (Trental) as a Modulator of Tumor Necrosis Factor and of HIV Replication in Patients With AIDS
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Concurrent Medication:

Required:

- Zidovudine (AZT), didanosine (ddI), dideoxycytidine (ddC), or a combination thereof, at current dosage for the 8 weeks of study treatment.

- Prophylaxis (e.g., aerosolized pentamidine, trimethoprim / sulfamethoxazole (TMP / SMX), dapsone for Pneumocystis carinii pneumonia (PCP) if CD4 cell count is < 200 cells/mm3

Allowed:

- Concurrent maintenance therapy for opportunistic infections.

Prior Medication: Required:

- Zidovudine (AZT), didanosine (ddI), dideoxycytidine (ddC), or a combination thereof, for at least 2 months.

Patients must have the following:

- Diagnosis of AIDS.

- Documented HIV seropositivity.

- Ability to give informed consent and willingness to comply with visit schedule and all procedures.

Exclusion Criteria

Co-existing Condition:

Patients with the following conditions or symptoms are excluded:

- Lymphoma or visceral Kaposi's sarcoma.

- Active peptic ulcer or bleeding disorder.

- Hemophilia. Known intolerance to pentoxifylline, theophylline, or caffeine.

Concurrent Medication:

Excluded:

- Warfarin and heparin.

- Biological response modifiers (e.g., erythropoietin, interferon, G-CSF, GM-CSF).

Cytotoxic chemotherapy.

- Megestrol acetate. Corticosteroids.

Concurrent Treatment:

Excluded:

- Radiation therapy. Blood products or transfusions.

Patients with the following are excluded:

- Presence of an active opportunistic infection.

- Major surgery within 30 days of study treatment.

Prior Medication:

Excluded:

- Biological response modifiers (including interferon, interleukin), corticosteroids, or
megestrol acetate within 14 days of first (screening) TNF level.

- Erythropoietin dependency or within 30 days of study treatment.

Prior Treatment:

Excluded:

- Transfusion or blood product dependency or use within 30 days of study treatment.

Overall Status: Completed
Phase: Phase 1

NCTID: NCT00000634
Intervention Type: Drug
Intervention Name: Nevirapine
Title: A Pilot Pharmacokinetic Phase I Evaluation of BI-RG-587 in HIV-Infected Children
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Concurrent Medication:

Allowed:

- Intravenous gammaglobulin. Pneumocystis prophylaxis according to published guidelines.

Patients must have the following:

- HIV infection.

- Parent or guardian must be available to give written informed consent.

Exclusion Criteria

Concurrent Medication:

Excluded:

- Zidovudine (AZT).

- Steroid dependency.

Excluded within 1 hour before and 4 hours after study drug administration:

- Drugs that might interfere with the absorption of study drug (H2 blockers, antacids, carafate, cholestyramine).

- Benzodiazepines.

- Alcohol-containing substances.

Concurrent Treatment:

Excluded:

- Requiring supplemental oxygen.

Patients with the following are excluded:

- Active opportunistic or serious bacterial infection.

- Lymphoid interstitial pneumonitis (LIP) and steroid dependent or requiring supplemental oxygen or have a pretreatment pa02 < 70 mm Hg.

- Pre-existing malignancies.

Prior Medication:

Excluded:

- Zidovudine (AZT) within 7 days prior to administration of study drug.

Excluded for at least 4 weeks prior to drug administration:

- Other approved or investigational antiretroviral agents. All other investigational agents. Biologic response modifiers (e.g., interferon) or immunomodulators. Immunosuppressive agents (including glucocorticoids). Coumadin and other anticoagulant medications.

Prior Treatment:

Excluded:

- Red blood cell transfusion within 4 weeks of study entry.

Patients may not have the following:

- Opportunistic or serious bacterial infection.

Zidovudine (AZT) > 7 days prior to administration of study drug.

Active alcohol or drug abuse.
Overall Status: Completed

Phase: nan

NCTID: NCT00000645
Intervention Type: Drug
Intervention Name: Hypericin
Title: A Phase I Dose Escalation Study of Synthetic Hypericin in HIV-Infected Patients With Less Than 300 CD4 Lymphocytes
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Concurrent Medication:

Allowed:

- Prophylaxis for Pneumocystis carinii pneumonia (required for patients with CD4+ < 200).

- Symptomatic treatment with analgesics, antihistamines, antiemetics, antidiarrheal agents, or other supportive therapy.

- Short courses (< 10 days) with ketoconazole or fluconazole for oral candidiasis or acyclovir for herpes lesions.

- Topical medications such as clotrimazole troches or nystatin suspensions.

Concurrent Treatment:

Allowed:

- Blood transfusions.

Patients must have HIV infection with CD+4 lymphocyte count of < 300 cells/mm3.

Exclusion Criteria

Co-existing Condition:

Patients with the following conditions or symptoms are excluded.

- Kaposi's sarcoma requiring systemic therapy.

Concurrent Medication:

Excluded:

- Continued use of opiates or drugs known to induce photosensitivity.

Patients with the following are excluded:

- Active or chronic opportunistic infection at time of study entry that required curative or suppressive therapy.

- Significant liver disease, orthostatic hypotension, cardiac disease, seizure disorder, lymphoma, hypotension.

Prior Medication:

Excluded:

- Zidovudine (AZT), dideoxyinosine (ddI), dideoxycytidine (ddC), interferon, other antiretroviral agents or immunomodulating drugs within 1 month prior to study entry.
  Ribavirin within 3 months of study entry.

- Ganciclovir (DHPG), antimycobacterial drugs, MAO inhibitors, hypertension-inducing, nephrotoxic, or hepatotoxic drugs within 14 days of entry.

- Cytotoxic chemotherapy within 1 month prior to study entry.

Active substance abuse.
Overall Status: Completed
Phase: Phase 1

NCTID: NCT00000662
Intervention Type: Drug
Intervention Name: Zidovudine
Title: A Treatment IND for Retrovir Brand Zidovudine (AZT) Therapy of Pediatric Patients With HIV Disease
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Concurrent Treatment:

Allowed:

- Blood transfusions for hematologic toxicity.

Criteria for children 3 months to less than 15 months of age:

- Patient must be HIV antibody-positive by repeated reactive screening test (e.g., ELISA) and positive confirmatory test (e.g., Western blot).

OR

- If antibody-negative, patient must have two positive p24 antigen determinations performed at least one week apart or have had a positive HIV culture.

Patients must meet two of the following criteria:

- Be HIV culture positive or p24 antigen positive.

- Have at least one of the Class P-2 symptoms (by CDC criteria).

Be immunosuppressed defined as having:

- CD4+(T4) lymphocytes = or < 400 cells/mm3.

- Abnormal age adjusted immunoglobulin levels (IgG or IgA). Decreased helper/suppressor ratio < 1.0.

Note:

- In general, abnormal values for any of the above lab tests should be confirmed in 2 measurements at least 1 week apart, and other clinical causes for

these abnormalities
should be ruled out.

Criteria for children 15 months to 12 years of age:

- Patient must be HIV antibody-positive by repeated reactive screening test (e.g.,
ELISA) and positive confirmatory test (e.g., Western blot).

OR

- If antibody-negative, patient must have two positive p24 antigen determinations
performed at least one week apart or have had a positive HIV culture.

Patients must meet one of the following criteria:

- Have at least one of the class P-2 symptoms (by CDC criteria).

- Be immunosuppressed defined as having CD4+(T4) lymphocytes = or < 400 cells/mm3, based
on two measurements at least 1 week apart.

Exclusion Criteria

Co-existing Condition:

Patients with known hypersensitivity to AZT are excluded.

Patients with the following are excluded:

- Failure to meet inclusion criteria.

- Inability to obtain signed informed consent from a parent or legal guardian.

- Enrollment in another treatment protocol that expressly prohibits concomitant
treatment with zidovudine (AZT).

- Enrollment in another clinical trial in which AZT is a treatment.

- Known hypersensitivity to AZT.
Overall Status: Completed
Phase: nan

NCTID: NCT00000692
Intervention Type: Drug
Intervention Name: Butyldeoxynojirimycin
Title: Phase I Rising Dose Tolerability Study of SC-48334 in Patients With Acquired Immunodeficiency Syndrome (AIDS) and Advanced AIDS Related Complex
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Concurrent Medication:

Allowed:

- Aerosolized pentamidine.

- Nystatin.

- Clotrimazole.

- Topical acyclovir.

Concurrent Treatment:

Allowed:

- Blood transfusions for = or > grade 3 hemoglobin toxicity.

Exclusion Criteria

Co-existing Condition:

Patients with the following conditions will be excluded:

- Clinical significant diarrhea (> 3 stools per day for > 7 days without definable cause).

- Active opportunistic infection, requiring ongoing therapy, at time of enrollment.

- Any malignancy besides Kaposi's sarcoma, basal cell carcinoma, or squamous cell carcinoma unless the squamous cell carcinoma requires ongoing therapy.

- Neurologic disease including dementia, peripheral neuropathy, myelopathy (CDC category IVb).

Concurrent Medication:

Excluded:

- Antimetabolites.

- Alkylating agents.

- Drugs with known hepatic or bone marrow toxicity.

Patients with significant organ dysfunction will be excluded.

Prior Medication:

Excluded:

- Antimetabolites.

- Alkylating agents.

- Excluded within 30 days of study entry:

- Any investigational medication.

- Drugs with anti-HIV activity.

- Excluded within 90 days of study entry:

- Ribavirin treatment.

- Excluded within 6 months of study entry:

- Cancer chemotherapy.

Prior Treatment:

Excluded within 6 months of study entry:

- Radiation therapy.

Patients must demonstrate the following clinical and laboratory findings:

- AIDS or advanced AIDS related complex (ARC), according to Centers for Disease Control (CDC) category IV, excluding neurologic disease in IVb.

- Ability to understand the terms of study participation.

Current use of illicit drugs or abuse of alcohol.
Overall Status: Completed
Phase: Phase 1

NCTID: NCT00000663
Intervention Type: Drug
Intervention Name: CD4-IgG
Title: A Phase I Study of the Safety and Pharmacokinetics of Recombinant CD4 Immunoglobulin G (rCD4-IgG) in Infants and Children With Documented HIV-1 Infection
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Patients must have the following:

- HIV-1 infection, or if less than 15 months old, born to mother with HIV-1 infection.

- Legally qualified guardian with the ability to sign a written, informed consent form.

- Willingness to abstain from all other experimental therapy for HIV-1 infection during the first 12 weeks of the study period.

- Anticipated life expectancy of at least 3 months.

Prior Medication:

Allowed:

- Prophylactic anti-Pneumocystis carinii pneumonia (PCP) or antifungal therapy.

- Gamma globulin as prophylaxis for measles and varicella.

Exclusion Criteria

Co-existing Condition:

Patients with the following conditions or symptoms are excluded:

- Past or present history of neurological abnormalities including withdrawal syndrome or seizures.

- Past or present history of any serious active opportunistic infection including

Pneumocystis carinii pneumonia (PCP).

- Echocardiogram values > 2 standard deviations from normal.

- Hematologic, renal, or hepatic insufficiency.

Concurrent Medication:

Excluded:

- Zidovudine (AZT).

- Intravenous gamma globulin (IVIG) except as prophylaxis for measles and varicella.

- Cancer chemotherapy.

- Corticosteroids.

- Other known immunomodulatory agents.

- Other experimental therapy not specifically allowed.

Patients with the following are excluded:

- Hematologic, renal, or hepatic insufficiency.

- Past or present history of any serious active opportunistic infection.

