Subject Code Number

Subject Initials

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Visit Date

DAY	MONTH	YEAR
	Jan 1	
	Feb 2	
00	Mar 3	00
11	Apr 4	11
22	May 5	22
33	June 6	33
4	July 7	44
5	Aug 8	55
6	Sept 9	66
7	Oct 10	77
8	Nov 11	88
9	Dec 12	99

VADF_000

Site ID Number

Subject Code Number

Visit

- ● Baseline Visit
- 2 Week 0 / Cycle 1 Visit
- 4 Week 3 / Cycle 2 Visit
- 5 Week 5 Visit
- 6 Week 6 / Cycle 3 Visit
- 8 Week 9 / Cycle 4 Visit
- 10 Week 12 / Cycle 5 Visit
- 12 Week 15 / Cycle 6 / End of Study Visit
- 14 30 Day Follow Up Visit
- 15 Six Month Follow Up Visit
- 16 Survival Endpoint
- 99 Unscheduled Visit

Forms to be submitted this visit:

Numbered Pages:

- ☐ Eligibility (pg 2)
- ☐ Demographics (pg 3)
- ☐ Initial Breast Carcinoma History (pg 4)
- ☐ Prior Treatments (pg 5-6)
- ☐ Relapse Information (pg 7)
- ☐ Medical History (pg 8-9)
- ☐ Physical Exam (pg 10-11)
- ☐ Vital Signs (pg 12)
- ☐ Subject Assessment of Peripheral Neuropathy (pg 13)
- ☐ Performance Score and Peripheral Neuropathy (pg 14)
- ☐ Report of Scans and Lab Submissions (pg 15)
- ☐ EORTC QLQ-C30 Questionnaire (pg 16-17)
- ☐ Echocardiogram / MUGA (pg 18)
- ☐ EKG (pg 18a)
- ☐ Baseline Evaluation of Lesions (pg 19)

Unnumbered Pages (submit as many as necessary):

- ☐ Pre-Treatment Signs & Symptoms
- ☐ Concurrent Procedures
- ☐ Adverse Experiences
- ☐ Prior Medications
- ☐ Lesion Identification Form
- ☐ Non-Target Lesion Evaluation Form
- ☐ Target Lesion Measurement Form

Subject Code Number	

Subject Initials		

ELIG_001

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Eligibility Criteria

*Please fill in the appropriate bubble. If "No" is answered for any question, the subject is **not eligible** to enter the study and should not receive a Subject Code Number.*	YES	NO
ELIG_002 **Did the subject sign and date the Informed Consent Form?**	1	2
ELIG_003 **Does the subject meet all of the eligibility requirements set forth in the protocol?**	1	2

ELIG_004 **If the subject did not meet the eligibility requirements but was enrolled anyway (e.g., received an eligibility waiver that was approved by the medical monitor), please explain:**

_____

_____

_____

_____

_____

Date of Eligibility Verification

DAY	MONTH	YEAR
	Jan 1	
	Feb 2	
00	Mar 3	00
11	Apr 4	11
22	May 5	22
33	June 6	33
4	July 7	44
5	Aug 8	55
6	Sept 9	66
7	Oct 10	77
8	Nov 11	88
9	Dec 12	99

ELIG_005

I certify that I am satisfied that the subject meets the eligibility criteria for entry into this study as set forth in the protocol.

_____

Principal Investigator's (or designee's) Signature and Date

ELIG_006 1 Please bubble if signature is present

Randomized Treatment Assignment:

ELIG_007 A **ABI-007**
B **TAXOL**

Subject Code Number

Subject Initials

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Date of Birth

DAY		MONTH		YEAR	
		Jan	1		
		Feb	2		
0	0	Mar	3	0	0
1	1	Apr	4	1	1
2	2	May	5	2	2
3	3	June	6	3	3
	4	July	7	4	4
	5	Aug	8	5	5
	6	Sept	9	6	6
	7	Oct	10	7	7
	8	Nov	11	8	8
	9	Dec	12	9	9

DEMO_001

Race

DEMO_002 *(Bubble one)*

1. Caucasian
2. Black
3. Asian
4. Indian - Eastern
5. Hispanic
6. Other, *specify*_____

DEMO_003

Height (cm)

0	0	0
1	1	1
2	2	2
3	3	3
4	4	4
5	5	5
6	6	6
7	7	7
8	8	8
9	9	9

DEMO_004

Child-Bearing Potential

DEMO_005

1. Female of childbearing potential
2. Sterile female of childbearing age
3. Post-Menopausal female

Subject Code Number

Subject Initials

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Please provide the following information for the initial diagnosis and treatment of breast cancer.

Initial Diagnosis

DAY	MONTH	YEAR
	Jan 1	
	Feb 2	
00	Mar 3	00
11	Apr 4	11
22	May 5	22
33	June 6	33
4	July 7	44
5	Aug 8	55
6	Sept 9	66
7	Oct 10	77
8	Nov 11	88
9	Dec 12	99

BRST_001

Initial Tumor Longest Diameter (cm)

. 00 11 22 33 44 55 66 77 88 99

BRST_002

Number of Positive Nodes

00 11 22 33 44 55 66 77 88 99

BRST_003

Were nodes matted and/or fixed?

1 Yes
2 No

BRST_004

Were any metastases present?

1 Yes
2 No

BRST_005

Initial Treatment Modalities

BRST_006	Surgery	1 Yes	2 No
BRST_007	Radiotherapy	1 Yes	2 No
BRST_008	Hormonal Therapy	1 Yes	2 No
BRST_009	Chemotherapy	1 Yes	2 No

Initial ER Status

1 ER Positive
2 ER Negative
3 Unknown

BRST_010

Initial PgR Status

1 PgR Positive
2 PgR Negative
3 Unknown

BRST_011

Initial Involved Breast

1 Left only
2 Right only
3 Both

BRST_012

Subject Code Number	

Subject Initials	

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Please provide the staging information for the initial diagnosis of breast cancer.

Tumor Stage	Lymph Node Stage	Metastatic Stage
① **TX:** Not assessable	① **NX:** Not assessable	① **MX:** Distant metastases cannot be assessed
② **T0:** No evidence of primary tumor	② **N0:** No regional lymph node metastases present	② **M0:** No distant metastases are present
③ **Tis:** Carcinoma in situ	③ **N1:** Metastases to movable ipsilateral lymph nodes	③ **M1**: Distant metastases are present
④ **T1:** Tumor size ≤ 2.0 cm	④ **N2:** Metastases to ipsilateral axilary lymph nodes fixed to one another or to other structures	
⑤ **T2:** Tumor size > 2 cm and ≤ 5 cm	**N3:** Metastases to ipsilateral internal mammary lymph nodes	
⑥ **T3:** Tumor size > 5 cm		
⑦ **T4:** Tumor of any size with direct extension to wall or skin		
BRST_013	BRST_014	BRST_015

Histology at Initial Diagnosis (bubble all that apply)		
BRST_016	①	**Ductal (scirrhous) carcinoma**
BRST_017	①	**Lobular carcinoma**
BRST_018	①	**Medullary carcinoma**
BRST_019	①	**Mucinous or colloid carcinoma**
BRST_020	①	**Tubular carcinoma**
BRST_021	①	**Inflammatory breast cancer**
BRST_022	①	**Cystosarcoma phylloides**
BRST_023		**Other:** _____ BRST_024

Subject Code Number

Subject Initials

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Please record all prior adjuvant usage of Anthracycline or Taxane therapies.

Prior Adjuvant Anthracycline Therapy

PRTX_001 (1) **Bubble if no prior adjuvant Anthracycline therapy was used**

Prior Anthracycline agents used in adjuvant setting
(bubble all that apply)

PRTX_002 (1) **Daunorubicin**
PRTX_003 (1) **Doxorubicin**
PRTX_004 (1) **Epirubicin**
PRTX_005 (1) **Idarubicin**

Prior Anthracycline-Related Cardiac Abnormalities
PRTX_006
(1) **No abnormalities**
(2) **Yes; abnormalities resolved**
(3) **Yes; abnormalities unresolved**

Date of Last Dose

DAY	MONTH	YEAR
	(1) Jan	
	(2) Feb	
0 0	(3) Mar	0 0
1 1	(4) Apr	1 1
2 2	(5) May	2 2
3 3	(6) June	3 3
4	(7) July	4 4
5	(8) Aug	5 5
6	(9) Sept	6 6
7	(10) Oct	7 7
8	(11) Nov	8 8
9	(12) Dec	9 9

PRTX_007

Cumulative Dose (mg)

0 0 0 0 0
1 1 1 1 1
2 2 2 2 2
3 3 3 3 3
4 4 4 4 4
5 5 5 5 5
6 6 6 6 6
7 7 7 7 7
8 8 8 8 8
9 9 9 9 9

PRTX_008

Prior Adjuvant Taxol Therapy

PRTX_009 (1) **Bubble if no prior adjuvant Taxol therapy used**

Date of Last Dose

DAY	MONTH	YEAR
	(1) Jan	
	(2) Feb	
0 0	(3) Mar	0 0
1 1	(4) Apr	1 1
2 2	(5) May	2 2
3 3	(6) June	3 3
4	(7) July	4 4
5	(8) Aug	5 5
6	(9) Sept	6 6
7	(10) Oct	7 7
8	(11) Nov	8 8
9	(12) Dec	9 9

PRTX_010

Cumulative Dose (mg)

0 0 0 0 0
1 1 1 1 1
2 2 2 2 2
3 3 3 3 3
4 4 4 4 4
5 5 5 5 5
6 6 6 6 6
7 7 7 7 7
8 8 8 8 8
9 9 9 9 9

PRTX_011

Prior Adjuvant Taxotere Therapy

PRTX_012 (1) **Bubble if no prior adjuvant Taxotere therapy used**

Date of Last Dose

DAY	MONTH	YEAR
	(1) Jan	
	(2) Feb	
0 0	(3) Mar	0 0
1 1	(4) Apr	1 1
2 2	(5) May	2 2
3 3	(6) June	3 3
4	(7) July	4 4
5	(8) Aug	5 5
6	(9) Sept	6 6
7	(10) Oct	7 7
8	(11) Nov	8 8
9	(12) Dec	9 9

PRTX_013

Cumulative Dose (mg)

0 0 0 0 0
1 1 1 1 1
2 2 2 2 2
3 3 3 3 3
4 4 4 4 4
5 5 5 5 5
6 6 6 6 6
7 7 7 7 7
8 8 8 8 8
9 9 9 9 9

PRTX_014

Subject Code Number

Subject Initials

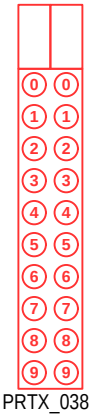
An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Indicate which chemotherapy and hormonal agents have been used for the treatment of metastatic disease.

PRTX_015	1	Herceptin		
PRTX_016	1	5-Fluorouracil		
PRTX_017	1	Cisplatin	PRTX_030	Other: _____
PRTX_018	1	Cyclophosphamide		
PRTX_019	1	Gemcitabine	PRTX_031	Other: _____
PRTX_020	1	Anthracycline		
PRTX_021	1	Methotrexate	PRTX_032	Other: _____
PRTX_022	1	Thiotepa		
PRTX_023	1	Vinorelbine	PRTX_033	Other: _____
PRTX_024	1	Tamoxifen		
PRTX_025	1	Letrozole	PRTX_034	Other: _____
PRTX_026	1	Toremifene		
PRTX_027	1	Arimidex	PRTX_035	Other: _____
PRTX_028	1	Megace		
PRTX_029	1	High dose stem cell therapy	PRTX_036	Other: _____
			PRTX_037	Other: _____

Total Number of Metastatic Treatment Regimens Given Prior to Enrollment



PRTX_038

Ovarian Ablation

Has the subject undergone ovarian ablation?

PRTX_039

1 Yes
2 No

If yes, indicate method:

PRTX_040	1	Surgical
PRTX_041	1	Radiotherapy
PRTX_042	1	Hormone Manipulation (e.g. Zoladex)

Subject Code Number

Subject Initials

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Please provide information about the relapse that led to enrollment on this study.

Most Recent Disease Free Interval (DFI)

Start of DFI

DAY	MONTH	YEAR
	Jan 1	
	Feb 2	
00	Mar 3	00
11	Apr 4	11
22	May 5	22
33	June 6	33
4	July 7	44
5	Aug 8	55
6	Sept 9	66
7	Oct 10	77
8	Nov 11	88
9	Dec 12	99

RLPS_001

Relapse Date

DAY	MONTH	YEAR
	Jan 1	
	Feb 2	
00	Mar 3	00
11	Apr 4	11
22	May 5	22
33	June 6	33
4	July 7	44
5	Aug 8	55
6	Sept 9	66
7	Oct 10	77
8	Nov 11	88
9	Dec 12	99

RLPS_002

Relapse Site(s)

(bubble all that apply)

RLPS_003	1	**Breast**
RLPS_004	1	**Liver**
RLPS_005	1	**Lung**
RLPS_006	1	**Bone**
RLPS_007	1	**Lymph Nodes**
RLPS_008	1	**Skin / Soft Tissue**
RLPS_009	1	**Other Visceral**

Latest ER Status

1. **ER Positive**
2. **ER Negative**
3. **Unknown**

RLPS_010

Latest HER-2 / neu Status

1. **not overexpressed**
2. **1+**
3. **2+**
4. **3+**
5. **unknown**

RLPS_012

Number of Metastatic Sites

00 11 22 33 44 55 66 77 88 99

RLPS_013

Latest PgR Status

1. **PgR Positive**
2. **PgR Negative**
3. **Unknown**

RLPS_011

Subject Code Number		

Subject Initials		

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Indicate if this subject has any relevant medical history or pre-existing conditions by responding "Yes" or "No" to each category. If "Yes," please specify details about the condition.

System or Condition	Relevant History? Yes	No	If YES, specify
MEHX_001 **Non-Drug Allergic Conditions**	1	2	MEHX_002
MEHX_003 **Drug Allergies**	1	2	MEHX_004
MEHX_005 **Cardiovascular**	1	2	MEHX_006
MEHX_007 **Gastrointestinal**	1	2	MEHX_008
MEHX_009 **Hepatic**	1	2	MEHX_010
MEHX_011 **Endocrine/Metabolic**	1	2	MEHX_012
MEHX_013 **Genitourinary**	1	2	MEHX_014
MEHX_015 **Hematologic**	1	2	MEHX_016
MEHX_017 **Neurological**	1	2	MEHX_018

Subject Code Number	

Subject Initials	

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

System or Condition	Relevant History? Yes	No	If YES, specify
MEHX_019 **Psychiatric**	1	2	MEHX_020
MEHX_021 **Respiratory**	1	2	MEHX_022
MEHX_023 **Immunological**	1	2	MEHX_024
MEHX_025 **Musculoskeletal**	1	2	MEHX_026
MEHX_027 **Skin / Hair**	1	2	MEHX_028
MEHX_029 **Cancer (apart from current diagnosis)**	1	2	MEHX_030
MEHX_031 **HEENT**	1	2	MEHX_032
MEHX_033 **Substance Abuse**	1	2	MEHX_034

Subject Code Number

Subject Initials

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Date of Assessment

DAY	MONTH	YEAR
	1 Jan	
	2 Feb	
00	3 Mar	00
11	4 Apr	11
22	5 May	22
33	6 June	33
4	7 July	44
5	8 Aug	55
6	9 Sept	66
7	10 Oct	77
8	11 Nov	88
9	12 Dec	99

PHEX_001

Weight (kg)

000 . 0
111 1
222 2
333 3
444 4
555 5
666 6
777 7
888 8
999 9

PHEX_002

Serum Pregnancy Test

1 Positive
2 Negative
3 Not Done

PHEX_003

Site	Normal	Abnormal	Not Done	Describe Abnormalities
PHEX_004 **General Appearance**	1	2	3	PHEX_005
PHEX_006 **Head**	1	2	3	PHEX_007
PHEX_008 **Ears**	1	2	3	PHEX_009
PHEX_010 **Eyes**	1	2	3	PHEX_011
PHEX_012 **Nose**	1	2	3	PHEX_013
PHEX_014 **Throat**	1	2	3	PHEX_015
PHEX_016 **Mouth**	1	2	3	PHEX_017
PHEX_018 **Neck**	1	2	3	PHEX_019
PHEX_020 **Thyroid**	1	2	3	PHEX_021

Subject Code Number		

Subject Initials		

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Site	Normal	Abnormal	Not Done	Describe Abnormalities
PHEX_022 **Lungs / Thorax**	1	2	3	PHEX_023
PHEX_024 **Heart**	1	2	3	PHEX_025
PHEX_026 **Breasts**	1	2	3	PHEX_027
PHEX_028 **Liver**	1	2	3	PHEX_029
PHEX_030 **Abdomen**	1	2	3	PHEX_031
PHEX_032 **Musculoskeletal**	1	2	3	PHEX_033
PHEX_034 **Extremities**	1	2	3	PHEX_035
PHEX_036 **Pulses**	1	2	3	PHEX_037
PHEX_038 **Lymph Nodes**	1	2	3	PHEX_039
PHEX_040 **Skin**	1	2	3	PHEX_041
PHEX_042 **Neurological**	1	2	3	PHEX_043
PHEX_044 **Genitourinary (including pelvic)**	1	2	3	PHEX_045
PHEX_046 **Rectal**	1	2	3	PHEX_047

Vital Signs (VITL)

Subject Code Number

Subject Initials

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Bubble the correct visit number:

- ● Baseline
- ② Week 0 / Cycle 1
- ③ Week 3 / Cycle 2
- ⑥ Week 6 / Cycle 3
- ⑧ Week 9 / Cycle 4
- ⑩ Week 12 / Cycle 5
- ⑫ Week 15 / Cycle 6
- ⑭ 30 Day Follow-up

Date and Time of Vitals

DAY | MONTH | YEAR | 00:00 - 23:59

Jan ① Feb ② Mar ③ Apr ④ May ⑤ June ⑥ July ⑦ Aug ⑧ Sept ⑨ Oct ⑩ Nov ⑪ Dec ⑫

VITL_000 VITL_001

Temp. (C)

VITL_002

Blood Pressure (mmHG)

Systolic Diastolic

VITL_003 VITL_004

Pulse (beats/min)

VITL_005

Respiration (breaths/min)

VITL_006

Subject Code Number		

Subject Initials		

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Evaluation Date					
DAY		MONTH		YEAR	
		Jan	1		
		Feb	2		
0	0	Mar	3	0	0
1	1	Apr	4	1	1
2	2	May	5	2	2
3	3	June	6	3	3
	4	July	7	4	4
	5	Aug	8	5	5
	6	Sept	9	6	6
	7	Oct	10	7	7
	8	Nov	11	8	8
	9	Dec	12	9	9

FACT_000

FACT-Taxane (Version 4); "Additional Concerns"