Prior Medication:

Excluded for a minimum of 3 weeks prior to study entry:

- Zidovudine (AZT).

- Intravenous gamma globulin (IVIG).

- Cancer chemotherapy.

- Immunomodulatory agents.

- Acyclovir and other experimental therapy.

Risk Behavior:

Excluded:

- Patients born to substance abusing mothers (including alcohol) during the pregnancy.

Overall Status: Completed
Phase: Phase 1

NCTID: NCT00000675
Intervention Type: Drug
Intervention Name: CD4-IgG
Title: A Phase I Study of the Safety and Pharmacokinetics of Recombinant Human CD4 Immunoglobulin (rCd4-IgG) Administered by Intravenous Bolus in Patients With AIDS and AIDS Related Complex
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Patients must fulfill the following criteria:

- Diagnosis of AIDS or AIDS-related complex, according to CDC criteria, in previously documented HIV seropositive individuals.

- Failure to tolerate or respond to zidovudine (AZT) therapy for HIV infection or a decision to decline such therapy.

- Willingness to abstain from all other experimental therapy for HIV infection during study period.

- Life expectancy of at least 3 months.

- Patients must be able to sign a written informed consent form.

Exclusion Criteria

Co-existing Condition:

Patients with the following are excluded:

- Serious active opportunistic infection or malignancies not specifically allowed.

Concurrent Medication:

Excluded:

- Oral or intravenous acyclovir for herpes.

- Zidovudine (AZT).

- Interferon.

- Corticosteroids.

- Nonsteroidal anti-inflammatory agents (NSAIDS).

- Intravenous acyclovir.

- Other known immunomodulatory agents.

- Other experimental therapy.

Patients with the following are excluded:

- Serious active opportunistic infection or malignancies not specifically allowed.

Prior Medication:

Excluded within 4 weeks of study entry:

- Zidovudine (AZT).

- Chemotherapy.

- Immunomodulatory agents.

- Other experimental therapy.

Overall Status: Completed
Phase: Phase 1

NCTID: NCT00000672
Intervention Type: Drug
Intervention Name: Didanosine
Title: An Efficacy Study of 2',3'-Dideoxyinosine (ddI) (BMY-40900) Administered Orally Twice Daily to Zidovudine Intolerant Patients With AIDS or AIDS-Related Complex
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Concurrent Medication:

Required:

- Aerosolized pentamidine (300 mg every 4 weeks). In the event of physiological intolerance, alternative PCP prophylaxis may be trimethoprim/sulfamethoxazole 1 DS tab per day or dapsone 50 - 100 mg per day.

Allowed:

- Chronic suppressive treatment for toxoplasmosis, Pneumocystis carinii pneumonia (PCP), cryptococcal meningitis, herpes simplex virus, cytomegalovirus, coccidioidomycosis, and histoplasmosis (absorption of ketoconazole or dapsone may be inhibited if given at the same time as the buffered solution of ddI, and should be taken 2 hours before or 2 hours after taking ddI; oral acidifying agents are not allowed). Isoniazid is permitted only if no acceptable alternative therapy is available. Metronidazole may be used for single courses not to exceed 14 days within consecutive 90 day intervals, the first of which begins at the initiation of the study. Erythropoietin for patients under the relevant treatment IND. Intravenous acyclovir for short courses of therapy.

Patients must:

- Have documented hematologic intolerance to zidovudine (AZT).

- Have the diagnosis of AIDS or advanced AIDS related complex (ARC).

- Have ended treatment for acute Pneumocystis carinii pneumonia (PCP) at least 2 weeks before study entry.

Have previous intolerance on at least two courses of AZT therapy (one of which must have been at daily doses of 500 mg of AZT or less).

- Be able to provide informed consent (and/or guardian as appropriate).

- Be available for follow-up for at least 6 months.

- Have baseline laboratory values as measured within 7 days before initial drug dosing.

- Allowed:

- Development of new opportunistic infections during the study - patients remain in the protocol.

Prior Medication:

Required:

- Prior use and intolerance to zidovudine (AZT).

- Allowed:

- Intralesional agents.

Exclusion Criteria

Co-existing Condition:

Patients with the following are excluded:

- Presence of Kaposi's sarcoma (KS) with known or suspected visceral disease or where KS requires chemotherapy.

- Active AIDS defining opportunistic infections not specifically allowed.

- Intractable diarrhea.

- Stage 2 AIDS-dementia complex.

- History of intolerance to aerosolized pentamidine.

- Grade 2 neuropathy, based on the Neuropathy Targeted Symptom Questionnaire, or any moderate abnormality indicative of peripheral neuropathy, particularly impaired sensation of sharp pain, light touch, or vibration in the lower extremities, distal extremity weakness, or distal extremity hyporeflexia.

- Prior history of acute or chronic pancreatitis.

- History of seizures within past 2 years or currently requiring anticonvulsants for control.

- Any other clinical conditions or prior therapy which, in the opinion of the investigator, would make the patient unsuitable for study or unable to comply with the dosing requirements.

Concurrent Medication:

Excluded:

- Isoniazid (INH).

Patients with the following are excluded:

- Active AIDS-defining opportunistic infections not specifically allowed.

- Intractable diarrhea.

- AIDS-dementia complex = or > stage 2.

- History of intolerance to aerosolized pentamidine. Grade 2 neuropathy, based on the Neuropathy Targeted Symptom Questionnaire, or any moderate abnormality indicative of peripheral neuropathy, particularly impaired sensation of sharp pain, light touch, or vibration in the lower extremities, distal extremity weakness, or distal extremity hyporeflexia.

- Prior history of acute or chronic pancreatitis.

- History of seizures within past 2 years or currently requiring anticonvulsants for control.

- Any other clinical conditions or prior therapy which, in the opinion of the investigator, would make the patient unsuitable for study or unable to comply with the dosing requirements.

- Previous participation in any Phase I ddI study.

- Life expectancy < 6 months.

Prior Medication:

Excluded:

- Chronic therapy for cytomegalovirus infection with ganciclovir.

- ddI.

- d4T.

- ddC.

Excluded within 2 weeks of study entry:

- Zidovudine (AZT).

Excluded within 1 month of study entry:

- Therapy with any other antiretroviral drug or investigational agent not specifically allowed, including interferon and immunomodulating drugs.

- Ganciclovir.

- Neurotoxic drugs.

Excluded within 3 months of study entry:

- Ribavirin.

- Cytotoxic anticancer therapy.

Prior Treatment:

Excluded within 2 weeks of study randomization:

- Transfusion.

Active alcohol or drug abuse that is sufficient, in investigator's opinion, to prevent adequate compliance with study therapy.

Overall Status: Completed
Phase: Phase 2

NCTID: NCT00000686
Intervention Type: Drug
Intervention Name: Stavudine
Title: A Study of d4T in Patients With AIDS or AIDS-Related Complex Who Cannot Take AZT
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Patients must have:

- Diagnosis of AIDS or AIDS related complex (ARC).

- Previous intolerance to daily doses of up to 1200 mg of zidovudine (AZT) demonstrated by a decrease in hemoglobin levels of 2 - 8.5 g/dl or AZT-related depression of neutrophils of 200 - 750 cells/mm3.

- Ability to provide informed consent.

Prior Medication:

Allowed:

- Zidovudine (AZT).

Exclusion Criteria

Co-existing Condition:

Patients with the following are excluded:

- AIDS-defining opportunistic infection on enrollment.

- Intractable diarrhea.

- History of seizures within past 2 years or currently requiring anticonvulsants for control.

- Any other clinical conditions or prior therapy which in the opinion of the investigator would make the patient unsuitable for study or unable to comply with the dosing requirements.

Concurrent Medication:

Excluded:

- Systemic maintenance or chemoprophylaxis for opportunistic infection (includes dapsone, acyclovir).

- Systemic therapy with this or any other antiretroviral drug (except zidovudine (AZT)) or investigational drug.

- Ribavirin.

- Cytotoxic anticancer therapy.

- Any agent known as a potent inducer or inhibitor of drug-metabolizing enzymes (includes rifampin and barbiturates).

- Trimethoprim / sulfamethoxazole (TMP / SMX).

Patients with the following are excluded:

- AIDS-defining opportunistic infection on enrollment.

- Intractable diarrhea.

- History of seizures within past 2 years or currently requiring anticonvulsants for control.

- Any other clinical conditions or prior therapy which in the opinion of the investigator would make the patient unsuitable for study or unable to comply with the dosing requirements.

Prior Medication:

Excluded within 2 weeks of study entry:

- Any agent known as a potent inducer or inhibitor of drug-metabolizing enzymes (includes rifampin and barbiturates).

Excluded within 1 month of study entry:

- Systemic therapy with this or any other antiretroviral drug (except zidovudine (AZT)) or investigational drug.

Excluded within 3 months of study entry:

- Ribavirin.

- Cytotoxic anticancer therapy.

Active alcohol or drug abuse sufficient in investigator's opinion to prevent adequate compliance with study therapy.
Overall Status: Terminated
Phase: Phase 1

NCTID: NCT00000690
Intervention Type: Drug
Intervention Name: Dextran sulfate
Title: Single Dose Pharmacokinetics of Oral Dextran Sulfate (UA001) and Intravenous Dextran Sulfate in Healthy Volunteers
Condition: HIV Infections
Eligibility Criteria: Exclusion Criteria

Co-existing Condition:

Volunteers with any of the following are excluded:

- Disorders of coagulation or disorders of plasma lipids.
- Allergy to dextran sulfate, other sulfates, other dextrans.

Concurrent Medication:

Excluded:

- Volunteers who anticipate need for medication during study.

Volunteers with any of the following are excluded:

- Disorders of coagulation or disorders of plasma lipids.
- Allergy to dextran sulfate, other sulfates, other dextrans.

Prior Medication:

Excluded within 2 weeks of study entry:

- Any medication.

Risk Behavior:

Excluded:

- Ingestion of alcohol within 48 hours prior to study.
- History of recent drug or alcohol abuse.
- Disorders of coagulation or disorders of plasma lipids.
- Allergy to dextran sulfate, other sulfates, other dextrans.

Volunteers selected are:

- In good general health as determined by screening history, physical examination, and laboratory panel within established limits of normal for hospital laboratory.
- Consenting volunteers.
- Available for 6 days of continuous hospitalization.

Overall Status: Completed
Phase: Phase 1

NCTID: NCT00000684
Intervention Type: Drug
Intervention Name: Dextran sulfate
Title: Continuous High-Dose Intravenous Dextran Sulfate in Human Immunodeficiency Virus-Infected Individuals
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Concurrent Medication:

Allowed:

- Acetaminophen.

Patients must have:

-

Clinically documented AIDS or AIDS-related complex (ARC) defined as CDC group IVA or
history of any of the findings that define CDC group IV subgroup C-2:

- oral candidiasis, oral hairy leukoplakia, multidermatomal herpes zoster, recurrent
nontyphoidal Salmonella bacteremia, or nocardiosis.

Prior Medication:

Allowed:

- Acetaminophen.

Exclusion Criteria

Concurrent Treatment:

Excluded:

- Intramuscular injections.

Patients will be excluded from the study for the following reasons:

- Acute illness requiring hospitalization or antiviral drug therapy for treatment.

- Volunteers who have taken any antiviral medications, anticoagulants, antiplatelet
medications, or any nonsteroidal anti-inflammatory drugs, except acetaminophen, within
2 weeks of study entry, or those who anticipate the need for such medication during
the study.

- Positive stool guaiac at screening.

- Disorders of coagulation or any known contraindication to anticoagulation, including
but not limited to gastrointestinal or other serious bleeding, major trauma or surgery
within the past 2 months, stroke or suspicion of central nervous system (CNS)
bleeding, Kaposi sarcoma (with or without proven gastrointestinal involvement), and
any known CNS lesions that might be prone to bleed.

- Allergy to dextran sulfate or heparin.

- Acute or asymptomatic HIV infection.

Prior Medication:

Excluded:

- Antiviral medications.

- Anticoagulants.

- Antiplatelet medications.

- Any nonsteroidal anti-inflammatory drugs (except acetaminophen).

Prior Treatment:

Excluded:

- Hospitalization for acute illness.

Patients may not have any of the following diseases or symptoms:

- Allergy to dextran sulfate or heparin.

- Acute or asymptomatic HIV infection.

- Acute illness requiring hospitalization.

- Chronic anemia requiring transfusion within the past month.

- Disorders of coagulation or any known contraindication to anticoagulation, including but not limited to gastrointestinal or other serious bleeding, major trauma or surgery within the past 2 months, stroke or suspicion of central nervous system (CNS) bleeding, Kaposi's sarcoma, and any known CNS lesions which might be prone to bleed.

Overall Status: Completed
Phase: nan

NCTID: NCT00000669
Intervention Type: Drug
Intervention Name: Didanosine
Title: A Phase I Safety and Pharmacokinetics Study of 2',3'-Dideoxyinosine (ddI) Administered Twice Daily to Infants and Children With AIDS or Symptomatic HIV Infection
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Concurrent Medication:

Allowed:

- Aerosolized pentamidine for Pneumocystis carinii pneumonia (PCP) prophylaxis if this drug is extended to children.

- Acute therapy not exceeding 7 days with oral or intravenous acyclovir for herpes simplex infections.

- Trimethoprim / sulfamethoxazole for Pneumocystis carinii infections during course of study at discretion of investigator after discussion with the sponsor.

- Symptomatic therapy with analgesics, antihistamines, antiemetics, antidiarrheal agents, or other supportive therapy as deemed necessary by the principal investigator.

Patients must have:

- Diagnosis of AIDS as defined by CDC or meeting CDC P2 classification.

- Patients must be free of opportunistic infection or other serious bacterial, fungal, or parasitic infection at time of entry into study.

- Life expectancy > 6 months.

- Parent or guardian (and patient as applicable) able to give informed consent.

- Available for follow-up for at least 6 months.

- Allowed: Hemophilia.

Exclusion Criteria

Co-existing Condition:

Children with the following are excluded:

- Chronic hematologic disorders unrelated to coagulation defects, hemoglobinopathies, or ITP.

- Intractable diarrhea.

- No venous access.

- History of seizures within previous 2 years or currently requiring anticonvulsants for control.

- Currently active heart disease as evidenced by a cardiac arrhythmia or other significant abnormality on routine electrocardiography (ECG) or shortening fraction of < 10 percent on echocardiogram.

- Renal disease.

- Any other clinical condition that in the opinion of the investigator makes the patient unsuitable for study.

Concurrent Medication:

Excluded:

- Antiretroviral drugs.

- Zidovudine (AZT).

- AL 721.

- Interferon.

- Corticosteroids.

- Immunomodulating drugs.

- Other systemic investigation agent.

- Ribavirin.

- Rifampin, barbiturates, or any other potent inducer or inhibitor of drug-metabolizing enzymes.

- Cytotoxic anticancer therapy.

- H-2 blockers.

- Intravenous ketoconazole.

- Immunoglobulin preparations.

Children with the following are excluded:

- Chronic hematologic disorders unrelated to coagulation defects, hemoglobinopathies, or ITP.

- Intractable diarrhea.

- No venous access.

- History of seizures within previous 2 years or currently requiring anticonvulsants for control.

- Currently active heart disease as evidenced by a cardiac arrhythmia or other significant abnormality on routine electrocardiography (ECG) or shortening fraction of < 10 percent on echocardiogram.

- Renal disease.

- Any other clinical condition that in the opinion of the investigator makes the patient unsuitable for study.

- Renal disease.

Prior Medication:

Excluded:

- Any prior therapy which in the opinion of the investigator would make the patient unsuitable for study.

Excluded within 2 weeks of study entry:

- Trimethoprim / sulfamethoxazole.

Excluded within 1 month of study entry:

- Study drug or other antiretroviral drug or systemic investigational agent.

- Any agent known as a potent inducer or inhibitor of drug metabolizing enzymes.

- H-2 blockers.

- Ketoconazole.

- Immunoglobulin preparations.

Excluded within 3 months of study entry:

- Ribavirin.

Excluded:

- Zidovudine (AZT) for > 6 months.

- Cytotoxic anticancer therapy.

Prior Treatment:

Excluded within 4 weeks of study entry:

- Blood transfusion.

- Lymphocyte transfusions for immune reconstitution.

- Bone marrow transplant.

Overall Status: Completed
Phase: Phase 1

NCTID: NCT00000713
Intervention Type: Drug
Intervention Name: Ampligen
Title: A Phase I Clinical Trial To Evaluate the Toxicity, Antiviral and Immunomodulatory Effects of a Range of Doses of Ampligen in HIV-Infected Subjects
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Concurrent Medication:

Allowed:

- Short-course therapy (7 days) with oral acyclovir or ketoconazole.

Patients must have:

- Evidence of HIV infection as measured by a confirmed positive antibody test.

- A confirmed or pending HIV blood culture, and serum p24 antigen test.

- The ELISA test confirmed by a licensed Western blot analysis if they are asymptomatic.

Exclusion Criteria

Concurrent Medication:

Excluded:

- Aspirin or acetaminophen beyond 72 hours without contacting investigator.

- Chemoprophylaxis for Pneumocystis carinii pneumonia (PCP).

Patients with the following are excluded:

- AIDS.

- AIDS related symptoms or with advanced ARC and < 200 CD4 cells/mm3 and at least two of
  the following:

- Weight loss in excess of 10 lbs or 10 percent of body weight within a 6-month
  interval.

- Temperature > 38.5 degrees C with or without night sweats, persisting for more than 14
  consecutive days or more than 15 days in a 30-day interval.

- Diarrhea defined as = or > 3 liquid stools per day, persisting for more than 30 days
  without definable cause.

- Recurrent oral candidiasis as documented by morphology or by response to antifungal
  therapy.

- Patients cannot have active oral candidiasis at the time of entry into the study; they
  must be free of candidiasis from baseline 1 to enrollment.

- Multidermatomal herpes zoster within the past 2 years.

- Hairy leukoplakia within the past 3 years.

Prior Medication:

Excluded within 14 days of study entry:

- Other biologic response modifiers.

- Corticosteroids.

- Systemic antibiotics.

- Excluded within 30 days of study entry:

- Other antiretroviral agents.

- Excluded within 60 days of study entry:

- Ribavirin.

- Zidovudine.

Concurrent neoplasms other than basal cell carcinoma of the skin.

Active drug or alcohol abuse.
Overall Status: Completed
Phase: Phase 1

NCTID: NCT00000701
Intervention Type: Drug
Intervention Name: Zidovudine
Title: A Phase I Evaluation of Azidothymidine (AZT) in Children With Acquired Immune Deficiency Syndrome (AIDS) or AIDS Related Complex (ARC)
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Concurrent Treatment:

Allowed:

- Nutritional support not exceeding 120 calories/kg/day (hyperalimentation or dietary supplements including vitamin, folate, iron supplements).

Exclusion Criteria

Co-existing Condition:

Children with the following conditions are excluded:

- Asymptomatic with T-lymphocyte deficiency.

- Asymptomatic viremic patients or those not meeting definition criteria of AIDS related complex (ARC) or AIDS.

- Clinical evidence of active infection of acute nature or active significant or clinically apparent opportunistic infection at time of entry into study.

- Hemoglobinopathy including sickle cell anemia.

- Congenital infections such as toxoplasmosis or herpes simplex virus infection in the first month after birth or cytomegalovirus infection in the first 6 months after birth.

Children with the following conditions are excluded:

- Asymptomatic with T-lymphocyte deficiency.

- Asymptomatic viremic patients or those not meeting definition criteria of AIDS related complex (ARC) or AIDS.

- Clinical evidence of active infection of acute nature or active significant or clinically apparent opportunistic infection at time of entry into study.

- Hemoglobinopathy including sickle cell anemia.

- Congenital infections such as toxoplasmosis or herpes simplex virus infection in the first month after birth or cytomegalovirus infection in the first 6 months after birth.

Prior Medication:

Excluded:

- Suramin.

- Ribavirin.

- HPA 23.

- Phosphonoformate.

- Ansamycin.

- Interleukin 2.

- Interferon.

- Excluded within 30 days of study entry:

- All cytolytic chemotherapeutic agents, immunomodulating agents including steroids and immunoglobulin preparations.

- Antivirals (acyclovir, ganciclovir).

Prior Treatment:

Excluded within 4 weeks of study entry:

- Lymphocyte transfusions for immune reconstitution.

- Excluded within 3 months of study entry:

- Bone marrow transplant.

Child who is seropositive for HIV antibody or has HIV viremia and presents with one or more of following clinical criteria and at least one of the laboratory criteria may be considered an ARC patient for purpose of study:

- Clinical criteria:

- Persistent oral candidiasis despite appropriate therapy.

- Wasting syndrome characterized by failure to thrive and malnutrition.

- Recurrent or chronic unexplained diarrhea.

- Lymphadenopathy (more than 1 cm) at 2 or more noncontiguous sites.

- Hepatomegaly with or without splenomegaly.

- Encephalopathy with loss of developmental milestones and cortical atrophy present on computed tomography (CT) examination.

- Recurrent bacterial infections (bacteremia, pneumonia, septic arthritis, meningitis).

- Cutaneous anergy as defined by lack of delayed cutaneous hypersensitivity to selected antigens.

- Laboratory criteria:

- Hypergammaglobulinemia (IgG or IgA) defined as immunoglobulin values exceeding the maximum age-adjusted level.

- Decreased number of total T-lymphocytes (2 SD from mean).

- Absolute depression in T-helper cells to less than 500/mm3.

- Depressed (equal to or more than 2 SD from normal mean) in vitro mitogen response to at least one antigen.

- One positive HIV culture within 3 months of study entry into the study or blood obtained and culture pending.

- Life expectancy greater than 6 months.

- Ambulatory and free of opportunistic infection at time of entry.

- Reliably diagnosed disease at least moderately indicative of underlying cellular immunodeficiency and no known cause of underlying cellular immunodeficiency or other reduced resistance reported to be associated with that disease.

- Disease accepted as sufficiently indicative of underlying cellular immunodeficiency by CDC. In absence of these opportunistic diseases, a histologically confirmed diagnosis of chronic lymphoid interstitial pneumonitis will be considered indicative of AIDS unless test(s) for HIV are negative.

Overall Status: Completed
Phase: Phase 1

NCTID: NCT00000700
Intervention Type: Drug
Intervention Name: Zidovudine
Title: A Multi-Center Clinical Trial To Evaluate Azidothymidine (AZT) in the Treatment of Human Immunodeficiency Virus (HIV) Infection in Patients With AIDS Post First Episode PCP
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Concurrent Medication:

Allowed:

- All concomitant medication to minimum and record.

- Any approved medications can be used to treat an opportunistic infection.

- Dapsone may be used for Pneumocystis carinii pneumonia (PCP).

- Pyrimethamine - sulfadoxine may be used for toxoplasmosis.

- Ganciclovir for cytomegalovirus may be used for maintenance only.

- Prophylactic therapy for PCP.