FACT_017 (1) **Bubble here if this questionnaire was not completed.**

Indicate how true each statement has been for the subject <u>during the past 7 days</u>.		Not at all	A little bit	Some-what	Quite a bit	Very much
FACT_001	I have numbness or tingling in my hands.	0	1	2	3	4
FACT_002	I have numbness or tingling in my feet.	0	1	2	3	4
FACT_003	I feel discomfort in my hands.	0	1	2	3	4
FACT_004	I feel discomfort in my feet.	0	1	2	3	4
FACT_005	I have joint pain or muscle cramps.	0	1	2	3	4
FACT_006	I feel weak all over.	0	1	2	3	4
FACT_007	I have trouble hearing.	0	1	2	3	4
FACT_008	I get a ringing or buzzing in my ears.	0	1	2	3	4
FACT_009	I have trouble buttoning buttons.	0	1	2	3	4
FACT_010	I have trouble feeling the shape of small objects when they are in my hand.	0	1	2	3	4
FACT_011	I have trouble walking.	0	1	2	3	4
FACT_012	I feel bloated.	0	1	2	3	4
FACT_013	My hands are swollen.	0	1	2	3	4
FACT_014	My legs or feet are swollen.	0	1	2	3	4
FACT_015	I have pain in my fingertips.	0	1	2	3	4
FACT_016	I am bothered by the way my hands or nails look.	0	1	2	3	4

Subject Code Number		

Subject Initials		

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Evaluation Date

DAY		MONTH		YEAR	
		Jan	1		
		Feb	2		
0	0	Mar	3	0	0
1	1	Apr	4	1	1
2	2	May	5	2	2
3	3	June	6	3	3
	4	July	7	4	4
	5	Aug	8	5	5
	6	Sept	9	6	6
	7	Oct	10	7	7
	8	Nov	11	8	8
	9	Dec	12	9	9

PSPN_000

Current ECOG Performance Score	PSPN_001
Fully active, able to carry on all pre-disease performance without restriction.	0
Restricted in physically strenuous activity, but ambulatory and able to carry out work of a light or sedentary nature, e.g., light housework, office work.	1
Ambulatory and capable of all self-care, but unable to carry out any work activities. Up and about more than 50% of waking hours.	2
Capable of only limited self-care, confined to bed or chair more than 50% of waking hours.	3
Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair.	4

Physician Assessment of Peripheral Neuropathy	PSPN_002
Normal	0
Loss of deep tendon reflexes or paresthesia (including tingling) but not interfering with function	1
Objective sensory loss or paresthesia (including tingling) interfering with function, but not interfering with activities of daily living	2
Sensory loss or paresthesia interfering with activities of daily living	3
Permanent sensory loss that interferes with function	4

Subject Code Number		

Subject Initials		

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Scan Type	Scan Performed Yes	Scan Performed No	Bubble if Abnormalities found		Lesions Detected Yes	Lesions Detected No
SCAN_001 **Head CT**	1	2	SCAN_002	1	SCAN_003 1	2
SCAN_004 **Chest CT**	1	2	SCAN_005	1	SCAN_006 1	2
SCAN_007 **Abdomen CT**	1	2	SCAN_008	1	SCAN_009 1	2
SCAN_010 **Bone Scan**	1	2	SCAN_011	1	SCAN_012 1	2
SCAN_013 **Plain Radiographs**	1	2	SCAN_014	1	SCAN_015 1	2
SCAN_016 **Other (specify:)** _____ SCAN_017	1	2	SCAN_018	1	SCAN_019 1	2

Laboratory Tests	Performed Yes	Performed No	Bubble if sent to central lab	
SCAN_020 **CBC, Differential Platelet Count**	1	2	SCAN_021	1
SCAN_022 **Clinical Chemistry Panel**	1	2	SCAN_023	1

Subject Code Number

Subject Initials

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

DAY	MONTH	YEAR
	Jan 1	
	Feb 2	
0 0	Mar 3	0 0
1 1	Apr 4	1 1
2 2	May 5	2 2
3 3	June 6	3 3
4	July 7	4 4
5	Aug 8	5 5
6	Sept 9	6 6
7	Oct 10	7 7
8	Nov 11	8 8
9	Dec 12	9 9

EQLQ_000

EQLQ_031 (1) **Bubble here if this questionnaire was not completed.**

		Not at All	A Little	Quite a Bit	Very Much
EQLQ_001	Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?	1	2	3	4
EQLQ_002	Do you have any trouble taking a long walk?	1	2	3	4
EQLQ_003	Do you have any trouble taking a short walk outside the house?	1	2	3	4
EQLQ_004	Do you need to stay in a bed or a chair during the day?	1	2	3	4
EQLQ_005	Do you need help with eating, dressing, washing yourself or using the toilet?	1	2	3	4

During the past week:		Not at All	A Little	Quite a Bit	Very Much
EQLQ_006	Were you limited in doing either your work or other daily activities?	1	2	3	4
EQLQ_007	Were you limited in pursuing your hobbies or other leisure time activities?	1	2	3	4
EQLQ_008	Were you short of breath?	1	2	3	4
EQLQ_009	Have you had pain?	1	2	3	4
EQLQ_010	Did you need to rest?	1	2	3	4
EQLQ_011	Have you had trouble sleeping?	1	2	3	4
EQLQ_012	Have you felt weak?	1	2	3	4
EQLQ_013	Have you lacked appetite?	1	2	3	4
EQLQ_014	Have you felt nauseated?	1	2	3	4
EQLQ_015	Have you vomited?	1	2	3	4
EQLQ_016	Have you been constipated?	1	2	3	4
EQLQ_017	Have you had diarrhea?	1	2	3	4

Subject Code Number		

Subject Initials		

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

During the past week:		Not at All	A Little	Quite a Bit	Very Much
EQLQ_018	Were you tired?	1	2	3	4
EQLQ_019	Did pain interfere with your daily activities?	1	2	3	4
EQLQ_020	Have you had difficulty in concentrating on things, like reading a newspaper or watching television?	1	2	3	4
EQLQ_021	Did you feel tense?	1	2	3	4
EQLQ_022	Did you worry?	1	2	3	4
EQLQ_023	Did you feel irritable?	1	2	3	4
EQLQ_024	Did you feel depressed?	1	2	3	4
EQLQ_025	Have you had difficulty remembering things?	1	2	3	4
EQLQ_026	Has your physical condition or medical treatment interfered with your family life?	1	2	3	4
EQLQ_027	Has your physical condition or medical treatment interfered with your social activities?	1	2	3	4
EQLQ_028	Has your physical condition or medical treatment caused you financial difficulties?	1	2	3	4

EQLQ_029 How would you rate your overall health during the past week?

1	2	3	4	5	6	7
Very Poor						Excellent

EQLQ_030 How would you rate your overall quality of life during the past week?

1	2	3	4	5	6	7
Very Poor						Excellent

Subject Code Number

Subject Initials

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

ECHO Performed

① Yes
② No

ECHO_001

Date Performed

DAY	MONTH	YEAR
	Jan 1	
	Feb 2	
00	Mar 3	00
11	Apr 4	11
22	May 5	22
33	June 6	33
	July 7	44
	Aug 8	55
	Sept 9	66
	Oct 10	77
	Nov 11	88
	Dec 12	99

ECHO_002

LVEF

① Normal
② Abnormal

ECHO_003

%

00 11 22 33 44 55 66 77 88 99

ECHO_004

Wall Motion

① Normal
② Abnormal

ECHO_005

Valvular Function

① Normal
② Abnormal

ECHO_006

Evidence of Hypertrophy

① Yes
② No

ECHO_007

MUGA Performed

① Yes
② No

MUGA_001

Date Performed

DAY	MONTH	YEAR
	Jan 1	
	Feb 2	
00	Mar 3	00
11	Apr 4	11
22	May 5	22
33	June 6	33
	July 7	44
	Aug 8	55
	Sept 9	66
	Oct 10	77
	Nov 11	88
	Dec 12	99

MUGA_002

LVEF

① Normal
② Abnormal

MUGA_003

%

00 11 22 33 44 55 66 77 88 99

MUGA_004

Subject Code Number		

Subject Initials		

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Date Performed

DAY		MONTH		YEAR	
		Jan	1		
		Feb	2		
0	0	Mar	3	0	0
1	1	Apr	4	1	1
2	2	May	5	2	2
3	3	June	6	3	3
	4	July	7	4	4
	5	Aug	8	5	5
	6	Sept	9	6	6
	7	Oct	10	7	7
	8	Nov	11	8	8
	9	Dec	12	9	9

EKGR_000

EKG Results

1. **Normal**
2. **Abnormal, clinically significant** ***(provide comments below)***
3. **Abnormal, not clinically significant** ***(provide comments below)***
4. **Not done**

EKGR_001

Comment on Abnormal EKG:

EKGR_002

Subject Code Number

Subject Initials

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Assessment Date

DAY	MONTH	YEAR
	Jan 1	
	Feb 2	
00	Mar 3	00
11	Apr 4	11
22	May 5	22
33	June 6	33
4	July 7	44
5	Aug 8	55
6	Sept 9	66
7	Oct 10	77
8	Nov 11	88
9	Dec 12	99

BASE_000

Target Lesions

Number of Lesions

BASE_001

Sum of Longest Diameters (mm)

BASE_002

Non-Target Lesions

Number of Lesions

BASE_003

Subject Code Number

Subject Initials

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Visit Date

DAY	MONTH		YEAR
	Jan	1	
	Feb	2	
0 0	Mar	3	0 0
1 1	Apr	4	1 1
2 2	May	5	2 2
3 3	June	6	3 3
4	July	7	4 4
5	Aug	8	5 5
6	Sept	9	6 6
7	Oct	10	7 7
8	Nov	11	8 8
9	Dec	12	9 9

VADF_000

Site ID Number

0 0 0
1 1 1
2 2 2
3 3 3
4 4 4
5 5 5
6 6 6
7 7 7
8 8 8
9 9 9

Subject Code Number

0 0 0
1 1 1
2 2 2
3 3 3
4 4 4
5 5 5
6 6 6
7 7 7
8 8 8
9 9 9

Visit

1. Baseline Visit
2. Week 0 / Cycle 1 Visit
4. Week 3 / Cycle 2 Visit
5. Week 5 Visit
6. Week 6 / Cycle 3 Visit
8. Week 9 / Cycle 4 Visit
10. Week 12 / Cycle 5 Visit
12. Week 15 / Cycle 6 / End of Study Visit
14. 30 Day Follow Up Visit
15. Six Month Follow Up Visit
16. Survival Endpoint
99. Unscheduled Visit

Forms to be submitted this visit:

Numbered Pages:

- ☐ Physical Exam (pg 21-22)
- ☐ Subject Assessment of Peripheral Neuropathy (pg 23)
- ☐ Performance Score and Peripheral Neuropathy (pg 24)
- ☐ Report of Scans and Lab Submissions (pg 25)
- ☐ Dosing Record (pg 26)
- ☐ Toxicity Assessment (pg 27)

Unnumbered Pages (submit as many as necessary):

- ☐ Vital Signs
- ☐ Concurrent Procedures
- ☐ Adverse Experiences
- ☐ Concomitant Medications
- ☐ Lesion Identification Form
- ☐ Non-Target Lesion Evaluation Form
- ☐ Target Lesion Measurement Form

Subject Code Number		

Subject Initials		

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Date of Assessment

DAY		MONTH		YEAR	
		Jan	1		
		Feb	2		
0	0	Mar	3	0	0
1	1	Apr	4	1	1
2	2	May	5	2	2
3	3	June	6	3	3
	4	July	7	4	4
	5	Aug	8	5	5
	6	Sept	9	6	6
	7	Oct	10	7	7
	8	Nov	11	8	8
	9	Dec	12	9	9

PHEX_001

Weight (kg)

			.	
0	0	0		0
1	1	1		1
2	2	2		2
3	3	3		3
4	4	4		4
5	5	5		5
6	6	6		6
7	7	7		7
8	8	8		8
9	9	9		9

PHEX_002

Site	Normal	Abnormal	Not Done	Describe Abnormalities
PHEX_004 **General Appearance**	1	2	3	PHEX_005
PHEX_006 **Head**	1	2	3	PHEX_007
PHEX_008 **Ears**	1	2	3	PHEX_009
PHEX_010 **Eyes**	1	2	3	PHEX_011
PHEX_012 **Nose**	1	2	3	PHEX_013
PHEX_014 **Throat**	1	2	3	PHEX_015
PHEX_016 **Mouth**	1	2	3	PHEX_017
PHEX_018 **Neck**	1	2	3	PHEX_019
PHEX_020 **Thyroid**	1	2	3	PHEX_021

Subject Code Number		

Subject Initials		

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Site	Normal	Abnormal	Not Done	Describe Abnormalities
PHEX_022 **Lungs / Thorax**	1	2	3	PHEX_023
PHEX_024 **Heart**	1	2	3	PHEX_025
PHEX_026 **Breasts**	1	2	3	PHEX_027
PHEX_028 **Liver**	1	2	3	PHEX_029
PHEX_030 **Abdomen**	1	2	3	PHEX_031
PHEX_032 **Musculoskeletal**	1	2	3	PHEX_033
PHEX_034 **Extremities**	1	2	3	PHEX_035
PHEX_036 **Pulses**	1	2	3	PHEX_037
PHEX_038 **Lymph Nodes**	1	2	3	PHEX_039
PHEX_040 **Skin**	1	2	3	PHEX_041
PHEX_042 **Neurological**	1	2	3	PHEX_043
PHEX_044 **Genitourinary (including pelvic)**	1	2	3	PHEX_045
PHEX_046 **Rectal**	1	2	3	PHEX_047

Subject Code Number

Subject Initials

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Evaluation Date					
DAY		MONTH		YEAR	
		Jan	1		
		Feb	2		
0	0	Mar	3	0	0
1	1	Apr	4	1	1
2	2	May	5	2	2
3	3	June	6	3	3
	4	July	7	4	4
	5	Aug	8	5	5
	6	Sept	9	6	6
	7	Oct	10	7	7
	8	Nov	11	8	8
	9	Dec	12	9	9

FACT_000

FACT-Taxane (Version 4); "Additional Concerns"

FACT_017 (1) **Bubble here if this questionnaire was not completed.**

Indicate how true each statement has been for the subject <u>during the past 7 days</u>.		Not at all	A little bit	Some-what	Quite a bit	Very much
FACT_001	I have numbness or tingling in my hands.	0	1	2	3	4
FACT_002	I have numbness or tingling in my feet.	0	1	2	3	4
FACT_003	I feel discomfort in my hands.	0	1	2	3	4
FACT_004	I feel discomfort in my feet.	0	1	2	3	4
FACT_005	I have joint pain or muscle cramps.	0	1	2	3	4
FACT_006	I feel weak all over.	0	1	2	3	4
FACT_007	I have trouble hearing.	0	1	2	3	4
FACT_008	I get a ringing or buzzing in my ears.	0	1	2	3	4
FACT_009	I have trouble buttoning buttons.	0	1	2	3	4
FACT_010	I have trouble feeling the shape of small objects when they are in my hand.	0	1	2	3	4
FACT_011	I have trouble walking.	0	1	2	3	4
FACT_012	I feel bloated.	0	1	2	3	4
FACT_013	My hands are swollen.	0	1	2	3	4
FACT_014	My legs or feet are swollen.	0	1	2	3	4
FACT_015	I have pain in my fingertips.	0	1	2	3	4
FACT_016	I am bothered by the way my hands or nails look.	0	1	2	3	4

Subject Code Number		

Subject Initials		

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Evaluation Date

DAY		MONTH		YEAR	
		Jan	1		
		Feb	2		
0	0	Mar	3	0	0
1	1	Apr	4	1	1
2	2	May	5	2	2
3	3	June	6	3	3
	4	July	7	4	4
	5	Aug	8	5	5
	6	Sept	9	6	6
	7	Oct	10	7	7
	8	Nov	11	8	8
	9	Dec	12	9	9

PSPN_000

Current ECOG Performance Score	PSPN_001
Fully active, able to carry on all pre-disease performance without restriction.	0
Restricted in physically strenuous activity, but ambulatory and able to carry out work of a light or sedentary nature, e.g., light housework, office work.	1
Ambulatory and capable of all self-care, but unable to carry out any work activities. Up and about more than 50% of waking hours.	2
Capable of only limited self-care, confined to bed or chair more than 50% of waking hours.	3
Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair.	4

Physician Assessment of Peripheral Neuropathy	PSPN_002
Normal	0
Loss of deep tendon reflexes or paresthesia (including tingling) but not interfering with function	1
Objective sensory loss or paresthesia (including tingling) interfering with function, but not interfering with activities of daily living	2
Sensory loss or paresthesia interfering with activities of daily living	3
Permanent sensory loss that interferes with function	4

Subject Code Number		

Subject Initials		

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Scan Type	Scan Performed Yes	Scan Performed No	Bubble if Abnormalities found		Lesions Detected Yes	Lesions Detected No
SCAN_001 **Head CT**	1	2	SCAN_002	1	SCAN_003 1	2
SCAN_004 **Chest CT**	1	2	SCAN_005	1	SCAN_006 1	2
SCAN_007 **Abdomen CT**	1	2	SCAN_008	1	SCAN_009 1	2
SCAN_010 **Bone Scan**	1	2	SCAN_011	1	SCAN_012 1	2
SCAN_013 **Plain Radiographs**	1	2	SCAN_014	1	SCAN_015 1	2
SCAN_016 **Other (specify:)** _____ SCAN_017	1	2	SCAN_018	1	SCAN_019 1	2

Laboratory Tests	Performed Yes	Performed No	Bubble if sent to central lab	
SCAN_020 **CBC, Differential Platelet Count**	1	2	SCAN_021	1
SCAN_022 **Clinical Chemistry Panel**	1	2	SCAN_023	1

Subject Code Number

Subject Initials

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Dosing Start Date and Time

DAY | MONTH | YEAR | 00:00 - 23:59

Jan 1, Feb 2, Mar 3, Apr 4, May 5, June 6, July 7, Aug 8, Sept 9, Oct 10, Nov 11, Dec 12

DOSE_001 DOSE_002

Dosing Stop Date and Time

DAY | MONTH | YEAR | 00:00 - 23:59

Jan 1, Feb 2, Mar 3, Apr 4, May 5, June 6, July 7, Aug 8, Sept 9, Oct 10, Nov 11, Dec 12

DOSE_003 DOSE_004

Body Surface Area (sq. m)

DOSE_005

Assigned Dose (mg/m^2)

DOSE_006

Dose Reduction

DOSE_007 **Was this dose a reduced dose?**

1. **Yes** ***(complete this section)***
2. **No** ***(skip to DOSE_010)***

DOSE_008 **Primary reason for dose reduction:**

1. **Hematological toxicity**
2. **Grade 3 or 4 neurotoxicity**
3. **Other Grade 3 or 4 toxicity, per investigator's discretion - Specify:**

_____

_____

DOSE_009

Infusion Status

DOSE_010 **Infusion Status**

1. **Infusion complete; no interruption**
2. **Infusion complete with interruption**
3. **Infusion initiated but not completed**