Concurrent Treatment:

Allowed:

- Local, limited radiation therapy to isolated Kaposi's sarcoma lesions provided total area is < 5 x 5 cm and a 6-MeV electron beam or 90 kV x-ray = or <

3000 rads total is
used.

Patients must have:

- HIV seropositivity as confirmed by any federally licensed ELISA test kit.

- Allowed:

- Malignancy in past which has been in complete remission for 1 year without therapy.

Exclusion Criteria

Co-existing Condition:

Patients with active opportunistic infections will be excluded.

Concurrent Medication:

Excluded:

- Aspirin on a regular basis or beyond 72 hours without contacting investigator.

- Cimetidine.

- Flurazepam.

- Indomethacin.

- Ranitidine.

- Probenecid.

Patients with the following are excluded:

- Status post-Pneumocystis carinii pneumonia with symptomatic visceral Kaposi's sarcoma
(KS) or progression of KS within the month prior to study entry.

- Other concurrent neoplasms other than basal cell carcinoma of the skin.

- Requiring blood transfusions > once per month. Last transfusion cannot have been given
within 7 days of entry.

- Active substance abuse. Unwilling to sign informed consent or to be followed at
medical center where enrolled for duration of study and follow-up if necessary.

Prior Medication:

Excluded within 2 weeks of study entry:

- Treatment for acute Pneumocystis carinii pneumonia (PCP).

- Excluded within 30 days of study entry:

- Other antiretroviral agents, immunomodulating agents, or corticosteroids.

Prior Treatment:

Excluded within 30 days of study entry:

- Radiation therapy or cytotoxic chemotherapy for Kaposi's sarcoma.

Required:

- Patients must be at least 2 weeks post- therapy status for acute Pneumocystis carinii pneumonia (PCP).

Overall Status: Completed
Phase: Phase 3

NCTID: NCT00000721
Intervention Type: Drug
Intervention Name: CD4 Antigens
Title: An Escalating Dose Tolerance Trial of BG8962 (rCD4) in Patients Who Are HIV Antibody Positive
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Concurrent Medication:

Allowed:

- Nystatin or clotrimazole for suppression of oral thrush.

- Aerosolized pentamidine for Pneumocystis prophylaxis in Group A patients.

- Trimethoprim / sulfamethoxazole for Pneumocystis prophylaxis in patients who are hematologically stable on trimethoprim / sulfamethoxazole.

Patients must have:

- Group A: AIDS and symptoms defined in disease status.

- Group B: AIDS related complex (ARC) and symptoms defined in disease status.

Exclusion Criteria

Co-existing Condition:

Patients with the following disease or conditions are excluded:

- Malignancies other than Kaposi's sarcoma.

- AIDS dementia.

- Opportunistic infections requiring ongoing therapy except oral thrush suppression with nystatin or clotrimazole or Pneumocystis prophylaxis in Group A patients.

- Significant organ system dysfunction including:

- Granulocytopenia with a granulocyte count < 1000 cells/mm3.

- Thrombocytopenia - < 75000 platelets/mm3.

- Anemia with a hemoglobin < 9.5 g/dl.

- Renal dysfunction - creatinine > 2 mg/dl.

- Hepatic dysfunction with enzymes or bilirubin > 3 x upper limit of normal.

Patients with the following are excluded:

- Preexisting antibodies to rCD4.

- Malignancies other than Kaposi's sarcoma.

- AIDS-dementia complex.

- Opportunistic infections requiring ongoing therapy.

- Significant organ system dysfunction.

- Inability to sign voluntarily the consent form.

Prior Medication:

Excluded:

- Recombinant soluble CD4 protein (rCD4).

- Excluded within 30 days of study entry:

- Immunomodulatory therapy or agent with anti-HIV activity.

- Chemotherapy.

Prior Treatment:

Excluded within 30 days of study entry:

- Radiotherapy.

Active illicit drug use or alcohol abuse at time of entry.
Overall Status: Completed
Phase: Phase 1

NCTID: NCT00000710
Intervention Type: Drug
Intervention Name: Didanosine
Title: A Phase I Safety, Efficacy, and Pharmacokinetic Study of 2',3'-Dideoxyinosine (ddI) Administered Twice Daily to Patients With AIDS or AIDS Related Complex
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Concurrent Medication:

Recommended:

- Allopurinol for consistent occurrence of hyperuricemia observed with
  2',3'-dideoxyinosine (ddI) administration.

Allowed:

- Aerosolized pentamidine for Pneumocystis carinii pneumonia (PCP) prophylaxis.

- Oral acyclovir for herpes simplex infections provided ddI dosing is suspended during this time.

- Ketoconazole for patients not responding to any other therapy and after consultation with the sponsor.

- Symptomatic therapy such as analgesics, antihistamines, antiemetics, antidiarrheal agents, or other supportive therapy may be administered as deemed necessary by the principal investigator.

- Aspirin rather than acetaminophen for fever.

Patients with the following will be included:

- An absence of life-threatening opportunistic infection on enrollment.

- A life expectancy less than 6 months.

- Available for follow-up for at least 6 months.

- Able to provide informed consent. Exclusion Criteria

Co-existing Condition:

Patients with the following are excluded:

- Intractable diarrhea.

- No venous access.

- A history of or propensity for seizure disorders.

- A history of past or current heart disease or other significant abnormality on routine EKG.

Concurrent Medication:

Excluded:

- Adenine deaminase inhibitors.

- Trimethoprim / sulfamethoxazole for Pneumocystis carinii pneumonia (PCP) infections.

- Antibiotics.

- Acetaminophen for therapy of fever.

Patients with the following are excluded:

- Intractable diarrhea.

- A life expectancy less than 6 months.

- No venous access.

- A history of or propensity for seizure disorders.

- A history of past or current heart disease or other significant abnormality on routine
EKG.

Prior Medication:

Excluded:

- Any agent known as a potent inducer or inhibitor of drug-metabolizing enzymes.

- Excluded within 2 weeks of study entry:

- Trimethoprim / sulfamethoxazole.

- Excluded within 1 month of study entry:

- Any antiretroviral drug.

- Investigational agents.

- 2',3'-didanosine.

- AL721.

- Interferons.

- Immunomodulating drugs.

- Excluded within 3 months of study entry:

- Ribavirin.

- Cytotoxic agents.

Risk Behavior:

Excluded:

Active alcohol or drug abuse sufficient in the investigator's opinion to prevent adequate
compliance.

Overall Status: Completed
Phase: Phase 1

NCTID: NCT00000704
Intervention Type: Drug
Intervention Name: Zalcitabine
Title: A Multicenter Dose Ranging Clinical Trial of 2',3'-Dideoxycytidine in the Treatment of Patients With AIDS and Advanced ARC.
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Concurrent Medication:

Allowed:

- Aspirin, acetaminophen, and nonsteroidal anti-inflammatory agents.

- Acute therapy (7 days) with oral acyclovir.

- Acute therapy with ketoconazole.

Exclusion Criteria

Co-existing Condition:

Patients with the following are excluded:

- Negative antigen test within 2 weeks of starting therapy.

- Significant malabsorption (> 10 percent weight loss within past 3 months with serum carotene < 75 IU/ml or vitamin A < 75 IU/ml).

- Significant cardiac, liver, or neurologic disease.

- For group A:

- Opportunistic infection or malignancy fulfilling definition of AIDS, or with concurrent neoplasm other than basal cell carcinoma of the skin or in situ carcinoma of the cervix.

- For group B:

- Active opportunistic infection, symptomatic visceral Kaposi's sarcoma (KS), progression of KS within the month prior to study entry, or with concurrent neoplasms other than KS, basal cell carcinoma of the skin, or in situ carcinoma of the cervix.

Concurrent Medication:

Excluded:

- Acyclovir therapy.

- Chemoprophylaxis for Pneumocystis carinii pneumonia.

- Other antiretroviral agents, biologic modifiers, or systemic corticosteroids.

- Other experimental medications, sedatives, and barbiturates.

- Group B:

- Therapy and/or prophylaxis for AIDS-defining opportunistic infection, antineoplastic therapy.

Concurrent Treatment:

Excluded:

- Transfusion dependency (requiring 2 units of blood more than once per month). Patients with history of idiopathic thrombocytopenia purpura are excluded.

Prior Medication:

Excluded within 30 days of study entry:

- Biologic modifiers or corticosteroids.

- Excluded within 90 days of study entry:

- Antiretroviral agents.

Prior Treatment:

Excluded within 2 weeks of study entry:

- Transfusion.

Inclusion criteria are:

- Consistently positive HIV antigen as defined by Abbott HIV antigen test. This demonstration will be seen on two occasions, each separated by at least 72 hours, the last of which must be within 2 weeks of starting therapy.

- HIV antigen titer must be = or > 100 pg.

- Positive antibody to HIV confirmed by any federally licensed enzyme-linked immunosorbent assay (ELISA) test kit.

The following conditions are allowed:

- Basal cell carcinoma of the skin or in situ carcinoma of the cervix. Active substance abuse.

Overall Status: Completed
Phase: Phase 1

NCTID: NCT00000729
Intervention Type: Drug
Intervention Name: Foscarnet sodium
Title: A Multicenter Study To Determine Foscarnet Dose Response in HIV Infected Patients With PGL and/or Constitutional Disease
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Concurrent Medication:

Allowed:

- Aerosolized pentamidine for secondary Pneumocystis carinii pneumonia (PCP) prophylaxis.

- Short course therapy with oral acyclovir (ACV) = or < 7 days. Short course therapy with ketoconazole = or < 7 days for patients who are not responding to any other therapy.

- Flurazepam.

- Diphenhydramine.

Prior Medication:

Allowed:

- Systemic therapy, prophylaxis or maintenance for an AIDS-defining opportunistic

infection.

Patients with any of the following findings may be included:

- Asymptomatic HIV patients with or without lymphadenopathy.

- Patients with AIDS as defined by the CDC surveillance case definitions.

- Patients with past or present mild to moderate signs or symptoms consistent with HIV infection.

- p24 antigen in the serum = or > 60 pg/ml.

Exclusion Criteria

Co-existing Condition:

Patients with the following will be excluded:

- Ongoing systemic therapy / prophylaxis / maintenance for an AIDS-defining opportunistic infection.

- Symptomatic visceral Kaposi's sarcoma (KS), progression of KS within the month prior to entry into the study, or with concurrent neoplasms other than KS or basal cell carcinoma of the skin or in situ carcinoma of the cervix.

- Cytomegalovirus (CMV) retinitis.

- AIDS dementia.

Concurrent Medication:

Excluded:

- Antiretrovirals.

- Immunomodulatory agents.

- Corticosteroids Other systemic antiviral or antimicrobial agents.

- Experimental medications.

- Excluded on chronic basis and discouraged for > 72 hours:

- Acetaminophen.

- Narcotics.

- Aspirin.

Concurrent Treatment:

Excluded:

- Transfusion dependency or requirement of 2 units of blood more than once per month.

Patients with the following will be excluded:

- Ongoing systemic therapy / prophylaxis / maintenance for an AIDS-defining opportunistic infection.

- Symptomatic visceral Kaposi's sarcoma (KS), progression of KS within the month prior to entry into the study, or with concurrent neoplasms other than KS or basal cell carcinoma of the skin or in situ carcinoma of the cervix.

- Cytomegalovirus (CMV) retinitis.

- AIDS dementia.

Prior Medication:

Excluded within 30 days of study entry:

- Antiretroviral agents (except ribavirin).

- Immunomodulatory agents.

- Excluded within 60 days of study entry:

- Ribavirin.

The last blood transfusion cannot have been given within 2 weeks of entry.

Active substance abuse which could impair compliance with the protocol.
Overall Status: Completed
Phase: Phase 1

NCTID: NCT00000716
Intervention Type: Drug
Intervention Name: Zidovudine
Title: A Multicenter Trial To Evaluate Oral Retrovir in the Treatment of Children With Symptomatic HIV Infection
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Concurrent Medication:

Allowed:

- Amphotericin B and antituberculosis chemotherapy.

- Children who have advanced lymphocytic interstitial pneumonitis (LIP) who are steroid dependent may remain on such therapy.

- Secondary prophylaxis for Pneumocystis carinii pneumonia (PCP) with careful monitoring for possible toxicity due to combination therapy with zidovudine (AZT).

Concurrent Treatment:

Allowed:

- Blood transfusions for hematologic toxicity.

- Immunoglobulin therapy for development of = or > 3 serious bacterial infections while

receiving zidovudine. A serious bacterial infection includes septicemia (not catheter related), pneumonia, meningitis, bone or joint infection, or abscess of the body cavity or internal organ.

- The pathogen must be one of the following organisms:

- Staphylococcus aureus, Streptococcus pyogenes, Escherichia coli, Streptococcus group B, Pseudomonas aeruginosa, Hemophilus influenzae B, and Pneumococcus. Laboratory documentation of the pathogen is required.

Patients must comply with the following:

- Life expectancy of more than 6 months.

- Children must have laboratory evidence of HIV infections as demonstrated by either a positive viral culture or detectable serum p24 antigen or repeated positive test for HIV antibody determined by a federally licensed ELISA test and confirmed by Western blot.

- Children under 15 months of age, who are thought to have acquired HIV through perinatal transmission and whose only laboratory evidence of HIV infection is a positive antibody test, must also have increased immunoglobulin levels and decreased absolute number of CD4+ cells or a decreased helper/suppressor ratio.

- AIDS:

- Must have clinical evidence of HIV infection as demonstrated by the presence of one or more of the indicator diseases as defined in the CDC Surveillance definition for AIDS. (NOTE:

- Children with lymphocytic interstitial pneumonitis are excluded unless they meet at least one of the following conditions:

- an additional AIDS-defining opportunistic infection, recurrent serious bacterial infection, HIV encephalopathy, wasting syndrome, or meet the definition of AIDS related complex (ARC).

- ARC:

- Children who present with at least one of the first three clinical findings and one of any other listed below within 2 months of entry or who present with two of the first three symptoms listed:

- <= 500 CD4 cells/mm3 within 4 weeks of entry, persistent (>= 2 months) or recurrent oral candidiasis despite therapy, diarrhea (defined as >= 3 loose

stools per day) that
is either persistent or recurrent, hepatomegaly, splenomegaly, cardiomyopathy,
nephropathy manifested by nephrotic syndrome without evidence of renal failure, 2 or
more episodes of herpes stomatitis within a 1-year period, or 2 or more episodes of
recurrent herpes zoster or chronic zoster (defined as = or > 30 days duration
regardless of therapy).

- Written informed consent from a parent or guardian.

Exclusion Criteria

Co-existing Condition:

Patients with the following will be excluded:

- Any active or chronic opportunistic infection at time of entry requiring acute therapy
with experimental agents or agents which may affect zidovudine (AZT) toxicity or
safety, nor serious bacterial, fungal, or parasitic infections requiring parenteral
therapy at the time of entry.

Concurrent Medication:

Concomitant medications should be kept to a minimum.

Excluded:

- Chronic use of drugs that are metabolized by hepatic glucuronidation, such as
acetaminophen.

- Acute therapy for active or chronic opportunistic infection with experimental agents
or agents which may affect zidovudine (AZT) toxicity.

- Parenteral therapy for serious bacterial, fungal, or parasitic infections.

- Prophylaxis for Pneumocystis carinii pneumonia (PCP) for children who have not had a
previous episode of PCP, oral candidiasis, or otitis media.

- Immunoglobulin therapy. Note: Immunoglobulin therapy may be administered to children
who develop = > 3 serious bacterial infections while receiving AZT.

Children with lymphocytic interstitial pneumonitis (LIP) as their only clinical sign of HIV
infection will be excluded from the study. Children with any of the following laboratory
findings within 2 weeks of entry will be excluded:

- A total bilirubin > 3 times Upper Limit of Normal (ULN).

- SGOT > 5 x Upper Limit of Normal in the presence of an age-adjusted abnormal
bilirubin.

- Creatinine clearance < 50 ml/min/1.73 m2.

- White blood cells < 2000 cells/mm3.

- Neutrophils < 800 cells/mm3.

- Hematocrit < 24 percent.

- Hemoglobin < 8.0 g /dl.

- Children who will be unable to be followed by their original study center for the 24
weeks of the study will be excluded.

Prior Medication:

Excluded within 2 weeks of study entry:

- Any other experimental therapy or drugs which cause prolonged neutropenia or
significant nephrotoxicity.

- Excluded within 4 weeks of study entry:

- Immunomodulating agents including steroids, interferon, isoprinosine, and
interleukin-2.

- Excluded within 2 months of study entry:

- Other antiretroviral agents.

- Note: Children with advanced lymphocytic interstitial pneumonitis (LIP) who are
steroid dependent may remain on such therapy.

Prior Treatment:

Excluded within 4 weeks of study entry:

- Immunoglobulin.

- Lymphocyte transfusions for immune reconstitution.

- Excluded within 3 months of study entry:

- Bone marrow transplant.

Active alcohol or drug abuse.
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00000761
Intervention Type: Drug
Intervention Name: Interferon gamma-1b
Title: Phase I/II Study of Recombinant Human Interferon-gamma (rIFN-gamma) in HIV-Infected Children
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Concurrent Medication:

Required:

- AZT or ddI therapy.
- PCP prophylaxis.

Allowed:

- Antipyretics.
- Antiemetics.
- Antihistamines.
- Decongestants.
- Skin creams and lotions.
- Immunizations according to current recommendations.

Patients must have:

- Class P-2 symptomatic HIV infection.
- Ongoing AZT or ddI therapy of 6 months or longer duration.

Exclusion Criteria

Concurrent Medication:

Excluded:

- Antiretroviral therapy other than AZT or ddI.
- Chemotherapy for active malignancy.
- Amphotericin B for systemic fungal infections.

Patients with the following prior conditions are excluded:

- History of congestive heart failure or arrhythmias.
- History of congenital heart disease.
- History of seizure disorder requiring anticonvulsant medication. (NOTE: History of uncomplicated febrile seizures does not exclude.)

Prior Medication:

Excluded within 8 weeks prior to study entry:

- Immunomodulators other than IVIG.

Prior Treatment:

Excluded:

- Red blood cell transfusion within 4 weeks prior to study entry.

Required:

- Ongoing AZT or ddI therapy of 6 weeks or longer duration.
- Ongoing PCP prophylaxis for more than 6 weeks duration.

Ongoing alcohol or drug use.
Overall Status: Completed
Phase: Phase 1

NCTID: NCT00000735
Intervention Type: Drug
Intervention Name: Ampligen
Title: A Clinical Trial To Evaluate the Toxicity and Antiviral Effects of a Range of Doses of Ampligen in p24 Antigen Positive HIV-Infected Patients With AIDS or ARC
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Hemophiliacs are included. Patients must have:

- Consistently positive serum HIV p24 antigen (= or > 70 pg/ml) defined by the Abbott HIV antigen test. This demonstration must be seen on two occasions, each separated by at least 72 hours, the last of which must be within 2 weeks of starting therapy.

- Positive HIV antibody test.

Prior Medication:

Allowed:

- Acyclovir for short course (7 days).

- Ketoconazole for short course (7 days).

- Aerosolized pentamidine for Pneumocystis carinii pneumonia (PCP) prophylaxis.

- Trimethoprim / sulfamethoxazole for PCP prophylaxis.

Exclusion Criteria

Co-existing Condition:

Patients with AIDS encephalopathy as a sole indicator are excluded.

Patients with AIDS encephalopathy as a sole indicator are excluded.

Prior Medication:

Excluded:

- Other experimental medication.

- Antineoplastic therapy.

- Amphotericin B.

- Ganciclovir.

- Excluded within 14 days of study entry:

- Biologic modifiers.

- Corticosteroids.

- Excluded within 30 days of study entry:

- Other antiretroviral agents.

- Excluded within 60 days of study entry:

- Ribavirin.

Active drug or alcohol abuse.
Overall Status: Completed
Phase: Phase 1

NCTID: NCT00000756
Intervention Type: Drug
Intervention Name: Lymphocytes, Activated
Title: Evaluation of the Safety and Tolerance of Immunotherapy With Autologous, Ex-Vivo Expanded, HIV-Specific Cytotoxic T-Cells in HIV-Infected Patients With CD4+ Counts Between 100-400/mm3
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Concurrent Medication:

Allowed:

- Approved antiretroviral therapy and/or prophylactic PCP therapy, provided there was no change in such therapy in the 4 weeks prior to study entry.

- Other approved treatments for HIV-related diseases that are not known to affect cellular immune response.

- G-CSF.

- Erythropoietin.

- Supportive care for acute therapy-related toxicity.

Patients must have:

- HIV infection.

- CD4 count 100 - 400 cells/mm3.

- No current or previously documented AIDS-related opportunistic infection, malignancy, or encephalopathy other than mild Kaposi's sarcoma.

- FEV1 > 70 percent, DLCO > 50 percent predicted for height and age (initial infusion only).

- T cell lines with specific cytotoxicity against HIV-1.

Exclusion Criteria

Co-existing Condition:

Patients with the following symptoms or conditions are excluded:

- Significant autoimmune disease.

- Non-AIDS-associated malignancy.

- Symptoms of cardiac disease.

- Dyspnea on significant exertion.

- Acute infiltrates on chest radiographs.

Patients with the following prior conditions are excluded:

- History of significant arrhythmia, infarction, or heart failure.

- History of a major psychiatric illness.

Prior Medication:

Excluded within 4 weeks prior to study entry:

- Systemic immunosuppressive therapy (i.e., steroids, cyclosporine, chemotherapy, or alpha-interferon).

- Therapy for acute infection, AIDS-related opportunistic infection, or malignancy.

- Experimental AIDS therapy.

Prior Treatment:

Excluded:

- Potentially immunosuppressive local therapy or radiation therapy for Kaposi's sarcoma within 4 weeks prior to study entry.

Current substance abuse.
Overall Status: Completed
Phase: Phase 1

NCTID: NCT00000747
Intervention Type: Drug
Intervention Name: Nevirapine
Title: An Open-Label, Pilot Study to Evaluate the Development of Resistance to Nevirapine (BI-RG-587) in HIV-Infected Patients With CD4 Cell Count >= 500/mm3
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Patients must have:

- Positive serum antibody to HIV-1 by ELISA or Western blot.

- CD4 count >= 500 cells/mm3 within 2 months prior to study entry, with two additional counts averaging >= 450 cells/mm3 at baseline and on study day 0 (taken at least 48 hours apart).

- No AIDS-defining disease.

Exclusion Criteria

Co-existing Condition:

Patients with the following symptoms and conditions are excluded:

- More than four loose stools per day.

- Participation in other experimental trials including vaccine trials.

Concurrent Medication:

Excluded:

- Other approved or investigational antiretroviral agents, other investigational agents, or vaccines.

- Glucocorticoids and steroid hormones.

- Dicumarol, warfarin, and other anticoagulants.

- Digitoxin.

- Valproic acid.

- Tolbutamide.

- Doxycycline.

- Chloramphenicol.

- Phenobarbital and other barbiturates.

Excluded 4 hours before or after a nevirapine dose:

- Antacids (particularly those containing calcium carbonate).