Total Dose Administered (mg)

DOSE_011

Subject Code Number

Subject Initials

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Assessment Date

DAY	MONTH	YEAR
	Jan 1	
	Feb 2	
00	Mar 3	00
11	Apr 4	11
22	May 5	22
33	June 6	33
4	July 7	44
5	Aug 8	55
6	Sept 9	66
7	Oct 10	77
8	Nov 11	88
9	Dec 12	99

TOXY_000

Toxicity	Grade at visit	GRADE 0	1	2	3	4
Nausea TOXY_001	0 1 2 3	None	Able to eat reasonable intake	Intake significantly decreased but can eat	No significant intake	
Vomiting TOXY_002	0 1 2 3 4	None	One episode in 24 hours	2-5 episodes in 24 hours	6-10 episodes in 24 hours	>10 episodes in 24 hours or requiring parenteral support
Diarrhea TOXY_003	0 1 2 3 4	None	Increase of 2-3 stools per day over pre-Rx	Increase of 4-6 stools/day or nocturnal stools, or moderate cramping	Increase of 7-9 stools/day or incontinence, or severe cramping	Increase of 10 or more stools/day or grossly bloody diarrhea, or need for parenteral support
Mucositis / Stomatitis TOXY_004	0 1 2 3 4	None	Painless ulcers, erythema, or mild soreness	Painful erythema, edema, or ulcers but can eat	Painful erythema, edema, or ulcers and cannot eat	Requires parenteral or enteral support
Alopecia TOXY_005	0 1 2	No loss	Mild hair loss	Pronounced or total hair loss		
Infection TOXY_006	0 1 2 3 4	None	Mild	Moderate	Severe	Life threatening

Visit Administration Form (VADF)

Subject Code Number

Subject Initials

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Visit Date

DAY	MONTH	YEAR
	Jan 1	
	Feb 2	
0 0	Mar 3	0 0
1 1	Apr 4	1 1
2 2	May 5	2 2
3 3	June 6	3 3
4	July 7	4 4
5	Aug 8	5 5
6	Sept 9	6 6
7	Oct 10	7 7
8	Nov 11	8 8
9	Dec 12	9 9

VADF_000

Site ID Number

0 0 0
1 1 1
2 2 2
3 3 3
4 4 4
5 5 5
6 6 6
7 7 7
8 8 8
9 9 9

Subject Code Number

0 0 0
1 1 1
2 2 2
3 3 3
4 4 4
5 5 5
6 6 6
7 7 7
8 8 8
9 9 9

Visit

1. Baseline Visit
2. Week 0 / Cycle 1 Visit
3. Week 3 / Cycle 2 Visit
5. Week 5 Visit
6. Week 6 / Cycle 3 Visit
8. Week 9 / Cycle 4 Visit
10. Week 12 / Cycle 5 Visit
12. Week 15 / Cycle 6 / End of Study Visit
14. 30 Day Follow Up Visit
15. Six Month Follow Up Visit
16. Survival Endpoint
99. Unscheduled Visit

Forms to be submitted this visit:

Numbered Pages:

- ☐ Physical Exam (pg 29-30)
- ☐ Subject Assessment of Peripheral Neuropathy (pg 31)
- ☐ Performance Score and Peripheral Neuropathy (pg 32)
- ☐ Report of Scans and Lab Submissions (pg 33)
- ☐ Dosing Record (pg 34)
- ☐ Toxicity Assessment (pg 35)

Unnumbered Pages (submit as many as necessary):

- ☐ Vital Signs
- ☐ Concurrent Procedures
- ☐ Adverse Experiences
- ☐ Concomitant Medications
- ☐ Lesion Identification Form
- ☐ Non-Target Lesion Evaluation Form
- ☐ Target Lesion Measurement Form

Subject Code Number

Subject Initials

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Date of Assessment

DAY	MONTH	YEAR
	1 Jan	
	2 Feb	
00	3 Mar	00
11	4 Apr	11
22	5 May	22
33	6 June	33
4	7 July	44
5	8 Aug	55
6	9 Sept	66
7	10 Oct	77
8	11 Nov	88
9	12 Dec	99

PHEX_001

Weight (kg)

000 . 0
111 1
222 2
333 3
444 4
555 5
666 6
777 7
888 8
999 9

PHEX_002

Site	Normal	Abnormal	Not Done	Describe Abnormalities
PHEX_004 **General Appearance**	1	2	3	PHEX_005
PHEX_006 **Head**	1	2	3	PHEX_007
PHEX_008 **Ears**	1	2	3	PHEX_009
PHEX_010 **Eyes**	1	2	3	PHEX_011
PHEX_012 **Nose**	1	2	3	PHEX_013
PHEX_014 **Throat**	1	2	3	PHEX_015
PHEX_016 **Mouth**	1	2	3	PHEX_017
PHEX_018 **Neck**	1	2	3	PHEX_019
PHEX_020 **Thyroid**	1	2	3	PHEX_021

Subject Code Number

Subject Initials

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Site	Normal	Abnormal	Not Done	Describe Abnormalities
PHEX_022 **Lungs / Thorax**	1	2	3	PHEX_023
PHEX_024 **Heart**	1	2	3	PHEX_025
PHEX_026 **Breasts**	1	2	3	PHEX_027
PHEX_028 **Liver**	1	2	3	PHEX_029
PHEX_030 **Abdomen**	1	2	3	PHEX_031
PHEX_032 **Musculoskeletal**	1	2	3	PHEX_033
PHEX_034 **Extremities**	1	2	3	PHEX_035
PHEX_036 **Pulses**	1	2	3	PHEX_037
PHEX_038 **Lymph Nodes**	1	2	3	PHEX_039
PHEX_040 **Skin**	1	2	3	PHEX_041
PHEX_042 **Neurological**	1	2	3	PHEX_043
PHEX_044 **Genitourinary (including pelvic)**	1	2	3	PHEX_045
PHEX_046 **Rectal**	1	2	3	PHEX_047

Subject Code Number		

Subject Initials		

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Evaluation Date					
DAY		MONTH		YEAR	
		Jan	1		
		Feb	2		
0	0	Mar	3	0	0
1	1	Apr	4	1	1
2	2	May	5	2	2
3	3	June	6	3	3
	4	July	7	4	4
	5	Aug	8	5	5
	6	Sept	9	6	6
	7	Oct	10	7	7
	8	Nov	11	8	8
	9	Dec	12	9	9

FACT_000

FACT-Taxane (Version 4); "Additional Concerns"

FACT_017 (1) **Bubble here if this questionnaire was not completed.**

Indicate how true each statement has been for the subject <u>during the past 7 days</u>.		Not at all	A little bit	Some-what	Quite a bit	Very much
FACT_001	I have numbness or tingling in my hands.	0	1	2	3	4
FACT_002	I have numbness or tingling in my feet.	0	1	2	3	4
FACT_003	I feel discomfort in my hands.	0	1	2	3	4
FACT_004	I feel discomfort in my feet.	0	1	2	3	4
FACT_005	I have joint pain or muscle cramps.	0	1	2	3	4
FACT_006	I feel weak all over.	0	1	2	3	4
FACT_007	I have trouble hearing.	0	1	2	3	4
FACT_008	I get a ringing or buzzing in my ears.	0	1	2	3	4
FACT_009	I have trouble buttoning buttons.	0	1	2	3	4
FACT_010	I have trouble feeling the shape of small objects when they are in my hand.	0	1	2	3	4
FACT_011	I have trouble walking.	0	1	2	3	4
FACT_012	I feel bloated.	0	1	2	3	4
FACT_013	My hands are swollen.	0	1	2	3	4
FACT_014	My legs or feet are swollen.	0	1	2	3	4
FACT_015	I have pain in my fingertips.	0	1	2	3	4
FACT_016	I am bothered by the way my hands or nails look.	0	1	2	3	4

Subject Code Number		

Subject Initials		

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Evaluation Date

DAY		MONTH		YEAR	
		Jan	1		
		Feb	2		
0	0	Mar	3	0	0
1	1	Apr	4	1	1
2	2	May	5	2	2
3	3	June	6	3	3
	4	July	7	4	4
	5	Aug	8	5	5
	6	Sept	9	6	6
	7	Oct	10	7	7
	8	Nov	11	8	8
	9	Dec	12	9	9

PSPN_000

Current ECOG Performance Score	PSPN_001
Fully active, able to carry on all pre-disease performance without restriction.	0
Restricted in physically strenuous activity, but ambulatory and able to carry out work of a light or sedentary nature, e.g., light housework, office work.	1
Ambulatory and capable of all self-care, but unable to carry out any work activities. Up and about more than 50% of waking hours.	2
Capable of only limited self-care, confined to bed or chair more than 50% of waking hours.	3
Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair.	4

Physician Assessment of Peripheral Neuropathy	PSPN_002
Normal	0
Loss of deep tendon reflexes or paresthesia (including tingling) but not interfering with function	1
Objective sensory loss or paresthesia (including tingling) interfering with function, but not interfering with activities of daily living	2
Sensory loss or paresthesia interfering with activities of daily living	3
Permanent sensory loss that interferes with function	4

Subject Code Number		

Subject Initials		

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Scan Type	Scan Performed Yes	Scan Performed No	Bubble if Abnormalities found		Lesions Detected Yes	Lesions Detected No
SCAN_001 **Head CT**	1	2	SCAN_002	1	SCAN_003 1	2
SCAN_004 **Chest CT**	1	2	SCAN_005	1	SCAN_006 1	2
SCAN_007 **Abdomen CT**	1	2	SCAN_008	1	SCAN_009 1	2
SCAN_010 **Bone Scan**	1	2	SCAN_011	1	SCAN_012 1	2
SCAN_013 **Plain Radiographs**	1	2	SCAN_014	1	SCAN_015 1	2
SCAN_016 **Other (specify:)** _____ SCAN_017	1	2	SCAN_018	1	SCAN_019 1	2

Laboratory Tests	Performed Yes	Performed No	Bubble if sent to central lab	
SCAN_020 **CBC, Differential Platelet Count**	1	2	SCAN_021	1
SCAN_022 **Clinical Chemistry Panel**	1	2	SCAN_023	1

Subject Code Number

Subject Initials

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Dosing Start Date and Time

DAY | MONTH | YEAR | 00:00 - 23:59

Jan 1, Feb 2, Mar 3, Apr 4, May 5, June 6, July 7, Aug 8, Sept 9, Oct 10, Nov 11, Dec 12

DOSE_001 DOSE_002

Dosing Stop Date and Time

DAY | MONTH | YEAR | 00:00 - 23:59

Jan 1, Feb 2, Mar 3, Apr 4, May 5, June 6, July 7, Aug 8, Sept 9, Oct 10, Nov 11, Dec 12

DOSE_003 DOSE_004

Body Surface Area (sq. m)

DOSE_005

Assigned Dose (mg/m^2)

DOSE_006

Dose Reduction

DOSE_007 **Was this dose a reduced dose?**

1. **Yes** ***(complete this section)***
2. **No** ***(skip to DOSE_010)***

DOSE_008 **Primary reason for dose reduction:**

1. **Hematological toxicity**
2. **Grade 3 or 4 neurotoxicity**
3. **Other Grade 3 or 4 toxicity, per investigator's discretion - Specify:**

_____

_____

DOSE_009

Infusion Status

DOSE_010 **Infusion Status**

1. **Infusion complete; no interruption**
2. **Infusion complete with interruption**
3. **Infusion initiated but not completed**

Total Dose Administered (mg)

DOSE_011

Subject Code Number

Subject Initials

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Assessment Date

DAY	MONTH	YEAR
	Jan 1	
	Feb 2	
00	Mar 3	00
11	Apr 4	11
22	May 5	22
33	June 6	33
4	July 7	44
5	Aug 8	55
6	Sept 9	66
7	Oct 10	77
8	Nov 11	88
9	Dec 12	99

TOXY_000

Toxicity	Grade at visit	GRADE 0	1	2	3	4
Nausea TOXY_001	0 1 2 3	None	Able to eat reasonable intake	Intake significantly decreased but can eat	No significant intake	
Vomiting TOXY_002	0 1 2 3 4	None	One episode in 24 hours	2-5 episodes in 24 hours	6-10 episodes in 24 hours	>10 episodes in 24 hours or requiring parenteral support
Diarrhea TOXY_003	0 1 2 3 4	None	Increase of 2-3 stools per day over pre-Rx	Increase of 4-6 stools/day or nocturnal stools, or moderate cramping	Increase of 7-9 stools/day or incontinence, or severe cramping	Increase of 10 or more stools/day or grossly bloody diarrhea, or need for parenteral support
Mucositis / Stomatitis TOXY_004	0 1 2 3 4	None	Painless ulcers, erythema, or mild soreness	Painful erythema, edema, or ulcers but can eat	Painful erythema, edema, or ulcers and cannot eat	Requires parenteral or enteral support
Alopecia TOXY_005	0 1 2	No loss	Mild hair loss	Pronounced or total hair loss		
Infection TOXY_006	0 1 2 3 4	None	Mild	Moderate	Severe	Life threatening

Subject Code Number

Subject Initials

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Visit Date

DAY	MONTH	YEAR
	Jan 1	
	Feb 2	
00	Mar 3	00
11	Apr 4	11
22	May 5	22
33	June 6	33
4	July 7	44
5	Aug 8	55
6	Sept 9	66
7	Oct 10	77
8	Nov 11	88
9	Dec 12	99

VADF_000

Site ID Number

Subject Code Number

Visit

1. Baseline Visit
2. Week 0 / Cycle 1 Visit
4. Week 3 / Cycle 2 Visit
● Week 5 Visit
6. Week 6 / Cycle 3 Visit
8. Week 9 / Cycle 4 Visit
10. Week 12 / Cycle 5 Visit
12. Week 15 / Cycle 6 / End of Study Visit
14. 30 Day Follow Up Visit
15. Six Month Follow Up Visit
16. Survival Endpoint
99. Unscheduled Visit

Forms to be submitted this visit:

Numbered Pages:

- ☐ Report of Scans and Lab Submissions (pg 37)
- ☐ Response Evaluation (pg 38-39)

Unnumbered Pages (submit as many as necessary):

- ☐ Concurrent Procedures
- ☐ Adverse Experiences
- ☐ Concomitant Medications
- ☐ Lesion Identification Form
- ☐ Non-Target Lesion Evaluation Form
- ☐ Target Lesion Measurement Form

Subject Code Number

Subject Initials

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Scan Type	Scan Performed Yes	Scan Performed No	Bubble if Abnormalities found		Lesions Detected Yes	Lesions Detected No
SCAN_001 **Head CT**	1	2	SCAN_002	1	SCAN_003 1	2
SCAN_004 **Chest CT**	1	2	SCAN_005	1	SCAN_006 1	2
SCAN_007 **Abdomen CT**	1	2	SCAN_008	1	SCAN_009 1	2
SCAN_010 **Bone Scan**	1	2	SCAN_011	1	SCAN_012 1	2
SCAN_013 **Plain Radiographs**	1	2	SCAN_014	1	SCAN_015 1	2
SCAN_016 **Other (specify:)** _____ SCAN_017	1	2	SCAN_018	1	SCAN_019 1	2

Laboratory Tests	Performed Yes	Performed No	Bubble if sent to central lab
SCAN_020 **CBC, Differential Platelet Count**	1	2	SCAN_021 1
SCAN_022 **Clinical Chemistry Panel**	1	2	SCAN_023 1

Subject Code Number

Subject Initials

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Use the RECIST criteria to evaluate response.

Assessment Date

DAY	MONTH	YEAR
	Jan (1)	
	Feb (2)	
00	Mar (3)	00
11	Apr (4)	11
22	May (5)	22
33	June (6)	33
	July (7)	44
	Aug (8)	55
	Sept (9)	66
	Oct (10)	77
	Nov (11)	88
	Dec (12)	99

RESP_000

Target Lesions

Number of Lesions

RESP_001

Sum of Longest Diameters (mm)

RESP_002

Non-Target Lesions

Number of Lesions

RESP_003

Target Response Criteria	Definition
RESP_004	
① Complete Response	Disappearance of all target lesions.
② Partial Response	At least a 30% decrease in the sum of the longest diameters of target lesions, taking as a reference the baseline sum of the longest diameters.
③ Stable Disease	Neither sufficient shrinkage to qualify for partial response nor sufficient increase to qualify for progressive disease, taking as a reference the smallest sum of the longest diameters achieved since the treatment started.
④ Progressive Disease	At least a 20% increase in the sum of the longest diameters of target lesions, taking as reference the smallest sum longest diameter recorded since treatment began or the appearance of one or more lesions.
⑤ Not Able to Evaluate	*Explain:*

RESP_005

Subject Code Number	

Subject Initials	

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Non-Target Response Criteria	Definition
RESP_006 ① Complete Response	Disappearance of all non-target lesions.
② Incomplete Response / Stable Disease	Persistence of one or more non-target lesion(s).
③ Progressive Disease	The appearance of one or more non-target lesions and/or unequivocal progression of existing non-target lesions.
③ Not Applicable	No non-target lesions have ever existed for this subject.

Overall Response

Use the grid below to determine the overall response. Choose the row with the correct responses for target lesion response and non-target lesion response, then bubble in the appropriate overall response.

Target Response	Non-Target Response	RESP_007	Overall Response
Complete Response	Complete Response	①	Complete Response
Complete Response	Incomplete / SD	②	Partial Response
Partial Response	Non-PD	③	Partial Response
Stable Disease	Non-PD	④	Stable Disease
Progressive Disease	Any	⑤	Progressive Disease
Any	Progressive Disease	⑥	Progressive Disease
		⑦	Not Evaluated

Visit Administration Form (VADF)

Subject Code Number

Subject Initials

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Visit Date

DAY	MONTH	YEAR
	Jan 1	
	Feb 2	
00	Mar 3	00
11	Apr 4	11
22	May 5	22
33	June 6	33
4	July 7	44
5	Aug 8	55
6	Sept 9	66
7	Oct 10	77
8	Nov 11	88
9	Dec 12	99

VADF_000

Site ID Number

Subject Code Number

Visit

1. Baseline Visit
2. Week 0 / Cycle 1 Visit
4. Week 3 / Cycle 2 Visit
5. Week 5 Visit
6. Week 6 / Cycle 3 Visit
8. Week 9 / Cycle 4 Visit
10. Week 12 / Cycle 5 Visit
12. Week 15 / Cycle 6 / End of Study Visit
14. 30 Day Follow Up Visit
15. Six Month Follow Up Visit
16. Survival Endpoint
99. Unscheduled Visit

Forms to be submitted this visit:

Numbered Pages:

- ☐ Physical Exam (pg 41-42)
- ☐ Subject Assessment of Peripheral Neuropathy (pg 43)
- ☐ Performance Score and Peripheral Neuropathy (pg 44)
- ☐ Report of Scans and Lab Submissions (pg 45)
- ☐ EORTC QLQ-C30 Questionnaire (pg 46-47)
- ☐ Dosing Record (pg 48)
- ☐ Toxicity Assessment (pg 49)

Unnumbered Pages (submit as many as necessary):

- ☐ Vital Signs
- ☐ Concurrent Procedures
- ☐ Adverse Experiences
- ☐ Concomitant Medications
- ☐ Lesion Identification Form
- ☐ Non-Target Lesion Evaluation Form
- ☐ Target Lesion Measurement Form

Subject Code Number		

Subject Initials		

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Date of Assessment

DAY		MONTH		YEAR	
		Jan	1		
		Feb	2		
0	0	Mar	3	0	0
1	1	Apr	4	1	1
2	2	May	5	2	2
3	3	June	6	3	3
	4	July	7	4	4
	5	Aug	8	5	5
	6	Sept	9	6	6
	7	Oct	10	7	7
	8	Nov	11	8	8
	9	Dec	12	9	9

PHEX_001

Weight (kg)

			.	
0	0	0		0
1	1	1		1
2	2	2		2
3	3	3		3
4	4	4		4
5	5	5		5
6	6	6		6
7	7	7		7
8	8	8		8
9	9	9		9

PHEX_002

Site	Normal	Abnormal	Not Done	Describe Abnormalities
PHEX_004 **General Appearance**	1	2	3	PHEX_005
PHEX_006 **Head**	1	2	3	PHEX_007
PHEX_008 **Ears**	1	2	3	PHEX_009
PHEX_010 **Eyes**	1	2	3	PHEX_011
PHEX_012 **Nose**	1	2	3	PHEX_013
PHEX_014 **Throat**	1	2	3	PHEX_015
PHEX_016 **Mouth**	1	2	3	PHEX_017
PHEX_018 **Neck**	1	2	3	PHEX_019
PHEX_020 **Thyroid**	1	2	3	PHEX_021

Subject Code Number		

Subject Initials		

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Site	Normal	Abnormal	Not Done	Describe Abnormalities
PHEX_022 **Lungs / Thorax**	1	2	3	PHEX_023
PHEX_024 **Heart**	1	2	3	PHEX_025
PHEX_026 **Breasts**	1	2	3	PHEX_027
PHEX_028 **Liver**	1	2	3	PHEX_029
PHEX_030 **Abdomen**	1	2	3	PHEX_031
PHEX_032 **Musculoskeletal**	1	2	3	PHEX_033
PHEX_034 **Extremities**	1	2	3	PHEX_035
PHEX_036 **Pulses**	1	2	3	PHEX_037
PHEX_038 **Lymph Nodes**	1	2	3	PHEX_039
PHEX_040 **Skin**	1	2	3	PHEX_041
PHEX_042 **Neurological**	1	2	3	PHEX_043
PHEX_044 **Genitourinary (including pelvic)**	1	2	3	PHEX_045
PHEX_046 **Rectal**	1	2	3	PHEX_047

Subject Code Number		

Subject Initials		

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Evaluation Date					
DAY		MONTH		YEAR	
		Jan	1		
		Feb	2		
0	0	Mar	3	0	0
1	1	Apr	4	1	1
2	2	May	5	2	2
3	3	June	6	3	3
	4	July	7	4	4
	5	Aug	8	5	5
	6	Sept	9	6	6
	7	Oct	10	7	7
	8	Nov	11	8	8
	9	Dec	12	9	9

FACT_000

FACT-Taxane (Version 4); "Additional Concerns"

FACT_017 ① **Bubble here if this questionnaire was not completed.**

Indicate how true each statement has been for the subject <u>during the past 7 days</u>.		Not at all	A little bit	Some-what	Quite a bit	Very much
FACT_001	I have numbness or tingling in my hands.	0	1	2	3	4
FACT_002	I have numbness or tingling in my feet.	0	1	2	3	4
FACT_003	I feel discomfort in my hands.	0	1	2	3	4
FACT_004	I feel discomfort in my feet.	0	1	2	3	4
FACT_005	I have joint pain or muscle cramps.	0	1	2	3	4
FACT_006	I feel weak all over.	0	1	2	3	4
FACT_007	I have trouble hearing.	0	1	2	3	4
FACT_008	I get a ringing or buzzing in my ears.	0	1	2	3	4
FACT_009	I have trouble buttoning buttons.	0	1	2	3	4
FACT_010	I have trouble feeling the shape of small objects when they are in my hand.	0	1	2	3	4
FACT_011	I have trouble walking.	0	1	2	3	4
FACT_012	I feel bloated.	0	1	2	3	4
FACT_013	My hands are swollen.	0	1	2	3	4
FACT_014	My legs or feet are swollen.	0	1	2	3	4
FACT_015	I have pain in my fingertips.	0	1	2	3	4
FACT_016	I am bothered by the way my hands or nails look.	0	1	2	3	4

Subject Code Number		

Subject Initials		

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Evaluation Date

DAY		MONTH		YEAR	
		Jan	1		
		Feb	2		
0	0	Mar	3	0	0
1	1	Apr	4	1	1
2	2	May	5	2	2
3	3	June	6	3	3
	4	July	7	4	4
	5	Aug	8	5	5
	6	Sept	9	6	6
	7	Oct	10	7	7
	8	Nov	11	8	8
	9	Dec	12	9	9

PSPN_000

Current ECOG Performance Score	PSPN_001
Fully active, able to carry on all pre-disease performance without restriction.	0
Restricted in physically strenuous activity, but ambulatory and able to carry out work of a light or sedentary nature, e.g., light housework, office work.	1
Ambulatory and capable of all self-care, but unable to carry out any work activities. Up and about more than 50% of waking hours.	2
Capable of only limited self-care, confined to bed or chair more than 50% of waking hours.	3
Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair.	4

Physician Assessment of Peripheral Neuropathy	PSPN_002
Normal	0
Loss of deep tendon reflexes or paresthesia (including tingling) but not interfering with function	1
Objective sensory loss or paresthesia (including tingling) interfering with function, but not interfering with activities of daily living	2
Sensory loss or paresthesia interfering with activities of daily living	3
Permanent sensory loss that interferes with function	4

Subject Code Number		

Subject Initials		

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Scan Type	Scan Performed Yes	Scan Performed No	Bubble if Abnormalities found		Lesions Detected Yes	Lesions Detected No
SCAN_001 **Head CT**	1	2	SCAN_002	1	SCAN_003 1	2
SCAN_004 **Chest CT**	1	2	SCAN_005	1	SCAN_006 1	2
SCAN_007 **Abdomen CT**	1	2	SCAN_008	1	SCAN_009 1	2
SCAN_010 **Bone Scan**	1	2	SCAN_011	1	SCAN_012 1	2
SCAN_013 **Plain Radiographs**	1	2	SCAN_014	1	SCAN_015 1	2
SCAN_016 **Other (specify:)** _____ SCAN_017	1	2	SCAN_018	1	SCAN_019 1	2

Laboratory Tests	Performed Yes	Performed No	Bubble if sent to central lab	
SCAN_020 **CBC, Differential Platelet Count**	1	2	SCAN_021	1
SCAN_022 **Clinical Chemistry Panel**	1	2	SCAN_023	1

Subject Code Number

Subject Initials

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

DAY	MONTH	YEAR
	Jan 1	
	Feb 2	
0 0	Mar 3	0 0
1 1	Apr 4	1 1
2 2	May 5	2 2
3 3	June 6	3 3
4	July 7	4 4
5	Aug 8	5 5
6	Sept 9	6 6
7	Oct 10	7 7
8	Nov 11	8 8
9	Dec 12	9 9

EQLQ_000

EQLQ_031 (1) **Bubble here if this questionnaire was not completed.**

		Not at All	A Little	Quite a Bit	Very Much
EQLQ_001	Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?	1	2	3	4
EQLQ_002	Do you have any trouble taking a long walk?	1	2	3	4
EQLQ_003	Do you have any trouble taking a short walk outside the house?	1	2	3	4
EQLQ_004	Do you need to stay in a bed or a chair during the day?	1	2	3	4
EQLQ_005	Do you need help with eating, dressing, washing yourself or using the toilet?	1	2	3	4

During the past week:		Not at All	A Little	Quite a Bit	Very Much
EQLQ_006	Were you limited in doing either your work or other daily activities?	1	2	3	4
EQLQ_007	Were you limited in pursuing your hobbies or other leisure time activities?	1	2	3	4
EQLQ_008	Were you short of breath?	1	2	3	4
EQLQ_009	Have you had pain?	1	2	3	4
EQLQ_010	Did you need to rest?	1	2	3	4
EQLQ_011	Have you had trouble sleeping?	1	2	3	4
EQLQ_012	Have you felt weak?	1	2	3	4
EQLQ_013	Have you lacked appetite?	1	2	3	4
EQLQ_014	Have you felt nauseated?	1	2	3	4
EQLQ_015	Have you vomited?	1	2	3	4
EQLQ_016	Have you been constipated?	1	2	3	4
EQLQ_017	Have you had diarrhea?	1	2	3	4

Subject Code Number		

Subject Initials		

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

During the past week:		Not at All	A Little	Quite a Bit	Very Much
EQLQ_018	Were you tired?	1	2	3	4
EQLQ_019	Did pain interfere with your daily activities?	1	2	3	4
EQLQ_020	Have you had difficulty in concentrating on things, like reading a newspaper or watching television?	1	2	3	4
EQLQ_021	Did you feel tense?	1	2	3	4
EQLQ_022	Did you worry?	1	2	3	4
EQLQ_023	Did you feel irritable?	1	2	3	4
EQLQ_024	Did you feel depressed?	1	2	3	4
EQLQ_025	Have you had difficulty remembering things?	1	2	3	4
EQLQ_026	Has your physical condition or medical treatment interfered with your family life?	1	2	3	4
EQLQ_027	Has your physical condition or medical treatment interfered with your social activities?	1	2	3	4
EQLQ_028	Has your physical condition or medical treatment caused you financial difficulties?	1	2	3	4

EQLQ_029 How would you rate your overall health during the past week?

1	2	3	4	5	6	7
Very Poor						Excellent

EQLQ_030 How would you rate your overall quality of life during the past week?

1	2	3	4	5	6	7
Very Poor						Excellent

Subject Code Number

Subject Initials

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Dosing Start Date and Time

DAY | MONTH | YEAR | 00:00 - 23:59

Jan 1, Feb 2, Mar 3, Apr 4, May 5, June 6, July 7, Aug 8, Sept 9, Oct 10, Nov 11, Dec 12

DOSE_001 DOSE_002

Dosing Stop Date and Time

DAY | MONTH | YEAR | 00:00 - 23:59

Jan 1, Feb 2, Mar 3, Apr 4, May 5, June 6, July 7, Aug 8, Sept 9, Oct 10, Nov 11, Dec 12

DOSE_003 DOSE_004

Body Surface Area (sq. m)

DOSE_005

Assigned Dose (mg/m^2)

DOSE_006

Dose Reduction

DOSE_007 **Was this dose a reduced dose?**

1. **Yes** ***(complete this section)***
2. **No** ***(skip to DOSE_010)***

DOSE_008 **Primary reason for dose reduction:**

1. **Hematological toxicity**
2. **Grade 3 or 4 neurotoxicity**
3. **Other Grade 3 or 4 toxicity, per investigator's discretion - Specify:**

_____

_____

DOSE_009

Infusion Status

DOSE_010 **Infusion Status**

1. **Infusion complete; no interruption**
2. **Infusion complete with interruption**
3. **Infusion initiated but not completed**

Total Dose Administered (mg)

DOSE_011

Subject Code Number

Subject Initials

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Assessment Date

DAY	MONTH	YEAR
	Jan (1)	
	Feb (2)	
00	Mar (3)	00
11	Apr (4)	11
22	May (5)	22
33	June (6)	33
	July (7)	44
	Aug (8)	55
	Sept (9)	66
	Oct (10)	77
	Nov (11)	88
	Dec (12)	99

TOXY_000

Toxicity	Grade at visit	GRADE 0	1	2	3	4
Nausea TOXY_001	0 1 2 3	None	Able to eat reasonable intake	Intake significantly decreased but can eat	No significant intake	
Vomiting TOXY_002	0 1 2 3 4	None	One episode in 24 hours	2-5 episodes in 24 hours	6-10 episodes in 24 hours	>10 episodes in 24 hours or requiring parenteral support
Diarrhea TOXY_003	0 1 2 3 4	None	Increase of 2-3 stools per day over pre-Rx	Increase of 4-6 stools/day or nocturnal stools, or moderate cramping	Increase of 7-9 stools/day or incontinence, or severe cramping	Increase of 10 or more stools/day or grossly bloody diarrhea, or need for parenteral support
Mucositis / Stomatitis TOXY_004	0 1 2 3 4	None	Painless ulcers, erythema, or mild soreness	Painful erythema, edema, or ulcers but can eat	Painful erythema, edema, or ulcers and cannot eat	Requires parenteral or enteral support
Alopecia TOXY_005	0 1 2	No loss	Mild hair loss	Pronounced or total hair loss		
Infection TOXY_006	0 1 2 3 4	None	Mild	Moderate	Severe	Life threatening

Subject Code Number

Subject Initials

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Visit Date

DAY	MONTH	YEAR
	Jan 1	
	Feb 2	
00	Mar 3	00
11	Apr 4	11
22	May 5	22
33	June 6	33
4	July 7	44
5	Aug 8	55
6	Sept 9	66
7	Oct 10	77
8	Nov 11	88
9	Dec 12	99

VADF_000

Site ID Number

000 111 222 333 444 555 666 777 888 999

Subject Code Number

000 111 222 333 444 555 666 777 888 999

Visit

1. Baseline Visit
2. Week 0 / Cycle 1 Visit
4. Week 3 / Cycle 2 Visit
5. Week 5 Visit
6. Week 6 / Cycle 3 Visit
● Week 9 / Cycle 4 Visit
10. Week 12 / Cycle 5 Visit
12. Week 15 / Cycle 6 / End of Study Visit
14. 30 Day Follow Up Visit
15. Six Month Follow Up Visit
16. Survival Endpoint
99. Unscheduled Visit

Forms to be submitted this visit:

Numbered Pages:

- ☐ Physical Exam (pg 51-52)
- ☐ Subject Assessment of Peripheral Neuropathy (pg 53)
- ☐ Perfromance Score and Peripheral Neuropathy (pg 54)
- ☐ Report of Scans and Lab Submissions (pg 55)
- ☐ EORTC QLQ-C30 Questionnaire (pg 56-57)
- ☐ Echocardiogram / MUGA (pg 58)
- ☐ Response Evaluation (pg 59-60)
- ☐ Dosing Record (pg 61)
- ☐ Toxicity Assessment (pg 62)

Unnumbered Pages (submit as many as necessary):

- ☐ Vital Signs
- ☐ Concurrent Procedures
- ☐ Adverse Experiences
- ☐ Concomitant Medications
- ☐ Lesion Identification Form
- ☐ Non-Target Lesion Evaluation Form
- ☐ Target Lesion Measurement Form

Subject Code Number		

Subject Initials		

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Date of Assessment

DAY		MONTH		YEAR	
		Jan	1		
		Feb	2		
0	0	Mar	3	0	0
1	1	Apr	4	1	1
2	2	May	5	2	2
3	3	June	6	3	3
	4	July	7	4	4
	5	Aug	8	5	5
	6	Sept	9	6	6
	7	Oct	10	7	7
	8	Nov	11	8	8
	9	Dec	12	9	9

PHEX_001

Weight (kg)

			.	
0	0	0		0
1	1	1		1
2	2	2		2
3	3	3		3
4	4	4		4
5	5	5		5
6	6	6		6
7	7	7		7
8	8	8		8
9	9	9		9

PHEX_002

Site	Normal	Abnormal	Not Done	Describe Abnormalities
PHEX_004 **General Appearance**	1	2	3	PHEX_005
PHEX_006 **Head**	1	2	3	PHEX_007
PHEX_008 **Ears**	1	2	3	PHEX_009
PHEX_010 **Eyes**	1	2	3	PHEX_011
PHEX_012 **Nose**	1	2	3	PHEX_013
PHEX_014 **Throat**	1	2	3	PHEX_015
PHEX_016 **Mouth**	1	2	3	PHEX_017
PHEX_018 **Neck**	1	2	3	PHEX_019
PHEX_020 **Thyroid**	1	2	3	PHEX_021

Subject Code Number		

Subject Initials		

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Site	Normal	Abnormal	Not Done	Describe Abnormalities
PHEX_022 **Lungs / Thorax**	1	2	3	PHEX_023
PHEX_024 **Heart**	1	2	3	PHEX_025
PHEX_026 **Breasts**	1	2	3	PHEX_027
PHEX_028 **Liver**	1	2	3	PHEX_029
PHEX_030 **Abdomen**	1	2	3	PHEX_031
PHEX_032 **Musculoskeletal**	1	2	3	PHEX_033
PHEX_034 **Extremities**	1	2	3	PHEX_035
PHEX_036 **Pulses**	1	2	3	PHEX_037
PHEX_038 **Lymph Nodes**	1	2	3	PHEX_039
PHEX_040 **Skin**	1	2	3	PHEX_041
PHEX_042 **Neurological**	1	2	3	PHEX_043
PHEX_044 **Genitourinary (including pelvic)**	1	2	3	PHEX_045
PHEX_046 **Rectal**	1	2	3	PHEX_047

Subject Code Number

Subject Initials

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Evaluation Date					
DAY		MONTH		YEAR	
		Jan	1		
		Feb	2		
0	0	Mar	3	0	0
1	1	Apr	4	1	1
2	2	May	5	2	2
3	3	June	6	3	3
	4	July	7	4	4
	5	Aug	8	5	5
	6	Sept	9	6	6
	7	Oct	10	7	7
	8	Nov	11	8	8
	9	Dec	12	9	9

FACT_000

FACT-Taxane (Version 4); "Additional Concerns"

FACT_017 (1) **Bubble here if this questionnaire was not completed.**

Indicate how true each statement has been for the subject <u>during the past 7 days</u>.		Not at all	A little bit	Some-what	Quite a bit	Very much
FACT_001	I have numbness or tingling in my hands.	0	1	2	3	4
FACT_002	I have numbness or tingling in my feet.	0	1	2	3	4
FACT_003	I feel discomfort in my hands.	0	1	2	3	4
FACT_004	I feel discomfort in my feet.	0	1	2	3	4
FACT_005	I have joint pain or muscle cramps.	0	1	2	3	4
FACT_006	I feel weak all over.	0	1	2	3	4
FACT_007	I have trouble hearing.	0	1	2	3	4
FACT_008	I get a ringing or buzzing in my ears.	0	1	2	3	4
FACT_009	I have trouble buttoning buttons.	0	1	2	3	4
FACT_010	I have trouble feeling the shape of small objects when they are in my hand.	0	1	2	3	4
FACT_011	I have trouble walking.	0	1	2	3	4
FACT_012	I feel bloated.	0	1	2	3	4
FACT_013	My hands are swollen.	0	1	2	3	4
FACT_014	My legs or feet are swollen.	0	1	2	3	4
FACT_015	I have pain in my fingertips.	0	1	2	3	4
FACT_016	I am bothered by the way my hands or nails look.	0	1	2	3	4