- H-2 blockers, carafate, cholestyramine resin, alcohol and alcohol-containing substances, and benzodiazepines (e.g., diazepam, triazolam).

Patients with the following prior conditions are excluded:

- History of clinically important disease other than HIV infection.

Prior Medication:

Excluded within 1 month prior to study entry:

- Any immunosuppressive, immunomodulatory, or cytotoxic treatment.

Use of drugs or alcohol sufficient to impair compliance with protocol requirements.
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00000736
Intervention Type: Drug
Intervention Name: Zidovudine
Title: Safety and Efficacy of Zidovudine for Asymptomatic HIV-Infected Individuals
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Patients must:

- Be HIV seropositive and asymptomatic.

- Have normal neurologic exam as defined by the Micro Neuro-AIDS assessment.

Concurrent Medication

- Required: Prophylaxis for Pneumocystis carinii pneumonia (PCP). Aerosolized pentamidine is preferred but if not possible, Trimethoprim / sulfamethoxazole 1 DS tablet per day or Dapsone 50 - 100 mg per day is allowed.

Exclusion Criteria

- Active drug or alcohol abuse sufficient to prevent adequate compliance with study therapy in the investigator's opinion.

Co-existing Condition:

Patients with the following diseases or conditions are excluded:

- Hemophilia.

- Oral candida infection documented by morphology or by response to antifungal therapy within 2 years of study entry.

- Oral hairy leukoplakia at any time prior to study entry.

- Herpes zoster infection (including single dermatome infection) within 2 years of study entry.

- Active diarrhea as defined by 3 or more liquid stools per day.

- Temperature > 37.8 degrees C.

- Grade 1 impairment on two or more items (mild AIDS dementia complex) in the ACTG Micro Neuro-AIDS Assessment.

- Prior history of malignancy other than cutaneous basal cell carcinomas or cervical carcinoma in situ.

Patients with the following are excluded from entry:

- AIDS or AIDS-related complex defining symptoms.

- Significant, chronic underlying medical illnesses which would impair continuous participation in this 3-year clinical trial.

- Hemophilia.

Prior Medication: Excluded:

- Chemoprophylaxis for Pneumocystis carinii pneumonia (PCP).

- Other experimental medications.

- Excluded within 60 days of study entry:

- Antiretroviral drugs or immunomodulators (biologic response

modifiers).

- Excluded within 120 days of study entry:

- Systemic corticosteroids.

Prior Treatment: Excluded within 3 months of study entry:

- Blood transfusion.

Overall Status: Completed
Phase: Phase 3

NCTID: NCT00000733
Intervention Type: Drug
Intervention Name: Ribavirin
Title: Phase I Pharmacokinetic and Tolerance Study of Ribavirin in Human Immunodeficiency Virus (HIV) - Infected Patients
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Patients must be asymptomatic according to the following criteria:

- Normal neurologic exam.

- No unintentional weight loss of greater than 10 lbs. or more than 10 percent of usual body weight within 2 years prior to entering the study.

- No unexplained temperature above 38 degrees C on more than 5 consecutive days or on more than 10 days in any 30 days in the 2 years prior to expected entry into the study.

- No unexplained diarrhea defined by equal to or more than 3 liquid stools per day persisting more than 7 days within 2 years prior to expected entry into the study.

- No active hepatitis of any form. In addition, patients must not have previously had AIDS or an AIDS related illness.

Exclusion Criteria

Co-existing Condition:

Excluded:

- Temperature of greater than 37.8 degrees C.

- Development of an AIDS-defining opportunistic infection.

- Unexplained diarrhea defined by equal to or more than 3 liquid stools per day.

- Active hepatitis of any form.

Patients who have had oral candida infection documented by morphology, or by response to antifungal therapy, or oral hairy leukoplakia, or herpes zoster infection within 2 years of anticipated study entry at any time will be excluded. Patients with a prior history of a

malignancy other than cutaneous basal cell carcinomas or cervical carcinoma in situ and
patients with a significant chronic underlying medical illness that would impair continuous
participation in the study will be excluded.

Prior Medication:

Excluded within 90 days of study entry:

- Immunomodulators.

Active alcohol or drug abuse sufficient in the investigator's opinion to prevent adequate
compliance with the study therapy.
Overall Status: Completed
Phase: Phase 1

NCTID: NCT00000750
Intervention Type: Drug
Intervention Name: Zidovudine
Title: A Phase III Study to Evaluate the Safety, Tolerance, and Efficacy of Early Treatment With Zidovudine (AZT) in Asymptomatic Infants With HIV Infection
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Patients must have:

- HIV infection.

- CD4 count >= 2000 cells/mm3 AND >= 30 percent of total lymphocytes.

- No signs or symptoms of HIV infection (other than lymphadenopathy, mild hepatomegaly,
hypergammaglobulinemia, or splenomegaly, which is permitted).

- Consent of parent or guardian.

Exclusion Criteria

Co-existing Condition:

Patients with the following symptoms and conditions are excluded:

- Serious acute infection requiring parenteral therapy at time of entry.

- One or more serious, proven bacterial infections including any of the following:

- septicemia; pneumonia; meningitis; bone or joint infection; or abscess of an internal
organ or body cavity (excluding otitis media or superficial skin or mucosal abscesses)
that are caused by Haemophilus, Streptococcus (including pneumococcus), or other
pyogenic bacteria.

- Clinical neurologic/neuropsychologic deficits, or a head circumference less than the
fifth percentile.

Concurrent Medication:

Excluded:

- Any agent with known antiretroviral activity.

- Acetaminophen, ibuprofen, or aspirin for more than 72 hours continuously.

Prior Medication:

Excluded:

- More than 7 weeks of prior antiretroviral or immunomodulator therapy post-natally.

Recommended:

- PCP prophylaxis.

- Immunizations according to current recommendations.

Overall Status: Completed
Phase: Phase 3

NCTID: NCT00000765
Intervention Type: Drug
Intervention Name: Zidovudine
Title: Pilot Study to Evaluate the Efficacy of Zidovudine in Preventing CD4+ Lymphocyte Decline in Patients With Primary HIV Infection. (One Treatment Arm Receives Placebo)
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Concurrent Medication:

Allowed:

- Medications for nausea, vomiting, analgesia, or anxiety.

Patients must have:

- Asymptomatic or symptomatic primary HIV infection, plus one of the following two criteria:

  1. p24 antigenemia documented within 1 month prior to study entry and either HIV enzyme immunoassay (IA) negative or HIV IA positive with Western blot negative/indeterminate, within 1 month prior to study entry.

  2. Documented seroconversion within 1 month prior to study entry and Western blot negative/indeterminate.

- Consent of parent or guardian if less than 18 years of age.

Exclusion Criteria

Co-existing Condition:

Patients with the following condition are excluded:

- poor venous access.

Concurrent Medication:

Excluded:

- Chronic steroid use.

- Immunomodulators.

- Myelosuppressive agents.

- Other antiretroviral agents or experimental therapies (NOTE: FDA-approved therapies
permitted in patients who qualify after week 24; experimental therapies permitted
after study week 48).

Overall Status: Completed
Phase: nan

NCTID: NCT00000792
Intervention Type: Drug
Intervention Name: Hypericin
Title: A Pharmacologically Guided Phase I/II Study of Daily Orally Administered Synthetic Hypericin in HIV-Infected Subjects
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Concurrent Medication:

Required:

- PCP prophylaxis.

Allowed:

- Rifabutin, ketoconazole, fluconazole, and acyclovir, provided the medication has been
taken for at least 4 weeks prior to study entry without toxicity.

- Topical medications such as clotrimazole troches or nystatin suspension.

Patients must have:

- Documented HIV infection.

- CD4 count <= 350 cells/mm3.

- p24 antigen positive at >= 35 pcg/ml.

- No active opportunistic infection at study entry that would require curative or
suppressive therapy.

Exclusion Criteria

Co-existing Condition:

Patients with the following symptoms or conditions are excluded:

- Malignancy for which systemic chemotherapy is required.

- Medically significant liver disease, orthostatic hypotension, hypertension, cardiac
disease, seizure disorders, or lymphoma.

- Any medical condition that would interfere with evaluation of the patient.

Concurrent Medication:

Excluded:

- AZT, ddI, ddC, d4T, or any other antiretroviral medication.
- Interferon or other immunomodulating drugs.
- Cytotoxic chemotherapy.
- Foscarnet.
- Ganciclovir.
- Antimycobacterial drugs other than rifabutin.
- MAO inhibitors.
- Hypertension-inducing, nephrotoxic, or hepatotoxic drugs.
- Opiates.
- Drugs known to cause photosensitivity.

Prior Medication:

Excluded within 1 month prior to study entry:

- AZT, ddI, ddC, d4T, or any other antiretroviral medication.
- Interferon or other immunomodulating drugs.
- Cytotoxic chemotherapy.
- Preparations known to contain hypericin.

Excluded within 3 months prior to study entry:

- Ribavirin.
- Hyperforate (500 mg tablets or ampules for IV injection) manufactured by Kline.
- Psychotonin M Alcohol Extract manufactured by Steigerwald.
- Hypericin (40 mg vial) by VIMRx.

Excluded within 14 days prior to study entry:

- Foscarnet.
- Ganciclovir.
- Antimycobacterial drugs other than rifabutin.
- MAO inhibitors.
- Hypertension-inducing, nephrotoxic, or hepatotoxic drugs.

Overall Status: Completed
Phase: Phase 1

NCTID: NCT00000806
Intervention Type: Drug
Intervention Name: Telinavir
Title: A Phase I Randomized Dose/Formulation Comparison Study of SC-52151
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Concurrent Medication:

Required for patients with CD4 count <= 200 cells/mm3:

- PCP prophylaxis using TMP/SMX or aerosolized pentamidine.

Allowed:

- Topical antifungal agents.

- Up to 1000 mg/day acyclovir as maintenance therapy for herpes simplex virus.

- Antibiotics for bacterial infections.

- Antipyretics, analgesics, nonsteroidal anti-inflammatory agents, antiemetics, and methadone for symptomatic treatment.

Patients must have:

- HIV infection.

- CD4 count 150 - 500 cells/mm3.

Exclusion Criteria

Co-existing Condition:

Patients with the following symptoms or conditions are excluded:

- Unable to tolerate the standard diet required for the study.

- Unable to give informed consent.

Concurrent Medication:

Excluded:

- Antiretrovirals and biologic response modifiers (including HIV vaccines).

- Maintenance with ketoconazole, fluconazole, itraconazole, ganciclovir, foscarnet, pyrimethamine, sulfadiazine, clindamycin, azithromycin, isoniazid, rifampin, rifabutin, ethambutol, pyrazinamide, clofazimine, or clarithromycin.

- Prophylaxis for Mycobacterial infection or fungal infections other than Candidiasis.

- Allopurinol.

- Omeprazole.

- Astemizole.

- Terfenadine.
- Loratadine.
- Psychotropics.
- Phenylbutazone.
- Barbiturates.
- Benzodiazepines.
- Monoamine oxidase inhibitors.
- H-2 blockers.
- Anticonvulsants.
- Coumadin anticoagulants.
- Oral contraceptives.
- Antiarrhythmics.
- Diltiazem.
- Metronidazole.
- Erythromycin.
- Chloramphenicol.
- Fluoroquinolones.
- Disulfiram.
- Erythropoietin.
- G-CSF or GM-CSF.
- Systemic corticosteroids.
- Alcohol, including alcohol-containing medications.

Patients with the following prior conditions are excluded:

- Unexplained temperature >= 38.5 C for any 7 days within the 30 days prior to study entry.
- Chronic diarrhea (>= three stools per day) for any 15 days within the 30 days prior to study entry.
- Malignancy other than basal or squamous cell carcinoma of the skin, cervical intraepithelial neoplasia, and minimal Kaposi's sarcoma.

Prior Medication:

Excluded at any time:

- Prior HIV protease inhibitor.

Excluded within 30 days prior to study entry:

- Investigational drugs.
- Recombinant erythropoietin.
- G-CSF or GM-CSF.
- Interferon or interleukin.
- Any HIV-1 vaccine.

Excluded within 14 days prior to study entry:

- Antiretrovirals.
- Acute therapy for any opportunistic or other serious infection.
- Therapy for malignancy.
- Maintenance with ketoconazole, fluconazole, itraconazole, ganciclovir, foscarnet, pyrimethamine, sulfadiazine, clindamycin, azithromycin, isoniazid, rifampin, rifabutin, ethambutol, pyrazinamide, clofazimine, or clarithromycin.
- Prophylaxis for Mycobacterial infection or fungal infections other than Candidiasis.

Excluded within 7 days prior to study entry:

- Allopurinol.
- Omeprazole.
- Astemizole.
- Terfenadine.
- Loratadine.
- Psychotropics.
- Phenylbutazone.
- Barbiturates.
- Benzodiazepines.
- Monoamine oxidase inhibitors.
- H-2 blockers.
- Anticonvulsants.
- Coumadin anticoagulants.
- Oral contraceptives.
- Antiarrhythmics.
- Diltiazem.

- Metronidazole.

- Erythromycin.

- Chloramphenicol.

- Fluoroquinolones.

- Disulfiram.

Risk Behavior: Excluded:

- History of substance or alcohol abuse.

- Ingestion of more than 50 g alcohol daily within 6 months prior to study entry.

- Recovered alcoholic.

Overall Status: Completed
Phase: Phase 1

NCTID: NCT00000818
Intervention Type: Drug
Intervention Name: Zidovudine
Title: Evaluation of the Changes in HIV-1 Burden in Peripheral Blood and Lymphoid Tissue Following Zidovudine (AZT) Treatment in HIV-1-Infected Patients With CD4+ Cells Between 100 and 500 Cells/mm3.
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Concurrent Medication:

Allowed:

- Prophylaxis against AIDS-related opportunistic infections.

- Supportive therapies, such as medications for nausea, vomiting, anemia, and analgesia.

Patients must have:

- HIV infection.

- CD4 count 100 - 500 cells/mm3.

- At least two palpable lymph nodes.

- Plasma viremia.

- No CURRENT AIDS-defining conditions.

- No prior antiretroviral treatment.

Exclusion Criteria

Concurrent Medication:

Excluded during the first 8 weeks of study:

- Other antiretroviral agents.

- Steroids.

- Interleukins.

- Interferons.

- Cytotoxic chemotherapy.

Prior Medication:

Excluded:

- Prior antiretroviral therapy.

- Prior cytotoxic chemotherapy.

- Acute therapy for an infection or another medical illness within 14 days prior to study entry.

Overall Status: Completed
Phase: Phase 1

NCTID: NCT00000812
Intervention Type: Drug
Intervention Name: Thalidomide
Title: A Phase I, Placebo-Controlled, Dose-Escalation Study of the Safety, Tolerability, and Pharmacokinetics of Thalidomide in Subjects With HIV-1 Infection
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Concurrent Medication:

Allowed for occasional use (chronic use is permitted only if clinician deems that medication can be discontinued in the event of overlapping toxicity):

- CNS active agents, such as alcohol, narcotics (i.e., morphine, codeine, meperidine), barbiturates, benzodiazepines, tricyclic antidepressants, phenothiazines, sedating antihistamines, or over-the-counter sleeping aids.

Patients must have:

- HIV infection.

- CD4 count 200 - 500 cells/mm3.

- No active opportunistic infection requiring systemic therapy within the past 14 days.

- NOTE: Women must be post-menopausal or provide written documentation of surgical sterilization, and sexually active men must use a barrier method of contraception, beginning 4 weeks prior to study entry and continuing until 4 weeks following end of treatment.

PER AMENDMENT 8/2/96:

- Been on stable licensed antiretroviral treatment for 60 days prior to study entry or must not have received any antiretroviral medications for 60 days prior to study

entry.

Prior Medication:

Required:

- Patients must have been on stable licensed antiretroviral treatment for 60 days prior to study entry or must not have received any antiretroviral medications for 60 days prior to study entry.

Exclusion Criteria

Co-existing Condition:

Patients with the following symptoms or conditions are excluded:

- Malignancy requiring chemotherapy.

- Grade 2 or worse peripheral neuropathy.

- Medical condition that would interfere with evaluation of patient.

Concurrent Medication:

Excluded in all patients:

- Didanosine (ddI).

- Zalcitabine (ddC).

- Stavudine (d4T).

- Other immunologically active agents.

- Systemic cytotoxic chemotherapy.

Excluded in all patients unless taken only occasionally or unless medication could be stopped in the event of overlapping toxicity:

- CNS active agents, such as alcohol, narcotics (i.e., morphine, codeine, meperidine), barbiturates, benzodiazepines, tricyclic antidepressants, phenothiazines, sedating antihistamines, or over-the-counter sleeping aids.

Patients with the following prior conditions are excluded:

- History of active tuberculosis within 3 months prior to study entry.

- History of intolerance to thalidomide such as fever, rash, or neuropathy.

Prior Medication:

Excluded within 14 days prior to study entry:

- Systemic chemotherapy.

Excluded within 30 days prior to study entry:

- Topical, oral, and systemic corticosteroids.

- Pentoxifylline.

- Interferons.

- Interleukins.

- Cimetidines.

- Acetylcysteine or other glutathione depleting agents.

- Other putative immunomodulatory agents such as thymosin alpha 1, thymopentin, isoprinosine, ditiocarb sodium, ampligen, and immune globulin.

PER AMENDMENT 8/2/96:

Excluded within 60 days prior to study entry:

- Therapy with investigational antiretroviral medications.

Overall Status: Completed
Phase: Phase 1

NCTID: NCT00000804
Intervention Type: Drug
Intervention Name: Indinavir sulfate
Title: A Randomized Trial of L-735,524, An Inhibitor of the HIV Protease Enzyme, and Interleukin-2 in Persons Infected With HIV (NOTE: Only For Patients Who Previously Completed NIAID 93 CC-113)
Condition: HIV Infections
Eligibility Criteria: nan
Overall Status: Withdrawn
Phase: nan

NCTID: NCT00000824
Intervention Type: Drug
Intervention Name: Lymphocytes, Activated
Title: A Study of Cytotoxic T Lymphocyte (CTL) Therapy in HIV-Infected Patients
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Patients must have:

- HLA A2+.

- Other HLA matching with sibling.

- CD4 count 100-350 cells/mm3.

- No active opportunistic infection or malignancy (other than cutaneous Kaposi's sarcoma).

- Current stable antiviral regimen.

- Normal lab values and chest x-ray.

Donor siblings must have:

- HLA A2+.

- HIV negativity.

- Good venous access.

- Ability to donate on multiple occasions.

- Negative status for hepatitis B and C.

Exclusion Criteria

Concurrent Medication:

Excluded:

- Immunomodulators.

- Cytokines.

- Systemic steroids.

- IV pentamidine.

- Investigational drugs.

Overall Status: Terminated
Phase: nan

NCTID: NCT00000849
Intervention Type: Drug
Intervention Name: Aldesleukin
Title: A Study to Test the Safety of Recombinant Interleukin-2 (rIL-2) in HIV-Infected Children
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Children may be eligible for this study if they:

- Are HIV-positive.

- Have decreased immune system functioning (CD4 count 500-1000 for 3- to 5-year-olds or CD4 count 200-500 for 6- to 12-year-olds).

- Have symptomatic HIV infection.

- Have a viral level less than 400 copies/ml.

- Are between the ages of 3 and 12 (consent of parent or guardian required).

Exclusion Criteria

Children will not be eligible for this study if they:

- Have an active opportunistic infection.

- Are pregnant.

Overall Status: Completed
Phase: Phase 1

NCTID: NCT00000821
Intervention Type: Drug
Intervention Name: Aldesleukin
Title: Subcutaneously Administered Aldesleukin (Interleukin-2; IL-2) Therapy in HIV-Infected Patients
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Patients must have:

- HIV positivity.

- CD4 count >= 500 cells/mm3.

- No history of AIDS-defining opportunistic infection, or malignancy other than mucocutaneous Kaposi's sarcoma.

Concurrent Medication: Required:

- Concurrent FDA-approved antiretroviral therapy (AZT, ddI, ddC, d4T).

Prior Medication: Required:

- FDA-approved antiretroviral therapy for at least 6 weeks prior to study entry.

Exclusion Criteria

Co-existing Condition:

Patients with the following symptoms or conditions are excluded:

- Significant cardiac, pulmonary, thyroid, renal, or CNS disease.

Prior Medication:

Excluded:

- Prior IL-2.

- Systemic corticosteroids, chemotherapy, or experimental therapy within 4 weeks prior to study entry.

Overall Status: Completed
Phase: Phase 1

NCTID: NCT00000843
Intervention Type: Drug
Intervention Name: Adefovir dipivoxil
Title: The Safety and Effectiveness of Adefovir Dipivoxil in HIV-Infected Children
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Patients must have:

- Asymptomatic or mildly symptomatic HIV infection, with no worse than grade 1 toxicity for any symptoms.

- Consent of parent or guardian.

Prior Medication:

Allowed:

- IV gammaglobulin and aerosolized pentamidine for PCP prophylaxis.

- Antiretrovirals if discontinued by 72 hr prior to study entry.

Exclusion Criteria

Co-existing Condition:

Patients with the following symptoms or conditions are excluded:

- Acute or chronic infections that require treatment during study.

Concurrent Medication:

Excluded:

- Antiretrovirals other than study drug.
- Other investigational agents.
- Immunomodulators.
- HIV-1 vaccines.
- Glucocorticoids.
- Drugs with potential for adverse interaction with study drug or that would interfere with quantitation of study drug in serum or plasma.
- TMP / SMX and dapsone.

PER AMENDMENT 8/23/96:

- Drugs which may affect renal excretion:
- Probenecid, Acyclovir, Ganciclovir, Foscarnet, Amphotericin B and Pentamidine.

Prior Medication:

Excluded within 72 hr prior to study entry:

- Antiretrovirals other than study drug.
- Other investigational agents.
- Immunomodulators.
- HIV-1 vaccines.
- Glucocorticoids.
- Drugs with potential for adverse interaction with study drug or that would interfere with quantitation of study drug in serum or plasma.
- TMP / SMX and dapsone.

PER AMENDMENT 8/23/96:

- Drugs which may affect renal excretion:
- Probenecid, Acyclovir, Ganciclovir, Foscarnet, Amphotericin B and Pentamidine.

Overall Status: Completed
Phase: Phase 1

NCTID: NCT00000827
Intervention Type: Drug
Intervention Name: Anti-HIV Immune Serum Globulin (Human)
Title: A Phase I/II Study of Hyperimmune IVIG in Slowing Progression of Disease in HIV-Infected Children
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Concurrent Medication:

Required:

- PCP prophylaxis according to CDC guidelines.

Allowed:

- Varicella-zoster immunoglobulin.

- Hepatitis B immunoglobulin.

- Prophylactic therapies not involving immunoglobulin.

Patients must have:

- HIV infection.

- CD4 count > 200 cells/mm3 (ages 2-5 years) or > 100 cells/mm3 (age > 5 years).