Subject Code Number		

Subject Initials		

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Evaluation Date

DAY		MONTH		YEAR	
		Jan	1		
		Feb	2		
0	0	Mar	3	0	0
1	1	Apr	4	1	1
2	2	May	5	2	2
3	3	June	6	3	3
	4	July	7	4	4
	5	Aug	8	5	5
	6	Sept	9	6	6
	7	Oct	10	7	7
	8	Nov	11	8	8
	9	Dec	12	9	9

PSPN_000

Current ECOG Performance Score	PSPN_001
Fully active, able to carry on all pre-disease performance without restriction.	0
Restricted in physically strenuous activity, but ambulatory and able to carry out work of a light or sedentary nature, e.g., light housework, office work.	1
Ambulatory and capable of all self-care, but unable to carry out any work activities. Up and about more than 50% of waking hours.	2
Capable of only limited self-care, confined to bed or chair more than 50% of waking hours.	3
Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair.	4

Physician Assessment of Peripheral Neuropathy	PSPN_002
Normal	0
Loss of deep tendon reflexes or paresthesia (including tingling) but not interfering with function	1
Objective sensory loss or paresthesia (including tingling) interfering with function, but not interfering with activities of daily living	2
Sensory loss or paresthesia interfering with activities of daily living	3
Permanent sensory loss that interferes with function	4

Subject Code Number		

Subject Initials		

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Scan Type		Scan Performed Yes	Scan Performed No	Bubble if Abnormalities found		Lesions Detected Yes	Lesions Detected No
SCAN_001	**Head CT**	1	2	SCAN_002	1	SCAN_003	1	2
SCAN_004	**Chest CT**	1	2	SCAN_005	1	SCAN_006	1	2
SCAN_007	**Abdomen CT**	1	2	SCAN_008	1	SCAN_009	1	2
SCAN_010	**Bone Scan**	1	2	SCAN_011	1	SCAN_012	1	2
SCAN_013	**Plain Radiographs**	1	2	SCAN_014	1	SCAN_015	1	2
SCAN_016	**Other (specify:)** _____ SCAN_017	1	2	SCAN_018	1	SCAN_019	1	2

Laboratory Tests		Performed Yes	Performed No	Bubble if sent to central lab	
SCAN_020	**CBC, Differential Platelet Count**	1	2	SCAN_021	1
SCAN_022	**Clinical Chemistry Panel**	1	2	SCAN_023	1

Subject Code Number

Subject Initials

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

DAY		MONTH		YEAR	
		Jan	1		
		Feb	2		
0	0	Mar	3	0	0
1	1	Apr	4	1	1
2	2	May	5	2	2
3	3	June	6	3	3
	4	July	7	4	4
	5	Aug	8	5	5
	6	Sept	9	6	6
	7	Oct	10	7	7
	8	Nov	11	8	8
	9	Dec	12	9	9

EQLQ_000

EQLQ_031 (1) **Bubble here if this questionnaire was not completed.**

		Not at All	A Little	Quite a Bit	Very Much
EQLQ_001	Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?	(1)	(2)	(3)	(4)
EQLQ_002	Do you have any trouble taking a long walk?	(1)	(2)	(3)	(4)
EQLQ_003	Do you have any trouble taking a short walk outside the house?	(1)	(2)	(3)	(4)
EQLQ_004	Do you need to stay in a bed or a chair during the day?	(1)	(2)	(3)	(4)
EQLQ_005	Do you need help with eating, dressing, washing yourself or using the toilet?	(1)	(2)	(3)	(4)

During the past week:		Not at All	A Little	Quite a Bit	Very Much
EQLQ_006	Were you limited in doing either your work or other daily activities?	(1)	(2)	(3)	(4)
EQLQ_007	Were you limited in pursuing your hobbies or other leisure time activities?	(1)	(2)	(3)	(4)
EQLQ_008	Were you short of breath?	(1)	(2)	(3)	(4)
EQLQ_009	Have you had pain?	(1)	(2)	(3)	(4)
EQLQ_010	Did you need to rest?	(1)	(2)	(3)	(4)
EQLQ_011	Have you had trouble sleeping?	(1)	(2)	(3)	(4)
EQLQ_012	Have you felt weak?	(1)	(2)	(3)	(4)
EQLQ_013	Have you lacked appetite?	(1)	(2)	(3)	(4)
EQLQ_014	Have you felt nauseated?	(1)	(2)	(3)	(4)
EQLQ_015	Have you vomited?	(1)	(2)	(3)	(4)
EQLQ_016	Have you been constipated?	(1)	(2)	(3)	(4)
EQLQ_017	Have you had diarrhea?	(1)	(2)	(3)	(4)

Subject Code Number		

Subject Initials		

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

During the past week:		Not at All	A Little	Quite a Bit	Very Much
EQLQ_018	Were you tired?	1	2	3	4
EQLQ_019	Did pain interfere with your daily activities?	1	2	3	4
EQLQ_020	Have you had difficulty in concentrating on things, like reading a newspaper or watching television?	1	2	3	4
EQLQ_021	Did you feel tense?	1	2	3	4
EQLQ_022	Did you worry?	1	2	3	4
EQLQ_023	Did you feel irritable?	1	2	3	4
EQLQ_024	Did you feel depressed?	1	2	3	4
EQLQ_025	Have you had difficulty remembering things?	1	2	3	4
EQLQ_026	Has your physical condition or medical treatment interfered with your family life?	1	2	3	4
EQLQ_027	Has your physical condition or medical treatment interfered with your social activities?	1	2	3	4
EQLQ_028	Has your physical condition or medical treatment caused you financial difficulties?	1	2	3	4

EQLQ_029 How would you rate your overall health during the past week?

1	2	3	4	5	6	7
Very Poor						Excellent

EQLQ_030 How would you rate your overall quality of life during the past week?

1	2	3	4	5	6	7
Very Poor						Excellent

Subject Code Number

Subject Initials

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

ECHO Performed

① Yes
② No

ECHO_001

Date Performed

DAY	MONTH	YEAR
	Jan ①	
	Feb ②	
00	Mar ③	00
11	Apr ④	11
22	May ⑤	22
33	June ⑥	33
	July ⑦	44
	Aug ⑧	55
	Sept ⑨	66
	Oct ⑩	77
	Nov ⑪	88
	Dec ⑫	99

ECHO_002

LVEF

① Normal
② Abnormal

ECHO_003

%

00 11 22 33 44 55 66 77 88 99

ECHO_004

Wall Motion

① Normal
② Abnormal

ECHO_005

Valvular Function

① Normal
② Abnormal

ECHO_006

Evidence of Hypertrophy

① Yes
② No

ECHO_007

MUGA Performed

① Yes
② No

MUGA_001

Date Performed

DAY	MONTH	YEAR
	Jan ①	
	Feb ②	
00	Mar ③	00
11	Apr ④	11
22	May ⑤	22
33	June ⑥	33
	July ⑦	44
	Aug ⑧	55
	Sept ⑨	66
	Oct ⑩	77
	Nov ⑪	88
	Dec ⑫	99

MUGA_002

LVEF

① Normal
② Abnormal

MUGA_003

%

00 11 22 33 44 55 66 77 88 99

MUGA_004

Subject Code Number

Subject Initials

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Use the RECIST criteria to evaluate response.

Assessment Date

DAY	MONTH	YEAR
	Jan 1	
	Feb 2	
00	Mar 3	00
11	Apr 4	11
22	May 5	22
33	June 6	33
4	July 7	44
5	Aug 8	55
6	Sept 9	66
7	Oct 10	77
8	Nov 11	88
9	Dec 12	99

RESP_000

Target Lesions

Number of Lesions: 00 11 22 33 44 55 66 77 88 99

RESP_001

Sum of Longest Diameters (mm): 000.0 111.1 222.2 333.3 444.4 555.5 666.6 777.7 888.8 999.9

RESP_002

Non-Target Lesions

Number of Lesions: 00 11 22 33 44 55 66 77 88 99

RESP_003

Target Response Criteria	Definition
RESP_004	
① Complete Response	Disappearance of all target lesions.
② Partial Response	At least a 30% decrease in the sum of the longest diameters of target lesions, taking as a reference the baseline sum of the longest diameters.
③ Stable Disease	Neither sufficient shrinkage to qualify for partial response nor sufficient increase to qualify for progressive disease, taking as a reference the smallest sum of the longest diameters achieved since the treatment started.
④ Progressive Disease	At least a 20% increase in the sum of the longest diameters of target lesions, taking as reference the smallest sum longest diameter recorded since treatment began or the appearance of one or more lesions.
⑤ Not Able to Evaluate	*Explain:*

RESP_005

Subject Code Number	

Subject Initials	

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Non-Target Response Criteria	Definition
RESP_006 ① Complete Response	Disappearance of all non-target lesions.
② Incomplete Response / Stable Disease	Persistence of one or more non-target lesion(s).
③ Progressive Disease	The appearance of one or more non-target lesions and/or unequivocal progression of existing non-target lesions.
③ Not Applicable	No non-target lesions have ever existed for this subject.

Overall Response

Use the grid below to determine the overall response. Choose the row with the correct responses for target lesion response and non-target lesion response, then bubble in the appropriate overall response.

Target Response	Non-Target Response	RESP_007 Overall Response
Complete Response	Complete Response	① Complete Response
Complete Response	Incomplete / SD	② Partial Response
Partial Response	Non-PD	③ Partial Response
Stable Disease	Non-PD	④ Stable Disease
Progressive Disease	Any	⑤ Progressive Disease
Any	Progressive Disease	⑥ Progressive Disease
		⑦ Not Evaluated

Subject Code Number

Subject Initials

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Dosing Start Date and Time

DAY | MONTH | YEAR | 00:00 - 23:59

Jan 1, Feb 2, Mar 3, Apr 4, May 5, June 6, July 7, Aug 8, Sept 9, Oct 10, Nov 11, Dec 12

DOSE_001 DOSE_002

Dosing Stop Date and Time

DAY | MONTH | YEAR | 00:00 - 23:59

Jan 1, Feb 2, Mar 3, Apr 4, May 5, June 6, July 7, Aug 8, Sept 9, Oct 10, Nov 11, Dec 12

DOSE_003 DOSE_004

Body Surface Area (sq. m)

DOSE_005

Assigned Dose (mg/m^2)

DOSE_006

Dose Reduction

DOSE_007 **Was this dose a reduced dose?**

1. **Yes** ***(complete this section)***
2. **No** ***(skip to DOSE_010)***

DOSE_008 **Primary reason for dose reduction:**

1. **Hematological toxicity**
2. **Grade 3 or 4 neurotoxicity**
3. **Other Grade 3 or 4 toxicity, per investigator's discretion - Specify:**

_____

_____

DOSE_009

Infusion Status

DOSE_010 **Infusion Status**

1. **Infusion complete; no interruption**
2. **Infusion complete with interruption**
3. **Infusion initiated but not completed**

Total Dose Administered (mg)

DOSE_011

Subject Code Number

Subject Initials

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Assessment Date

DAY	MONTH	YEAR
	Jan (1)	
	Feb (2)	
00	Mar (3)	00
11	Apr (4)	11
22	May (5)	22
33	June (6)	33
4	July (7)	44
5	Aug (8)	55
6	Sept (9)	66
7	Oct (10)	77
8	Nov (11)	88
9	Dec (12)	99

TOXY_000

Toxicity	Grade at visit	GRADE 0	1	2	3	4
Nausea TOXY_001	0 1 2 3	None	Able to eat reasonable intake	Intake significantly decreased but can eat	No significant intake	
Vomiting TOXY_002	0 1 2 3 4	None	One episode in 24 hours	2-5 episodes in 24 hours	6-10 episodes in 24 hours	>10 episodes in 24 hours or requiring parenteral support
Diarrhea TOXY_003	0 1 2 3 4	None	Increase of 2-3 stools per day over pre-Rx	Increase of 4-6 stools/day or nocturnal stools, or moderate cramping	Increase of 7-9 stools/day or incontinence, or severe cramping	Increase of 10 or more stools/day or grossly bloody diarrhea, or need for parenteral support
Mucositis / Stomatitis TOXY_004	0 1 2 3 4	None	Painless ulcers, erythema, or mild soreness	Painful erythema, edema, or ulcers but can eat	Painful erythema, edema, or ulcers and cannot eat	Requires parenteral or enteral support
Alopecia TOXY_005	0 1 2	No loss	Mild hair loss	Pronounced or total hair loss		
Infection TOXY_006	0 1 2 3 4	None	Mild	Moderate	Severe	Life threatening

Visit Administration Form (VADF)

Subject Code Number

Subject Initials

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Visit Date

DAY	MONTH	YEAR
	Jan 1	
	Feb 2	
00	Mar 3	00
11	Apr 4	11
22	May 5	22
33	June 6	33
4	July 7	44
5	Aug 8	55
6	Sept 9	66
7	Oct 10	77
8	Nov 11	88
9	Dec 12	99

VADF_000

Site ID Number

Subject Code Number

Visit

1. Baseline Visit
2. Week 0 / Cycle 1 Visit
4. Week 3 / Cycle 2 Visit
5. Week 5 Visit
6. Week 6 / Cycle 3 Visit
8. Week 9 / Cycle 4 Visit
● Week 12 / Cycle 5 Visit
12. Week 15 / Cycle 6 / End of Study Visit
14. 30 Day Follow Up Visit
15. Six Month Follow Up Visit
16. Survival Endpoint
99. Unscheduled Visit

Forms to be submitted this visit:

Numbered Pages:

- ☐ Physical Exam (pg 64-65)
- ☐ Subject Assessment of Peripheral Neuropathy (pg 66)
- ☐ Perfromance Score and Peripheral Neuropathy (pg 67)
- ☐ Report of Scans and Lab Submissions (pg 68)
- ☐ Dosing Record (pg 69)
- ☐ Toxicity Assessment (pg 70)

Unnumbered Pages (submit as many as necessary):

- ☐ Vital Signs
- ☐ Concurrent Procedures
- ☐ Adverse Experiences
- ☐ Concomitant Medications
- ☐ Lesion Identification Form
- ☐ Non-Target Lesion Evaluation Form
- ☐ Target Lesion Measurement Form

Subject Code Number

Subject Initials

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Date of Assessment

DAY	MONTH	YEAR
	1 Jan	
	2 Feb	
0 0	3 Mar	0 0
1 1	4 Apr	1 1
2 2	5 May	2 2
3 3	6 June	3 3
4	7 July	4 4
5	8 Aug	5 5
6	9 Sept	6 6
7	10 Oct	7 7
8	11 Nov	8 8
9	12 Dec	9 9

PHEX_001

Weight (kg)

0 0 0 . 0
1 1 1 1
2 2 2 2
3 3 3 3
4 4 4 4
5 5 5 5
6 6 6 6
7 7 7 7
8 8 8 8
9 9 9 9

PHEX_002

Site	Normal	Abnormal	Not Done	Describe Abnormalities
PHEX_004 **General Appearance**	1	2	3	PHEX_005
PHEX_006 **Head**	1	2	3	PHEX_007
PHEX_008 **Ears**	1	2	3	PHEX_009
PHEX_010 **Eyes**	1	2	3	PHEX_011
PHEX_012 **Nose**	1	2	3	PHEX_013
PHEX_014 **Throat**	1	2	3	PHEX_015
PHEX_016 **Mouth**	1	2	3	PHEX_017
PHEX_018 **Neck**	1	2	3	PHEX_019
PHEX_020 **Thyroid**	1	2	3	PHEX_021

Subject Code Number

Subject Initials

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Site	Normal	Abnormal	Not Done	Describe Abnormalities
PHEX_022 **Lungs / Thorax**	1	2	3	PHEX_023
PHEX_024 **Heart**	1	2	3	PHEX_025
PHEX_026 **Breasts**	1	2	3	PHEX_027
PHEX_028 **Liver**	1	2	3	PHEX_029
PHEX_030 **Abdomen**	1	2	3	PHEX_031
PHEX_032 **Musculoskeletal**	1	2	3	PHEX_033
PHEX_034 **Extremities**	1	2	3	PHEX_035
PHEX_036 **Pulses**	1	2	3	PHEX_037
PHEX_038 **Lymph Nodes**	1	2	3	PHEX_039
PHEX_040 **Skin**	1	2	3	PHEX_041
PHEX_042 **Neurological**	1	2	3	PHEX_043
PHEX_044 **Genitourinary (including pelvic)**	1	2	3	PHEX_045
PHEX_046 **Rectal**	1	2	3	PHEX_047

Subject Assessment of Peripheral Neuropathy (FACT)

Subject Code Number		

Subject Initials		

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Evaluation Date					
DAY		MONTH		YEAR	
		Jan	1		
		Feb	2		
0	0	Mar	3	0	0
1	1	Apr	4	1	1
2	2	May	5	2	2
3	3	June	6	3	3
	4	July	7	4	4
	5	Aug	8	5	5
	6	Sept	9	6	6
	7	Oct	10	7	7
	8	Nov	11	8	8
	9	Dec	12	9	9

FACT_000

FACT-Taxane (Version 4); "Additional Concerns"

FACT_017 (1) **Bubble here if this questionnaire was not completed.**

Indicate how true each statement has been for the subject <u>during the past 7 days</u>.		Not at all	A little bit	Some-what	Quite a bit	Very much
FACT_001	I have numbness or tingling in my hands.	0	1	2	3	4
FACT_002	I have numbness or tingling in my feet.	0	1	2	3	4
FACT_003	I feel discomfort in my hands.	0	1	2	3	4
FACT_004	I feel discomfort in my feet.	0	1	2	3	4
FACT_005	I have joint pain or muscle cramps.	0	1	2	3	4
FACT_006	I feel weak all over.	0	1	2	3	4
FACT_007	I have trouble hearing.	0	1	2	3	4
FACT_008	I get a ringing or buzzing in my ears.	0	1	2	3	4
FACT_009	I have trouble buttoning buttons.	0	1	2	3	4
FACT_010	I have trouble feeling the shape of small objects when they are in my hand.	0	1	2	3	4
FACT_011	I have trouble walking.	0	1	2	3	4
FACT_012	I feel bloated.	0	1	2	3	4
FACT_013	My hands are swollen.	0	1	2	3	4
FACT_014	My legs or feet are swollen.	0	1	2	3	4
FACT_015	I have pain in my fingertips.	0	1	2	3	4
FACT_016	I am bothered by the way my hands or nails look.	0	1	2	3	4

Subject Code Number		

Subject Initials		

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Evaluation Date

DAY		MONTH		YEAR	
		Jan	1		
		Feb	2		
0	0	Mar	3	0	0
1	1	Apr	4	1	1
2	2	May	5	2	2
3	3	June	6	3	3
	4	July	7	4	4
	5	Aug	8	5	5
	6	Sept	9	6	6
	7	Oct	10	7	7
	8	Nov	11	8	8
	9	Dec	12	9	9

PSPN_000

Current ECOG Performance Score	PSPN_001
Fully active, able to carry on all pre-disease performance without restriction.	0
Restricted in physically strenuous activity, but ambulatory and able to carry out work of a light or sedentary nature, e.g., light housework, office work.	1
Ambulatory and capable of all self-care, but unable to carry out any work activities. Up and about more than 50% of waking hours.	2
Capable of only limited self-care, confined to bed or chair more than 50% of waking hours.	3
Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair.	4

Physician Assessment of Peripheral Neuropathy	PSPN_002
Normal	0
Loss of deep tendon reflexes or paresthesia (including tingling) but not interfering with function	1
Objective sensory loss or paresthesia (including tingling) interfering with function, but not interfering with activities of daily living	2
Sensory loss or paresthesia interfering with activities of daily living	3
Permanent sensory loss that interferes with function	4

Subject Code Number		

Subject Initials		

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Scan Type		Scan Performed Yes	Scan Performed No	Bubble if Abnormalities found		Lesions Detected Yes	Lesions Detected No
SCAN_001	**Head CT**	1	2	SCAN_002	1	SCAN_003 1	2
SCAN_004	**Chest CT**	1	2	SCAN_005	1	SCAN_006 1	2
SCAN_007	**Abdomen CT**	1	2	SCAN_008	1	SCAN_009 1	2
SCAN_010	**Bone Scan**	1	2	SCAN_011	1	SCAN_012 1	2
SCAN_013	**Plain Radiographs**	1	2	SCAN_014	1	SCAN_015 1	2
SCAN_016	**Other (specify:)** _____ SCAN_017	1	2	SCAN_018	1	SCAN_019 1	2

Laboratory Tests		Performed Yes	Performed No	Bubble if sent to central lab	
SCAN_020	**CBC, Differential Platelet Count**	1	2	SCAN_021	1
SCAN_022	**Clinical Chemistry Panel**	1	2	SCAN_023	1

Subject Code Number

Subject Initials

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Dosing Start Date and Time

DAY | MONTH | YEAR | 00:00 - 23:59

Jan 1, Feb 2, Mar 3, Apr 4, May 5, June 6, July 7, Aug 8, Sept 9, Oct 10, Nov 11, Dec 12

DOSE_001 DOSE_002

Dosing Stop Date and Time

DAY | MONTH | YEAR | 00:00 - 23:59

Jan 1, Feb 2, Mar 3, Apr 4, May 5, June 6, July 7, Aug 8, Sept 9, Oct 10, Nov 11, Dec 12

DOSE_003 DOSE_004

Body Surface Area (sq. m)

DOSE_005

Assigned Dose (mg/m^2)

DOSE_006

Dose Reduction

DOSE_007 **Was this dose a reduced dose?**

1. **Yes** ***(complete this section)***
2. **No** ***(skip to DOSE_010)***

DOSE_008 **Primary reason for dose reduction:**

1. **Hematological toxicity**
2. **Grade 3 or 4 neurotoxicity**
3. **Other Grade 3 or 4 toxicity, per investigator's discretion - Specify:**

_____

_____

DOSE_009

Infusion Status

DOSE_010 **Infusion Status**

1. **Infusion complete; no interruption**
2. **Infusion complete with interruption**
3. **Infusion initiated but not completed**

Total Dose Administered (mg)

DOSE_011

Subject Code Number

Subject Initials

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Assessment Date

DAY	MONTH	YEAR
	Jan 1	
	Feb 2	
00	Mar 3	00
11	Apr 4	11
22	May 5	22
33	June 6	33
4	July 7	44
5	Aug 8	55
6	Sept 9	66
7	Oct 10	77
8	Nov 11	88
9	Dec 12	99

TOXY_000

Toxicity	Grade at visit	GRADE 0	1	2	3	4
Nausea TOXY_001	0 1 2 3	None	Able to eat reasonable intake	Intake significantly decreased but can eat	No significant intake	
Vomiting TOXY_002	0 1 2 3 4	None	One episode in 24 hours	2-5 episodes in 24 hours	6-10 episodes in 24 hours	>10 episodes in 24 hours or requiring parenteral support
Diarrhea TOXY_003	0 1 2 3 4	None	Increase of 2-3 stools per day over pre-Rx	Increase of 4-6 stools/day or nocturnal stools, or moderate cramping	Increase of 7-9 stools/day or incontinence, or severe cramping	Increase of 10 or more stools/day or grossly bloody diarrhea, or need for parenteral support
Mucositis / Stomatitis TOXY_004	0 1 2 3 4	None	Painless ulcers, erythema, or mild soreness	Painful erythema, edema, or ulcers but can eat	Painful erythema, edema, or ulcers and cannot eat	Requires parenteral or enteral support
Alopecia TOXY_005	0 1 2	No loss	Mild hair loss	Pronounced or total hair loss		
Infection TOXY_006	0 1 2 3 4	None	Mild	Moderate	Severe	Life threatening

Subject Code Number

Subject Initials

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Visit Date

DAY	MONTH	YEAR
	Jan 1	
	Feb 2	
00	Mar 3	00
11	Apr 4	11
22	May 5	22
33	June 6	33
4	July 7	44
5	Aug 8	55
6	Sept 9	66
7	Oct 10	77
8	Nov 11	88
9	Dec 12	99

VADF_000

Site ID Number

000
111
222
333
444
555
666
777
888
999

Subject Code Number

000
111
222
333
444
555
666
777
888
999

Visit

1. Baseline Visit
2. Week 0 / Cycle 1 Visit
4. Week 3 / Cycle 2 Visit
5. Week 5 Visit
6. Week 6 / Cycle 3 Visit
8. Week 9 / Cycle 4 Visit
10. Week 12 / Cycle 5 Visit
● Week 15 / Cycle 6 / End of Study Visit
14. 30 Day Follow Up Visit
15. Six Month Follow Up Visit
16. Survival Endpoint
99. Unscheduled Visit

Forms to be submitted this visit:

Numbered Pages:

- ☐ Physical Exam (pg 72-73)
- ☐ Subject Assessment of Peripheral Neuropathy (pg 74)
- ☐ Performance Score and Peripheral Neuropathy (pg 75)
- ☐ Report of Scans and Lab Submissions (pg 76)
- ☐ EORTC QLQ-C30 Questionnaire (pg 77-78)
- ☐ Echocardiogram / MUGA (pg 79)
- ☐ EKG (pg 79a)
- ☐ Response Evaluation (pg 80-81)
- ☐ Dosing Record (pg 82)
- ☐ Toxicity Assessment (pg 83)
- ☐ End of Study Report (pg 84)

Unnumbered Pages (submit as many as necessary):

- ☐ Vital Signs
- ☐ Concurrent Procedures
- ☐ Adverse Experiences
- ☐ Concomitant Medications
- ☐ Lesion Identification Form
- ☐ Non-Target Lesion Evaluation Form
- ☐ Target Lesion Measurement Form

Physical Examination (PHEX)

Subject Code Number		

Subject Initials		

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Date of Assessment

DAY		MONTH		YEAR	
		Jan	1		
		Feb	2		
0	0	Mar	3	0	0
1	1	Apr	4	1	1
2	2	May	5	2	2
3	3	June	6	3	3
	4	July	7	4	4
	5	Aug	8	5	5
	6	Sept	9	6	6
	7	Oct	10	7	7
	8	Nov	11	8	8
	9	Dec	12	9	9

PHEX_001

Weight (kg)

			.	
0	0	0		0
1	1	1		1
2	2	2		2
3	3	3		3
4	4	4		4
5	5	5		5
6	6	6		6
7	7	7		7
8	8	8		8
9	9	9		9

PHEX_002

Site	Normal	Abnormal	Not Done	Describe Abnormalities
PHEX_004 **General Appearance**	1	2	3	PHEX_005
PHEX_006 **Head**	1	2	3	PHEX_007
PHEX_008 **Ears**	1	2	3	PHEX_009
PHEX_010 **Eyes**	1	2	3	PHEX_011
PHEX_012 **Nose**	1	2	3	PHEX_013
PHEX_014 **Throat**	1	2	3	PHEX_015
PHEX_016 **Mouth**	1	2	3	PHEX_017
PHEX_018 **Neck**	1	2	3	PHEX_019
PHEX_020 **Thyroid**	1	2	3	PHEX_021

Subject Code Number		

Subject Initials		

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Site	Normal	Abnormal	Not Done	Describe Abnormalities
PHEX_022 **Lungs / Thorax**	1	2	3	PHEX_023
PHEX_024 **Heart**	1	2	3	PHEX_025
PHEX_026 **Breasts**	1	2	3	PHEX_027
PHEX_028 **Liver**	1	2	3	PHEX_029
PHEX_030 **Abdomen**	1	2	3	PHEX_031
PHEX_032 **Musculoskeletal**	1	2	3	PHEX_033
PHEX_034 **Extremities**	1	2	3	PHEX_035
PHEX_036 **Pulses**	1	2	3	PHEX_037
PHEX_038 **Lymph Nodes**	1	2	3	PHEX_039
PHEX_040 **Skin**	1	2	3	PHEX_041
PHEX_042 **Neurological**	1	2	3	PHEX_043
PHEX_044 **Genitourinary (including pelvic)**	1	2	3	PHEX_045
PHEX_046 **Rectal**	1	2	3	PHEX_047

Subject Assessment of Peripheral Neuropathy (FACT)

Subject Code Number		

Subject Initials		

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Evaluation Date					
DAY		MONTH		YEAR	
		Jan	1		
		Feb	2		
0	0	Mar	3	0	0
1	1	Apr	4	1	1
2	2	May	5	2	2
3	3	June	6	3	3
	4	July	7	4	4
	5	Aug	8	5	5
	6	Sept	9	6	6
	7	Oct	10	7	7
	8	Nov	11	8	8
	9	Dec	12	9	9

FACT_000

FACT-Taxane (Version 4); "Additional Concerns"

FACT_017 (1) **Bubble here if this questionnaire was not completed.**

Indicate how true each statement has been for the subject <u>during the past 7 days</u>.		Not at all	A little bit	Some-what	Quite a bit	Very much
FACT_001	I have numbness or tingling in my hands.	0	1	2	3	4
FACT_002	I have numbness or tingling in my feet.	0	1	2	3	4
FACT_003	I feel discomfort in my hands.	0	1	2	3	4
FACT_004	I feel discomfort in my feet.	0	1	2	3	4
FACT_005	I have joint pain or muscle cramps.	0	1	2	3	4
FACT_006	I feel weak all over.	0	1	2	3	4
FACT_007	I have trouble hearing.	0	1	2	3	4
FACT_008	I get a ringing or buzzing in my ears.	0	1	2	3	4
FACT_009	I have trouble buttoning buttons.	0	1	2	3	4
FACT_010	I have trouble feeling the shape of small objects when they are in my hand.	0	1	2	3	4
FACT_011	I have trouble walking.	0	1	2	3	4
FACT_012	I feel bloated.	0	1	2	3	4
FACT_013	My hands are swollen.	0	1	2	3	4
FACT_014	My legs or feet are swollen.	0	1	2	3	4
FACT_015	I have pain in my fingertips.	0	1	2	3	4
FACT_016	I am bothered by the way my hands or nails look.	0	1	2	3	4

Subject Code Number		

Subject Initials		

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Evaluation Date

DAY		MONTH		YEAR	
		Jan	1		
		Feb	2		
0	0	Mar	3	0	0
1	1	Apr	4	1	1
2	2	May	5	2	2
3	3	June	6	3	3
	4	July	7	4	4
	5	Aug	8	5	5
	6	Sept	9	6	6
	7	Oct	10	7	7
	8	Nov	11	8	8
	9	Dec	12	9	9

PSPN_000

Current ECOG Performance Score	PSPN_001
Fully active, able to carry on all pre-disease performance without restriction.	0
Restricted in physically strenuous activity, but ambulatory and able to carry out work of a light or sedentary nature, e.g., light housework, office work.	1
Ambulatory and capable of all self-care, but unable to carry out any work activities. Up and about more than 50% of waking hours.	2
Capable of only limited self-care, confined to bed or chair more than 50% of waking hours.	3
Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair.	4

Physician Assessment of Peripheral Neuropathy	PSPN_002
Normal	0
Loss of deep tendon reflexes or paresthesia (including tingling) but not interfering with function	1
Objective sensory loss or paresthesia (including tingling) interfering with function, but not interfering with activities of daily living	2
Sensory loss or paresthesia interfering with activities of daily living	3
Permanent sensory loss that interferes with function	4

Subject Code Number		

Subject Initials		

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Scan Type		Scan Performed Yes	Scan Performed No	Bubble if Abnormalities found		Lesions Detected Yes	Lesions Detected No
SCAN_001	**Head CT**	1	2	SCAN_002	1	SCAN_003	1	2
SCAN_004	**Chest CT**	1	2	SCAN_005	1	SCAN_006	1	2
SCAN_007	**Abdomen CT**	1	2	SCAN_008	1	SCAN_009	1	2
SCAN_010	**Bone Scan**	1	2	SCAN_011	1	SCAN_012	1	2
SCAN_013	**Plain Radiographs**	1	2	SCAN_014	1	SCAN_015	1	2
SCAN_016	**Other (specify:)** _____ SCAN_017	1	2	SCAN_018	1	SCAN_019	1	2

Laboratory Tests		Performed Yes	Performed No	Bubble if sent to central lab	
SCAN_020	**CBC, Differential Platelet Count**	1	2	SCAN_021	1
SCAN_022	**Clinical Chemistry Panel**	1	2	SCAN_023	1

Subject Code Number

Subject Initials

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

DAY	MONTH	YEAR
	Jan 1	
	Feb 2	
0 0	Mar 3	0 0
1 1	Apr 4	1 1
2 2	May 5	2 2
3 3	June 6	3 3
4	July 7	4 4
5	Aug 8	5 5
6	Sept 9	6 6
7	Oct 10	7 7
8	Nov 11	8 8
9	Dec 12	9 9

EQLQ_000

EQLQ_031 (1) **Bubble here if this questionnaire was not completed.**

		Not at All	A Little	Quite a Bit	Very Much
EQLQ_001	Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?	1	2	3	4
EQLQ_002	Do you have any trouble taking a long walk?	1	2	3	4
EQLQ_003	Do you have any trouble taking a short walk outside the house?	1	2	3	4
EQLQ_004	Do you need to stay in a bed or a chair during the day?	1	2	3	4
EQLQ_005	Do you need help with eating, dressing, washing yourself or using the toilet?	1	2	3	4

During the past week:		Not at All	A Little	Quite a Bit	Very Much
EQLQ_006	Were you limited in doing either your work or other daily activities?	1	2	3	4
EQLQ_007	Were you limited in pursuing your hobbies or other leisure time activities?	1	2	3	4
EQLQ_008	Were you short of breath?	1	2	3	4
EQLQ_009	Have you had pain?	1	2	3	4
EQLQ_010	Did you need to rest?	1	2	3	4
EQLQ_011	Have you had trouble sleeping?	1	2	3	4
EQLQ_012	Have you felt weak?	1	2	3	4
EQLQ_013	Have you lacked appetite?	1	2	3	4
EQLQ_014	Have you felt nauseated?	1	2	3	4
EQLQ_015	Have you vomited?	1	2	3	4
EQLQ_016	Have you been constipated?	1	2	3	4
EQLQ_017	Have you had diarrhea?	1	2	3	4

Subject Code Number		

Subject Initials		

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

During the past week:		Not at All	A Little	Quite a Bit	Very Much
EQLQ_018	Were you tired?	1	2	3	4
EQLQ_019	Did pain interfere with your daily activities?	1	2	3	4
EQLQ_020	Have you had difficulty in concentrating on things, like reading a newspaper or watching television?	1	2	3	4
EQLQ_021	Did you feel tense?	1	2	3	4
EQLQ_022	Did you worry?	1	2	3	4
EQLQ_023	Did you feel irritable?	1	2	3	4
EQLQ_024	Did you feel depressed?	1	2	3	4
EQLQ_025	Have you had difficulty remembering things?	1	2	3	4
EQLQ_026	Has your physical condition or medical treatment interfered with your family life?	1	2	3	4
EQLQ_027	Has your physical condition or medical treatment interfered with your social activities?	1	2	3	4
EQLQ_028	Has your physical condition or medical treatment caused you financial difficulties?	1	2	3	4

EQLQ_029 How would you rate your overall health during the past week?

1	2	3	4	5	6	7
Very Poor						Excellent

EQLQ_030 How would you rate your overall quality of life during the past week?

1	2	3	4	5	6	7
Very Poor						Excellent

Subject Code Number

Subject Initials

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

ECHO Performed

① Yes
② No

ECHO_001

Date Performed

DAY	MONTH	YEAR
	Jan 1	
	Feb 2	
00	Mar 3	00
11	Apr 4	11
22	May 5	22
33	June 6	33
	July 7	44
	Aug 8	55
	Sept 9	66
	Oct 10	77
	Nov 11	88
	Dec 12	99

ECHO_002

LVEF

① Normal
② Abnormal

ECHO_003

%

00 11 22 33 44 55 66 77 88 99

ECHO_004

Wall Motion

① Normal
② Abnormal

ECHO_005

Valvular Function

① Normal
② Abnormal

ECHO_006

Evidence of Hypertrophy

① Yes
② No

ECHO_007

MUGA Performed

① Yes
② No

MUGA_001

Date Performed

DAY	MONTH	YEAR
	Jan 1	
	Feb 2	
00	Mar 3	00
11	Apr 4	11
22	May 5	22
33	June 6	33
	July 7	44
	Aug 8	55
	Sept 9	66
	Oct 10	77
	Nov 11	88
	Dec 12	99

MUGA_002

LVEF

① Normal
② Abnormal

MUGA_003

%

00 11 22 33 44 55 66 77 88 99

MUGA_004

Subject Code Number

Subject Initials

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Use the RECIST criteria to evaluate response.

Assessment Date

DAY	MONTH	YEAR
	Jan (1)	
	Feb (2)	
00	Mar (3)	00
11	Apr (4)	11
22	May (5)	22
33	June (6)	33
	July (7)	44
	Aug (8)	55
	Sept (9)	66
	Oct (10)	77
	Nov (11)	88
	Dec (12)	99

RESP_000

Target Lesions

Number of Lesions

RESP_001

Sum of Longest Diameters (mm)

RESP_002

Non-Target Lesions

Number of Lesions

RESP_003

Target Response Criteria	Definition
RESP_004	
(1) Complete Response	Disappearance of all target lesions.
(2) Partial Response	At least a 30% decrease in the sum of the longest diameters of target lesions, taking as a reference the baseline sum of the longest diameters.
(3) Stable Disease	Neither sufficient shrinkage to qualify for partial response nor sufficient increase to qualify for progressive disease, taking as a reference the smallest sum of the longest diameters achieved since the treatment started.
(4) Progressive Disease	At least a 20% increase in the sum of the longest diameters of target lesions, taking as reference the smallest sum longest diameter recorded since treatment began or the appearance of one or more lesions.
(5) Not Able to Evaluate	*Explain:* RESP_005

Subject Code Number		

Subject Initials		

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Non-Target Response Criteria	Definition
RESP_006 ① Complete Response	Disappearance of all non-target lesions.
② Incomplete Response / Stable Disease	Persistence of one or more non-target lesion(s).
③ Progressive Disease	The appearance of one or more non-target lesions and/or unequivocal progression of existing non-target lesions.
③ Not Applicable	No non-target lesions have ever existed for this subject.