- Antiretroviral therapy for at least 6 months, with no change in regimen for at least 3 months prior to study entry.

- Plasma ICD p24 >= 70 pg/ml that is stable or increasing prior to study entry.

- Life expectancy of at least 6 months.

Prior Medication: Required:

- Antiretroviral therapy for at least 6 months, with stable dose for at least 3 months.

Exclusion Criteria

Co-existing Condition:

Patients with the following symptoms or conditions are excluded:

- Severe diarrhea, nephrotic syndrome, or other protein-losing state that requires large doses of IVIG.

- Any other condition requiring dosing with IVIG (e.g., ITP, hypogammaglobulinemia).

- Acute illness with temperature >= 100 F and/or with IV antibiotics.

- Grade 3 or worse clinical toxicities.

- Unable to tolerate IV infusions at a minimum rate of 0.02 ml/kg/min.

- Concomitant participation in an experimental antiretroviral or HIV vaccine trial.

Concurrent Medication:

Excluded:

- IVIG.
- Chemotherapy for an active malignancy.
- MMR or rubella vaccinations.
- Intramuscular immunoglobulin.

Patients with the following prior condition are excluded:

- History of severe reaction to IVIG.

Prior Medication:

Excluded:

- IVIG within the past 60 days.
- Chemotherapy for an active malignancy within the past year.
- MMR or rubella vaccinations within the past 6 months.
- Intramuscular immunoglobulin within the past 60 days.

Ongoing drug or alcohol abuse.
Overall Status: Completed
Phase: Phase 1

NCTID: NCT00000825
Intervention Type: Drug
Intervention Name: Aldesleukin
Title: The Effects of Giving Interleukin-2 (IL-2) Plus Anti-HIV Therapy to HIV-Positive Patients With CD4 Cell Counts of at Least 350 Cells/mm3
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Patients may be eligible for this study if they:

- Are HIV-positive.
- Have a CD4 cell count greater than or equal to 300 cells/mm3.
- Have no AIDS-defining illnesses.
- Are at least 18 years old.
- Have been on antiretroviral therapy for at least 7 days prior to study entry.

Exclusion Criteria

Patients will not be eligible for this study if they:

- Abuse alcohol or drugs, or have any serious psychiatric or medical illnesses that would affect their safety or ability to complete the study.

- Have a history of the following: cancer (other than Kaposi's sarcoma), an AIDS-defining illness, a central nervous system abnormality, or an autoimmune/inflammatory disease.

- Are pregnant or breast-feeding.

- Have ever received IL-2.

Overall Status: Completed
Phase: Phase 2

NCTID: NCT00000820
Intervention Type: Drug
Intervention Name: Aldesleukin
Title: A Phase II Study of Low-Dose Interleukin-2 by Subcutaneous Injection in Combination With Antiretroviral Therapy Versus Antiretroviral Therapy Alone in Patients With HIV-1 Infection and at Least 3 Months Stable Antiretroviral Therapy
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Concurrent Medication:

Allowed:

- PCP prophylaxis.

- Therapy for an opportunistic infection that develops on study, with the exception of foscarnet for CMV disease or resistant Herpes simplex.

- Systemic corticosteroids ONLY IF given for no longer than 21 days for acute PCP.

- Topical corticosteroids to areas separate from a skin test or IL-2 injection site.

- Acyclovir up to 1000 mg/day as maintenance for recurrent genital Herpes.

- Erythropoietin and filgrastim.

- Antiemetics.

- Antibiotics as clinically indicated.

- Elective standard immunizations at week 8 or later.

Concurrent Treatment:

Allowed:

- Local radiation therapy.

Prior Medication: Required:

- Stable, approved antiretroviral therapy for at least 2 months (was 3 months, amended 3/26/96) prior to study entry.

Patients must have:

- HIV seropositivity.

- CD4 count 300 - 700 cells/mm3.

- Stable antiretroviral therapy for at least 2 months (was 3 months, amended 3/26/96) prior to study entry.

- No history of AIDS-defining illness except for limited cutaneous Kaposi's sarcoma.

- Normal EKG (isolated nonspecific ST and T wave changes permitted).

NOTE:

- This protocol is approved for prisoner participation.

Exclusion Criteria

Co-existing Condition:

Patients with the following symptoms or conditions are excluded:

- Malignancy requiring systemic or local cytotoxic chemotherapy.

- Untreated thyroid disease.

- Asthma requiring intermittent or chronic inhalation or systemic therapy.

- Any medical condition that precludes study entry.

Concurrent Medication:

Excluded:

- Antianginal agents such as nitrates, calcium channel blockers, beta blockers, and antiarrhythmics.

- Systemic or local cytotoxic chemotherapy.

- Interferons.

- Interleukins other than study drug.

- Pentoxifylline (Trental).

- Acetylcysteine (NAC).

- Sargramostim (GM-CSF).

- Dinitrochlorobenzene (DCNB).

- Thymosin alpha 1.

- Thymopentin.

- Inosiplex (Isoprinosine).

- Polyribonucleoside (Ampligen).

- Ditiocarb sodium (Imuthiol).

- Therapeutic HIV vaccines.

- Investigational antiretroviral agents such as lamivudine (3TC) and tat and protease inhibitors.

- Foscarnet.

- Aspirin.

- Immune globulin (IVIG).

- Thalidomide.

- Systemic corticosteroids (permitted for 21 days or less for PCP treatment only).

Concurrent Treatment:

Excluded:

- Ongoing transfusion.

Patients with the following prior conditions are excluded:

- History of autoimmune disease, including inflammatory bowel disease and psoriasis (although autoimmune thyroid disease that is stable is allowed).

- Clinically significant CNS disease or seizures that have been active within 1 year prior to study entry.

Prior Medication:

Excluded:

- IL-2 within 3 months prior to study entry.

- Any immunomodulatory therapy within 4 weeks prior to study entry.

- Foscarnet within 4 weeks prior to study entry.

- Acute therapy for an opportunistic infection within 14 days prior to study entry.

Active alcohol or substance abuse that would compromise study compliance.
Overall Status: Completed
Phase: Phase 2

NCTID: NCT00000855
Intervention Type: Drug
Intervention Name: Zidovudine
Title: A Study to Evaluate the Safety and Tolerability of Zidovudine (ZDV) in Premature Infants Born to HIV-Positive Women.
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Your baby may be eligible for this study if he/she:

- Requires ZDV (as decided by your doctor) because you are HIV-positive.

- Is 1-5 days old and was born prematurely.

Exclusion Criteria

Your baby will not be eligible for this study if he/she:

- Is not expected to live 6 weeks because of severe illness.

- Is having problems with blood pressure or is not urinating enough.

Overall Status: Completed
Phase: nan

NCTID: NCT00000857
Intervention Type: Drug
Intervention Name: Interleukin-12
Title: A Study to Evaluate the Effects of Interleukin-12 (rhIL-12) in HIV-Positive Patients With CD4 Cell Counts Less Than 50 Cells/mm3 or 300-500 Cells/mm3
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

You may be eligible for this study if you:

- Are HIV-positive.

- Are 18-60 years old.

- Have a CD4 count less than 50 cells/mm3 or between 300-500 cells/mm3 within 30 days of study entry.

- Are expected to live at least 12 weeks.

- Agree to practice abstinence or use effective methods of birth control during the study.

Exclusion Criteria

You will not be eligible for this study if you:

- Have a history of cytomegalovirus (CMV) end-organ disease.

- Have a history of invasive fungal disease, unless the condition has been stable for 2 months.

- Have a history of severe allergic reactions to IL-2 or IL-12.

- Have a history of heart problems, autoimmune or rheumatologic disease, gastrointestinal bleeding, or any condition that would keep you from completing the study.

- Have MAC-related symptoms (fever, weight loss, frequent diarrhea) for at least 2 months prior to study entry.

- Are enrolled in another experimental research treatment study.

- Abuse alcohol or drugs.

- Are pregnant or breast-feeding.

Overall Status: Completed
Phase: Phase 1

NCTID: NCT00000861
Intervention Type: Drug
Intervention Name: Indinavir sulfate
Title: The Addition of Indinavir to Anti-HIV Treatment in HIV-Infected Patients
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Concurrent Medication:

Allowed:

- Topical and/or antifungal agents, except ketoconazole.

- Treatment, maintenance, or chemoprophylaxis with approved agents for OIs will be given as clinically indicated.

- Clinically indicated antibiotics, unless excluded.

- Systemic corticosteroid use for <21 days for acute problems is permitted as clinically indicated. However, chronic systemic corticosteroid use should be avoided.

- Recombinant erythropoietin (rEPO) and granulocyte-colony stimulating factor (G-CSF, filgrastim).

- Didanosine (ddI).

- Regularly prescribed medications, such as antipyretics, antidepressants, oral contraceptives, megestrol acetate, testosterone, or any other medication.

Patients must have:

- A working diagnosis of HIV infection.

- A CD4+ count between 200 and 500 cells/mm3.

- Signed, informed parental consent if patient is less than 18.

NOTE:

- The DAIDS Clinical Science Research Committee (CSRC) has deemed this protocol appropriate for prisoner enrollment.

Exclusion Criteria

Co-existing Condition:

Patients with any of the following conditions or symptoms are excluded:

Febrile illness with temperature > 38.5 degrees C (101.3 degrees F) within 3 days prior to study entry.

Concurrent Medication:

Excluded:

- Non-nucleoside reverse transcriptase inhibitors.

- Protease inhibitors except IDV.

- Rifabutin and rifampin.

- Ketoconazole.

- Terfenadine, astemizole, cisapride, triazolam and midazolam.

Patients with any of the following prior conditions are excluded:

- History of prior saquinavir (SQV) therapy for more than 14 days.

- History of any prior protease inhibitor therapy other than SQV.

- History of serious opportunistic infection.

Overall Status: Completed
Phase: nan

NCTID: NCT00000876
Intervention Type: Drug
Intervention Name: CD4-IgG2
Title: Safety and Effectiveness of CD4-IgG2 in HIV-Positive Children
Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

Children may be eligible for this study if they:

- Are HIV-positive.

- Are 2-12 years old and have consent of parent or legal guardian.

- Have HIV levels of 10,000 copies/ml or more on at least 2 occasions and 30 days apart (Part 2 only).

- Have been on stable, unchanged anti-HIV therapy for 3 months before study entry.

Exclusion Criteria

Children will not be eligible for this study if they:

- Have an active opportunistic (HIV-related) infection.

- Are pregnant.

- Are taking certain medications.

- Have received any vaccinations within 30 days prior to study entry.

- Have a heart problem that would affect their ability to take part in the study. (This study has been changed. The original version didn't mention heart problems.)

Overall Status: Completed
Phase: Phase 1

NCTID: NCT00000880
Intervention Type: Drug
Intervention Name: Cyclosporine
Title: A Study to Test the Effect of Cyclosporine on the Immune System of Patients With Early HIV Disease

Condition: HIV Infections
Eligibility Criteria: Inclusion Criteria

You may be eligible for this study if you:

- Are HIV-positive.

- Have a CD4 count greater than or equal to 500/mm3.

- Have a plasma HIV RNA level greater than 600 copies/ml.

- Are over 18 years of age.

- Agree to practice abstinence or use barrier methods of birth control during the study.

Exclusion Criteria

You will not be eligible for this study if you:

- Have a history of an AIDS-defining illness, autoimmune disease, or hypertension.

- Have renal disease.

- Have any active infection other than HIV.

- Have used certain antiretroviral medications.

- Are pregnant.

Overall Status: Completed
Phase: Phase 2