Overall Response

Use the grid below to determine the overall response. Choose the row with the correct responses for target lesion response and non-target lesion response, then bubble in the appropriate overall response.

Target Response	Non-Target Response	RESP_007	Overall Response
Complete Response	Complete Response	①	Complete Response
Complete Response	Incomplete / SD	②	Partial Response
Partial Response	Non-PD	③	Partial Response
Stable Disease	Non-PD	④	Stable Disease
Progressive Disease	Any	⑤	Progressive Disease
Any	Progressive Disease	⑥	Progressive Disease
		⑦	Not Evaluated

Subject Code Number

Subject Initials

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Dosing Start Date and Time

DAY | MONTH | YEAR | 00:00 - 23:59

Jan 1, Feb 2, Mar 3, Apr 4, May 5, June 6, July 7, Aug 8, Sept 9, Oct 10, Nov 11, Dec 12

DOSE_001 DOSE_002

Dosing Stop Date and Time

DAY | MONTH | YEAR | 00:00 - 23:59

Jan 1, Feb 2, Mar 3, Apr 4, May 5, June 6, July 7, Aug 8, Sept 9, Oct 10, Nov 11, Dec 12

DOSE_003 DOSE_004

Body Surface Area (sq. m)

DOSE_005

Assigned Dose (mg/m^2)

DOSE_006

Dose Reduction

DOSE_007 **Was this dose a reduced dose?**

1. **Yes** ***(complete this section)***
2. **No** ***(skip to DOSE_010)***

DOSE_008 **Primary reason for dose reduction:**

1. **Hematological toxicity**
2. **Grade 3 or 4 neurotoxicity**
3. **Other Grade 3 or 4 toxicity, per investigator's discretion - Specify:**

_____

_____

DOSE_009

Infusion Status

DOSE_010 **Infusion Status**

1. **Infusion complete; no interruption**
2. **Infusion complete with interruption**
3. **Infusion initiated but not completed**

Total Dose Administered (mg)

DOSE_011

Subject Code Number

Subject Initials

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Assessment Date

DAY	MONTH	YEAR
	Jan 1	
	Feb 2	
00	Mar 3	00
11	Apr 4	11
22	May 5	22
33	June 6	33
4	July 7	44
5	Aug 8	55
6	Sept 9	66
7	Oct 10	77
8	Nov 11	88
9	Dec 12	99

TOXY_000

Toxicity	Grade at visit	GRADE 0	1	2	3	4
Nausea TOXY_001	0 1 2 3	None	Able to eat reasonable intake	Intake significantly decreased but can eat	No significant intake	
Vomiting TOXY_002	0 1 2 3 4	None	One episode in 24 hours	2-5 episodes in 24 hours	6-10 episodes in 24 hours	>10 episodes in 24 hours or requiring parenteral support
Diarrhea TOXY_003	0 1 2 3 4	None	Increase of 2-3 stools per day over pre-Rx	Increase of 4-6 stools/day or nocturnal stools, or moderate cramping	Increase of 7-9 stools/day or incontinence, or severe cramping	Increase of 10 or more stools/day or grossly bloody diarrhea, or need for parenteral support
Mucositis / Stomatitis TOXY_004	0 1 2 3 4	None	Painless ulcers, erythema, or mild soreness	Painful erythema, edema, or ulcers but can eat	Painful erythema, edema, or ulcers and cannot eat	Requires parenteral or enteral support
Alopecia TOXY_005	0 1 2	No loss	Mild hair loss	Pronounced or total hair loss		
Infection TOXY_006	0 1 2 3 4	None	Mild	Moderate	Severe	Life threatening

Subject Code Number

Subject Initials

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

End of Study Date

DAY	MONTH	YEAR
	(1) Jan	
	(2) Feb	
00	(3) Mar	00
11	(4) Apr	11
22	(5) May	22
33	(6) June	33
4	(7) July	44
5	(8) Aug	55
6	(9) Sept	66
7	(10) Oct	77
8	(11) Nov	88
9	(12) Dec	99

EOSR_001

Total Number of Complete Cycles Administered

(1) One cycle
(2) Two cycles
(3) Three cycles
(4) Four cycles
(5) Five cycles
(6) Six cycles

EOSR_002

Did the subject discontinue prematurely?

(1) Yes
(2) No

EOSR_003

EOSR_004 Primary Reason for Premature Discontinuation

(1) Progressive Disease
(2) 2nd recurrence of Hematological toxicity
(3) 2nd recurrence of Grade 3 or 4 neurotoxicity
(4) Cardiotoxicity
(5) Other laboratory abnormality, specify: _____ EOSR_005
(6) Other grade 3 or 4 toxicity: _____ EOSR_006
(7) Death -- complete Survival Endpoint form
(8) Other adverse event, specify: _____ EOSR_007
(9) Lost to follow-up
(10) Withdrew Consent
(11) Protocol Violation, specify: _____ EOSR_008
(12) Investigator's discretion, specify: _____ EOSR_009
(13) Other, specify: _____ EOSR_010

I certify that I have carefully examined all entries on the case report forms. All information entered on the case report form by me or my associates for this subject is, to the best of my knowledge, correct.

Principal Investigator's signature: _____
(or designee) EOSR_011 (1) Please bubble here if signature is present

Date of Signature : ___/___/___ EOSR_012
DD MON YYYY (e.g. 30 SEP 2001)

Visit Administration Form (VADF)

Subject Code Number

Subject Initials

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Visit Date

DAY	MONTH	YEAR
	Jan 1	
	Feb 2	
00	Mar 3	00
11	Apr 4	11
22	May 5	22
33	June 6	33
4	July 7	44
5	Aug 8	55
6	Sept 9	66
7	Oct 10	77
8	Nov 11	88
9	Dec 12	99

VADF_000

Site ID Number

Subject Code Number

Visit

1. Baseline Visit
2. Week 0 / Cycle 1 Visit
4. Week 3 / Cycle 2 Visit
5. Week 5 Visit
6. Week 6 / Cycle 3 Visit
8. Week 9 / Cycle 4 Visit
10. Week 12 / Cycle 5 Visit
12. Week 15 / Cycle 6 / End of Study Visit
● 30 Day Follow Up Visit
15. Six Month Follow Up Visit
16. Survival Endpoint
99. Unscheduled Visit

Forms to be submitted this visit:

Numbered Pages:

- ☐ Physical Exam (pg 86-87)
- ☐ Vital Signs (pg 87a)
- ☐ Subject Assessment of Peripheral Neuropathy (pg 88)
- ☐ Performance Score and Peripheral Neuropathy (pg 89)
- ☐ Report of Scans and Lab Submissions (pg 90)
- ☐ EORTC QLQ-C30 Questionnaire (pg 91-92)
- ☐ Echocardiogram / MUGA (pg 93)
- ☐ Toxicity Assessment (pg 94)

Unnumbered Pages (submit as many as necessary):

- ☐ Concurrent Procedures
- ☐ Adverse Experiences
- ☐ Concomitant Medications

Physical Examination (PHEX)

Subject Code Number		

Subject Initials		

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Date of Assessment

DAY		MONTH		YEAR	
		Jan	1		
		Feb	2		
0	0	Mar	3	0	0
1	1	Apr	4	1	1
2	2	May	5	2	2
3	3	June	6	3	3
	4	July	7	4	4
	5	Aug	8	5	5
	6	Sept	9	6	6
	7	Oct	10	7	7
	8	Nov	11	8	8
	9	Dec	12	9	9

PHEX_001

Weight (kg)

			.	
0	0	0		0
1	1	1		1
2	2	2		2
3	3	3		3
4	4	4		4
5	5	5		5
6	6	6		6
7	7	7		7
8	8	8		8
9	9	9		9

PHEX_002

Site	Normal	Abnormal	Not Done	Describe Abnormalities
PHEX_004 **General Appearance**	1	2	3	PHEX_005
PHEX_006 **Head**	1	2	3	PHEX_007
PHEX_008 **Ears**	1	2	3	PHEX_009
PHEX_010 **Eyes**	1	2	3	PHEX_011
PHEX_012 **Nose**	1	2	3	PHEX_013
PHEX_014 **Throat**	1	2	3	PHEX_015
PHEX_016 **Mouth**	1	2	3	PHEX_017
PHEX_018 **Neck**	1	2	3	PHEX_019
PHEX_020 **Thyroid**	1	2	3	PHEX_021

Subject Code Number		

Subject Initials		

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Site	Normal	Abnormal	Not Done	Describe Abnormalities
PHEX_022 **Lungs / Thorax**	1	2	3	PHEX_023
PHEX_024 **Heart**	1	2	3	PHEX_025
PHEX_026 **Breasts**	1	2	3	PHEX_027
PHEX_028 **Liver**	1	2	3	PHEX_029
PHEX_030 **Abdomen**	1	2	3	PHEX_031
PHEX_032 **Musculoskeletal**	1	2	3	PHEX_033
PHEX_034 **Extremities**	1	2	3	PHEX_035
PHEX_036 **Pulses**	1	2	3	PHEX_037
PHEX_038 **Lymph Nodes**	1	2	3	PHEX_039
PHEX_040 **Skin**	1	2	3	PHEX_041
PHEX_042 **Neurological**	1	2	3	PHEX_043
PHEX_044 **Genitourinary (including pelvic)**	1	2	3	PHEX_045
PHEX_046 **Rectal**	1	2	3	PHEX_047

Vital Signs (VITL)

Subject Code Number

Subject Initials

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Bubble the correct visit number:

① Baseline	③ Week 3 / Cycle 2	⑧ Week 9 / Cycle 4	⑫ Week 15 / Cycle 6
② Week 0 / Cycle 1	⑥ Week 6 / Cycle 3	⑩ Week 12 / Cycle 5	● 30 Day Follow-up

Date and Time of Vitals

DAY | MONTH | YEAR | 00:00 - 23:59

Jan ① Feb ② Mar ③ Apr ④ May ⑤ June ⑥ July ⑦ Aug ⑧ Sept ⑨ Oct ⑩ Nov ⑪ Dec ⑫

VITL_000 VITL_001

Temp. (C)

VITL_002

Blood Pressure (mmHG)

Systolic Diastolic

VITL_003 VITL_004

Pulse (beats/min)

VITL_005

Respiration (breaths/min)

VITL_006

Subject Assessment of Peripheral Neuropathy (FACT)

Subject Code Number		

Subject Initials		

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Evaluation Date					
DAY		MONTH		YEAR	
		Jan	1		
		Feb	2		
0	0	Mar	3	0	0
1	1	Apr	4	1	1
2	2	May	5	2	2
3	3	June	6	3	3
	4	July	7	4	4
	5	Aug	8	5	5
	6	Sept	9	6	6
	7	Oct	10	7	7
	8	Nov	11	8	8
	9	Dec	12	9	9

FACT_000

FACT-Taxane (Version 4); "Additional Concerns"

FACT_017 (1) **Bubble here if this questionnaire was not completed.**

Indicate how true each statement has been for the subject <u>during the past 7 days</u>.		Not at all	A little bit	Some-what	Quite a bit	Very much
FACT_001	I have numbness or tingling in my hands.	0	1	2	3	4
FACT_002	I have numbness or tingling in my feet.	0	1	2	3	4
FACT_003	I feel discomfort in my hands.	0	1	2	3	4
FACT_004	I feel discomfort in my feet.	0	1	2	3	4
FACT_005	I have joint pain or muscle cramps.	0	1	2	3	4
FACT_006	I feel weak all over.	0	1	2	3	4
FACT_007	I have trouble hearing.	0	1	2	3	4
FACT_008	I get a ringing or buzzing in my ears.	0	1	2	3	4
FACT_009	I have trouble buttoning buttons.	0	1	2	3	4
FACT_010	I have trouble feeling the shape of small objects when they are in my hand.	0	1	2	3	4
FACT_011	I have trouble walking.	0	1	2	3	4
FACT_012	I feel bloated.	0	1	2	3	4
FACT_013	My hands are swollen.	0	1	2	3	4
FACT_014	My legs or feet are swollen.	0	1	2	3	4
FACT_015	I have pain in my fingertips.	0	1	2	3	4
FACT_016	I am bothered by the way my hands or nails look.	0	1	2	3	4

Subject Code Number		

Subject Initials		

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Evaluation Date

DAY		MONTH		YEAR	
		Jan	1		
		Feb	2		
0	0	Mar	3	0	0
1	1	Apr	4	1	1
2	2	May	5	2	2
3	3	June	6	3	3
	4	July	7	4	4
	5	Aug	8	5	5
	6	Sept	9	6	6
	7	Oct	10	7	7
	8	Nov	11	8	8
	9	Dec	12	9	9

PSPN_000

Current ECOG Performance Score	PSPN_001
Fully active, able to carry on all pre-disease performance without restriction.	0
Restricted in physically strenuous activity, but ambulatory and able to carry out work of a light or sedentary nature, e.g., light housework, office work.	1
Ambulatory and capable of all self-care, but unable to carry out any work activities. Up and about more than 50% of waking hours.	2
Capable of only limited self-care, confined to bed or chair more than 50% of waking hours.	3
Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair.	4

Physician Assessment of Peripheral Neuropathy	PSPN_002
Normal	0
Loss of deep tendon reflexes or paresthesia (including tingling) but not interfering with function	1
Objective sensory loss or paresthesia (including tingling) interfering with function, but not interfering with activities of daily living	2
Sensory loss or paresthesia interfering with activities of daily living	3
Permanent sensory loss that interferes with function	4

Subject Code Number

Subject Initials

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Scan Type	Scan Performed Yes	Scan Performed No	Bubble if Abnormalities found		Lesions Detected Yes	Lesions Detected No
SCAN_001 **Head CT**	1	2	SCAN_002	1	SCAN_003 1	2
SCAN_004 **Chest CT**	1	2	SCAN_005	1	SCAN_006 1	2
SCAN_007 **Abdomen CT**	1	2	SCAN_008	1	SCAN_009 1	2
SCAN_010 **Bone Scan**	1	2	SCAN_011	1	SCAN_012 1	2
SCAN_013 **Plain Radiographs**	1	2	SCAN_014	1	SCAN_015 1	2
SCAN_016 **Other (specify:)** _____ SCAN_017	1	2	SCAN_018	1	SCAN_019 1	2

Laboratory Tests	Performed Yes	Performed No	Bubble if sent to central lab
SCAN_020 **CBC, Differential Platelet Count**	1	2	SCAN_021 1
SCAN_022 **Clinical Chemistry Panel**	1	2	SCAN_023 1

Subject Code Number

Subject Initials

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

DAY	MONTH	YEAR
	Jan 1	
	Feb 2	
0 0	Mar 3	0 0
1 1	Apr 4	1 1
2 2	May 5	2 2
3 3	June 6	3 3
	July 7	4 4
	Aug 8	5 5
	Sept 9	6 6
	Oct 10	7 7
	Nov 11	8 8
	Dec 12	9 9

EQLQ_000

EQLQ_031 ① **Bubble here if this questionnaire was not completed.**

		Not at All	A Little	Quite a Bit	Very Much
EQLQ_001	Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?	①	②	③	④
EQLQ_002	Do you have any trouble taking a long walk?	①	②	③	④
EQLQ_003	Do you have any trouble taking a short walk outside the house?	①	②	③	④
EQLQ_004	Do you need to stay in a bed or a chair during the day?	①	②	③	④
EQLQ_005	Do you need help with eating, dressing, washing yourself or using the toilet?	①	②	③	④

During the past week:		Not at All	A Little	Quite a Bit	Very Much
EQLQ_006	Were you limited in doing either your work or other daily activities?	①	②	③	④
EQLQ_007	Were you limited in pursuing your hobbies or other leisure time activities?	①	②	③	④
EQLQ_008	Were you short of breath?	①	②	③	④
EQLQ_009	Have you had pain?	①	②	③	④
EQLQ_010	Did you need to rest?	①	②	③	④
EQLQ_011	Have you had trouble sleeping?	①	②	③	④
EQLQ_012	Have you felt weak?	①	②	③	④
EQLQ_013	Have you lacked appetite?	①	②	③	④
EQLQ_014	Have you felt nauseated?	①	②	③	④
EQLQ_015	Have you vomited?	①	②	③	④
EQLQ_016	Have you been constipated?	①	②	③	④
EQLQ_017	Have you had diarrhea?	①	②	③	④

Subject Code Number		

Subject Initials		

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

During the past week:		Not at All	A Little	Quite a Bit	Very Much
EQLQ_018	Were you tired?	1	2	3	4
EQLQ_019	Did pain interfere with your daily activities?	1	2	3	4
EQLQ_020	Have you had difficulty in concentrating on things, like reading a newspaper or watching television?	1	2	3	4
EQLQ_021	Did you feel tense?	1	2	3	4
EQLQ_022	Did you worry?	1	2	3	4
EQLQ_023	Did you feel irritable?	1	2	3	4
EQLQ_024	Did you feel depressed?	1	2	3	4
EQLQ_025	Have you had difficulty remembering things?	1	2	3	4
EQLQ_026	Has your physical condition or medical treatment interfered with your family life?	1	2	3	4
EQLQ_027	Has your physical condition or medical treatment interfered with your social activities?	1	2	3	4
EQLQ_028	Has your physical condition or medical treatment caused you financial difficulties?	1	2	3	4

EQLQ_029 How would you rate your overall health during the past week?

1	2	3	4	5	6	7
Very Poor						Excellent

EQLQ_030 How would you rate your overall quality of life during the past week?

1	2	3	4	5	6	7
Very Poor						Excellent

Subject Code Number

Subject Initials

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

ECHO Performed

① Yes
② No

ECHO_001

Date Performed

DAY	MONTH	YEAR
	Jan ①	
	Feb ②	
00	Mar ③	00
11	Apr ④	11
22	May ⑤	22
33	June ⑥	33
	July ⑦	44
	Aug ⑧	55
	Sept ⑨	66
	Oct ⑩	77
	Nov ⑪	88
	Dec ⑫	99

ECHO_002

LVEF

① Normal
② Abnormal

ECHO_003

%

00 11 22 33 44 55 66 77 88 99

ECHO_004

Wall Motion

① Normal
② Abnormal

ECHO_005

Valvular Function

① Normal
② Abnormal

ECHO_006

Evidence of Hypertrophy

① Yes
② No

ECHO_007

MUGA Performed

① Yes
② No

MUGA_001

Date Performed

DAY	MONTH	YEAR
	Jan ①	
	Feb ②	
00	Mar ③	00
11	Apr ④	11
22	May ⑤	22
33	June ⑥	33
	July ⑦	44
	Aug ⑧	55
	Sept ⑨	66
	Oct ⑩	77
	Nov ⑪	88
	Dec ⑫	99

MUGA_002

LVEF

① Normal
② Abnormal

MUGA_003

%

00 11 22 33 44 55 66 77 88 99

MUGA_004

Subject Code Number		

Subject Initials		

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Date Performed

DAY		MONTH		YEAR	
		Jan	1		
		Feb	2		
0	0	Mar	3	0	0
1	1	Apr	4	1	1
2	2	May	5	2	2
3	3	June	6	3	3
	4	July	7	4	4
	5	Aug	8	5	5
	6	Sept	9	6	6
	7	Oct	10	7	7
	8	Nov	11	8	8
	9	Dec	12	9	9

EKGR_000

EKG Results

1. **Normal**
2. **Abnormal, clinically significant** ***(provide comments below)***
3. **Abnormal, not clinically significant** ***(provide comments below)***
4. **Not done**

EKGR_001

Comment on Abnormal EKG:

EKGR_002

Subject Code Number

Subject Initials

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Assessment Date

DAY	MONTH	YEAR
	Jan 1	
	Feb 2	
00	Mar 3	00
11	Apr 4	11
22	May 5	22
33	June 6	33
4	July 7	44
5	Aug 8	55
6	Sept 9	66
7	Oct 10	77
8	Nov 11	88
9	Dec 12	99

TOXY_000

Toxicity	Grade at visit	GRADE 0	1	2	3	4
Nausea TOXY_001	0 1 2 3	None	Able to eat reasonable intake	Intake significantly decreased but can eat	No significant intake	
Vomiting TOXY_002	0 1 2 3 4	None	One episode in 24 hours	2-5 episodes in 24 hours	6-10 episodes in 24 hours	>10 episodes in 24 hours or requiring parenteral support
Diarrhea TOXY_003	0 1 2 3 4	None	Increase of 2-3 stools per day over pre-Rx	Increase of 4-6 stools/day or nocturnal stools, or moderate cramping	Increase of 7-9 stools/day or incontinence, or severe cramping	Increase of 10 or more stools/day or grossly bloody diarrhea, or need for parenteral support
Mucositis / Stomatitis TOXY_004	0 1 2 3 4	None	Painless ulcers, erythema, or mild soreness	Painful erythema, edema, or ulcers but can eat	Painful erythema, edema, or ulcers and cannot eat	Requires parenteral or enteral support
Alopecia TOXY_005	0 1 2	No loss	Mild hair loss	Pronounced or total hair loss		
Infection TOXY_006	0 1 2 3 4	None	Mild	Moderate	Severe	Life threatening

Visit Administration Form (VADF)

Subject Code Number

Subject Initials

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Visit Date

DAY	MONTH	YEAR
	Jan (1)	
	Feb (2)	
00	Mar (3)	00
11	Apr (4)	11
22	May (5)	22
33	June (6)	33
4	July (7)	44
5	Aug (8)	55
6	Sept (9)	66
7	Oct (10)	77
8	Nov (11)	88
9	Dec (12)	99

VADF_000

Site ID Number

Subject Code Number

Visit

1. Baseline Visit
2. Week 0 / Cycle 1 Visit
4. Week 3 / Cycle 2 Visit
5. Week 5 Visit
6. Week 6 / Cycle 3 Visit
8. Week 9 / Cycle 4 Visit
10. Week 12 / Cycle 5 Visit
12. Week 15 / Cycle 6 / End of Study Visit
14. 30 Day Follow Up Visit
- Six Month Follow Up Visit
16. Survival Endpoint
99. Unscheduled Visit

Forms to be submitted this visit:

Numbered Pages:

- ☐ Report of Scans and Lab Submissions (pg 96)
- ☐ Response Evaluation (pg 97-98)

Unnumbered Pages

- ☐ Lesion Identification Form
- ☐ Non-Target Lesion Evaluation Form
- ☐ Target Lesion Measurement Form

Subject Code Number		

Subject Initials		

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Scan Type	Scan Performed Yes	Scan Performed No	Bubble if Abnormalities found		Lesions Detected Yes	Lesions Detected No
SCAN_001 **Head CT**	1	2	SCAN_002	1	SCAN_003 1	2
SCAN_004 **Chest CT**	1	2	SCAN_005	1	SCAN_006 1	2
SCAN_007 **Abdomen CT**	1	2	SCAN_008	1	SCAN_009 1	2
SCAN_010 **Bone Scan**	1	2	SCAN_011	1	SCAN_012 1	2
SCAN_013 **Plain Radiographs**	1	2	SCAN_014	1	SCAN_015 1	2
SCAN_016 **Other (specify:)** _____ SCAN_017	1	2	SCAN_018	1	SCAN_019 1	2

Laboratory Tests	Performed Yes	Performed No	Bubble if sent to central lab
SCAN_020 **CBC, Differential Platelet Count**	1	2	SCAN_021 1
SCAN_022 **Clinical Chemistry Panel**	1	2	SCAN_023 1

Subject Code Number

Subject Initials

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Use the RECIST criteria to evaluate response.

Assessment Date

DAY	MONTH	YEAR
	Jan 1	
	Feb 2	
00	Mar 3	00
11	Apr 4	11
22	May 5	22
33	June 6	33
	July 7	44
	Aug 8	55
	Sept 9	66
	Oct 10	77
	Nov 11	88
	Dec 12	99

RESP_000

Target Lesions

Number of Lesions

RESP_001

Sum of Longest Diameters (mm)

RESP_002

Non-Target Lesions

Number of Lesions

RESP_003

Target Response Criteria	Definition
RESP_004	
① Complete Response	Disappearance of all target lesions.
② Partial Response	At least a 30% decrease in the sum of the longest diameters of target lesions, taking as a reference the baseline sum of the longest diameters.
③ Stable Disease	Neither sufficient shrinkage to qualify for partial response nor sufficient increase to qualify for progressive disease, taking as a reference the smallest sum of the longest diameters achieved since the treatment started.
④ Progressive Disease	At least a 20% increase in the sum of the longest diameters of target lesions, taking as reference the smallest sum longest diameter recorded since treatment began or the appearance of one or more lesions.
⑤ Not Able to Evaluate	*Explain:*

RESP_005

Subject Code Number	

Subject Initials	

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Non-Target Response Criteria	Definition
RESP_006 ① Complete Response	Disappearance of all non-target lesions.
② Incomplete Response / Stable Disease	Persistence of one or more non-target lesion(s).
③ Progressive Disease	The appearance of one or more non-target lesions and/or unequivocal progression of existing non-target lesions.
③ Not Applicable	No non-target lesions have ever existed for this subject.

Overall Response

Use the grid below to determine the overall response. Choose the row with the correct responses for target lesion response and non-target lesion response, then bubble in the appropriate overall response.

Target Response	Non-Target Response	RESP_007	Overall Response
Complete Response	Complete Response	①	Complete Response
Complete Response	Incomplete / SD	②	Partial Response
Partial Response	Non-PD	③	Partial Response
Stable Disease	Non-PD	④	Stable Disease
Progressive Disease	Any	⑤	Progressive Disease
Any	Progressive Disease	⑥	Progressive Disease
		⑦	Not Evaluated

Subject Code Number

Subject Initials

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Visit Date

DAY	MONTH	YEAR
	Jan 1	
	Feb 2	
00	Mar 3	00
11	Apr 4	11
22	May 5	22
33	June 6	33
4	July 7	44
5	Aug 8	55
6	Sept 9	66
7	Oct 10	77
8	Nov 11	88
9	Dec 12	99

VADF_000

Site ID Number

000 111 222 333 444 555 666 777 888 999

Subject Code Number

000 111 222 333 444 555 666 777 888 999

Visit

1. Baseline Visit
2. Week 0 / Cycle 1 Visit
4. Week 3 / Cycle 2 Visit
5. Week 5 Visit
6. Week 6 / Cycle 3 Visit
8. Week 9 / Cycle 4 Visit
10. Week 12 / Cycle 5 Visit
12. Week 15 / Cycle 6 / End of Study Visit
14. 30 Day Follow Up Visit
15. Six Month Follow Up Visit
- Survival Endpoint
99. Unscheduled Visit

Forms to be submitted this visit:

Numbered Pages:

- ☐ Phone Follow-up Contact Log (pg 100-101)
- ☐ Survival Endpoint (pg 102)

Subject Code Number		

Subject Initials		

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Use this form to record all successful follow-up phone calls made to the subject to assess the survival endpoint.

Contact Date

DAY		MONTH		YEAR	
		Jan	1		
		Feb	2		
0	0	Mar	3	0	0
1	1	Apr	4	1	1
2	2	May	5	2	2
3	3	June	6	3	3
	4	July	7	4	4
	5	Aug	8	5	5
	6	Sept	9	6	6
	7	Oct	10	7	7
	8	Nov	11	8	8
	9	Dec	12	9	9

PHON_001

Follow-up Status

1. **Alive, not on treatment**
2. **Alive, on treatment**
3. **Lost to Follow-up**
4. **Deceased**

If the subject is lost to follow-up or deceased, complete the Survival Endpoint page.

PHON_002

Contact Date

DAY		MONTH		YEAR	
		Jan	1		
		Feb	2		
0	0	Mar	3	0	0
1	1	Apr	4	1	1
2	2	May	5	2	2
3	3	June	6	3	3
	4	July	7	4	4
	5	Aug	8	5	5
	6	Sept	9	6	6
	7	Oct	10	7	7
	8	Nov	11	8	8
	9	Dec	12	9	9

PHON_001

Follow-up Status

1. **Alive, not on treatment**
2. **Alive, on treatment**
3. **Lost to Follow-up**
4. **Deceased**

If the subject is lost to follow-up or deceased, complete the Survival Endpoint page.

PHON_002

Contact Date

DAY		MONTH		YEAR	
		Jan	1		
		Feb	2		
0	0	Mar	3	0	0
1	1	Apr	4	1	1
2	2	May	5	2	2
3	3	June	6	3	3
	4	July	7	4	4
	5	Aug	8	5	5
	6	Sept	9	6	6
	7	Oct	10	7	7
	8	Nov	11	8	8
	9	Dec	12	9	9

PHON_001

Follow-up Status

1. **Alive, not on treatment**
2. **Alive, on treatment**
3. **Lost to Follow-up**
4. **Deceased**

If the subject is lost to follow-up or deceased, complete the Survival Endpoint page.

PHON_002

Contact Date

DAY		MONTH		YEAR	
		Jan	1		
		Feb	2		
0	0	Mar	3	0	0
1	1	Apr	4	1	1
2	2	May	5	2	2
3	3	June	6	3	3
	4	July	7	4	4
	5	Aug	8	5	5
	6	Sept	9	6	6
	7	Oct	10	7	7
	8	Nov	11	8	8
	9	Dec	12	9	9

PHON_001

Follow-up Status

1. **Alive, not on treatment**
2. **Alive, on treatment**
3. **Lost to Follow-up**
4. **Deceased**

If the subject is lost to follow-up or deceased, complete the Survival Endpoint page.

PHON_002

Contact Date

DAY		MONTH		YEAR	
		Jan	1		
		Feb	2		
0	0	Mar	3	0	0
1	1	Apr	4	1	1
2	2	May	5	2	2
3	3	June	6	3	3
	4	July	7	4	4
	5	Aug	8	5	5
	6	Sept	9	6	6
	7	Oct	10	7	7
	8	Nov	11	8	8
	9	Dec	12	9	9

PHON_001

Follow-up Status

1. **Alive, not on treatment**
2. **Alive, on treatment**
3. **Lost to Follow-up**
4. **Deceased**

If the subject is lost to follow-up or deceased, complete the Survival Endpoint page.

PHON_002

Contact Date

DAY		MONTH		YEAR	
		Jan	1		
		Feb	2		
0	0	Mar	3	0	0
1	1	Apr	4	1	1
2	2	May	5	2	2
3	3	June	6	3	3
	4	July	7	4	4
	5	Aug	8	5	5
	6	Sept	9	6	6
	7	Oct	10	7	7
	8	Nov	11	8	8
	9	Dec	12	9	9

PHON_001

Follow-up Status

1. **Alive, not on treatment**
2. **Alive, on treatment**
3. **Lost to Follow-up**
4. **Deceased**

If the subject is lost to follow-up or deceased, complete the Survival Endpoint page.

PHON_002

Subject Code Number		

Subject Initials		

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Use this form to record all successful follow-up phone calls made to the subject to assess the survival endpoint.

Contact Date

DAY		MONTH		YEAR	
		Jan	1		
		Feb	2		
0	0	Mar	3	0	0
1	1	Apr	4	1	1
2	2	May	5	2	2
3	3	June	6	3	3
	4	July	7	4	4
	5	Aug	8	5	5
	6	Sept	9	6	6
	7	Oct	10	7	7
	8	Nov	11	8	8
	9	Dec	12	9	9

PHON_001

Follow-up Status

1. Alive, not on treatment
2. Alive, on treatment
3. Lost to Follow-up
4. Deceased

If the subject is lost to follow-up or deceased, complete the Survival Endpoint page.

PHON_002

Contact Date

DAY		MONTH		YEAR	
		Jan	1		
		Feb	2		
0	0	Mar	3	0	0
1	1	Apr	4	1	1
2	2	May	5	2	2
3	3	June	6	3	3
	4	July	7	4	4
	5	Aug	8	5	5
	6	Sept	9	6	6
	7	Oct	10	7	7
	8	Nov	11	8	8
	9	Dec	12	9	9

PHON_001

Follow-up Status

1. Alive, not on treatment
2. Alive, on treatment
3. Lost to Follow-up
4. Deceased

If the subject is lost to follow-up or deceased, complete the Survival Endpoint page.

PHON_002

Contact Date

DAY		MONTH		YEAR	
		Jan	1		
		Feb	2		
0	0	Mar	3	0	0
1	1	Apr	4	1	1
2	2	May	5	2	2
3	3	June	6	3	3
	4	July	7	4	4
	5	Aug	8	5	5
	6	Sept	9	6	6
	7	Oct	10	7	7
	8	Nov	11	8	8
	9	Dec	12	9	9

PHON_001

Follow-up Status

1. Alive, not on treatment
2. Alive, on treatment
3. Lost to Follow-up
4. Deceased

If the subject is lost to follow-up or deceased, complete the Survival Endpoint page.

PHON_002

Contact Date

DAY		MONTH		YEAR	
		Jan	1		
		Feb	2		
0	0	Mar	3	0	0
1	1	Apr	4	1	1
2	2	May	5	2	2
3	3	June	6	3	3
	4	July	7	4	4
	5	Aug	8	5	5
	6	Sept	9	6	6
	7	Oct	10	7	7
	8	Nov	11	8	8
	9	Dec	12	9	9

PHON_001

Follow-up Status

1. Alive, not on treatment
2. Alive, on treatment
3. Lost to Follow-up
4. Deceased

If the subject is lost to follow-up or deceased, complete the Survival Endpoint page.

PHON_002

Contact Date

DAY		MONTH		YEAR	
		Jan	1		
		Feb	2		
0	0	Mar	3	0	0
1	1	Apr	4	1	1
2	2	May	5	2	2
3	3	June	6	3	3
	4	July	7	4	4
	5	Aug	8	5	5
	6	Sept	9	6	6
	7	Oct	10	7	7
	8	Nov	11	8	8
	9	Dec	12	9	9

PHON_001

Follow-up Status

1. Alive, not on treatment
2. Alive, on treatment
3. Lost to Follow-up
4. Deceased

If the subject is lost to follow-up or deceased, complete the Survival Endpoint page.

PHON_002

Contact Date

DAY		MONTH		YEAR	
		Jan	1		
		Feb	2		
0	0	Mar	3	0	0
1	1	Apr	4	1	1
2	2	May	5	2	2
3	3	June	6	3	3
	4	July	7	4	4
	5	Aug	8	5	5
	6	Sept	9	6	6
	7	Oct	10	7	7
	8	Nov	11	8	8
	9	Dec	12	9	9

PHON_001

Follow-up Status

1. Alive, not on treatment
2. Alive, on treatment
3. Lost to Follow-up
4. Deceased

If the subject is lost to follow-up or deceased, complete the Survival Endpoint page.

PHON_002

Subject Code Number

Subject Initials

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Survival Endpoint

SURV_001

1. Alive at analysis endpoint
2. Lost to follow-up
3. Deceased

Survival Endpoint Date

SURV_002

DAY	MONTH	YEAR
	Jan 1	
	Feb 2	
00	Mar 3	00
11	Apr 4	11
22	May 5	22
33	June 6	33
4	July 7	44
5	Aug 8	55
6	Sept 9	66
7	Oct 10	77
8	Nov 11	88
9	Dec 12	99

Progression Status

SURV_003

1. Subject Progressed (indicate date)
2. Subject did not Progress

Date of Progression

SURV_004

DAY	MONTH	YEAR
	Jan 1	
	Feb 2	
00	Mar 3	00
11	Apr 4	11
22	May 5	22
33	June 6	33
4	July 7	44
5	Aug 8	55
6	Sept 9	66
7	Oct 10	77
8	Nov 11	88
9	Dec 12	99

Cause of Death

SURV_005

_____

_____

_____

_____

_____

Relationship to Study Drug

1. Not related
2. Possibly related
3. Probably related
4. Definitely related

SURV_006

I certify that I have carefully examined all entries on the case report forms. All information entered on the case report form by me or my associates for this subject is, to the best of my knowledge, correct.

Principal Investigator's signature: _____
(or designee)

SURV_007 1 Please bubble here if signature is present

Date of Signature : ____/____/____

SURV_008

DD MON YYYY (e.g. 30 SEP 2001)

Lesion Identification Form (LESN)

Subject Code Number

Subject Initials

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Use this form to identify each lesion as it is encountered. Number the lesions sequentially. Use the codes at the bottom of the page to identify the location of the lesion.

Identification Date

DAY	MONTH	YEAR
	Jan 1	
	Feb 2	
00	Mar 3	00
11	Apr 4	11
22	May 5	22
33	June 6	33
	July 7	44
	Aug 8	55
	Sept 9	66
	Oct 10	77
	Nov 11	88
	Dec 12	99

LESN_001

Lesion #

00 11 22 33 44 55 66 77 88 99

LESN_002

Method of Assessment

1. MRI
2. CT
3. X-ray
4. Ultrasound
5. Physical Exam
6. Bone Scan
7. Whole Body Scan

LESN_003

Lesion Type

1. Target
2. Non-target

LESN_004

Location of Lesion (use codes below)

00 11 22 3 4 5 6 7 8 9

If 6, 16, 22 or 29 was chosen, please specify location:

_____

_____

_____

LESN_006

LESN_005

Identification Date

DAY	MONTH	YEAR
	Jan 1	
	Feb 2	
00	Mar 3	00
11	Apr 4	11
22	May 5	22
33	June 6	33
	July 7	44
	Aug 8	55
	Sept 9	66
	Oct 10	77
	Nov 11	88
	Dec 12	99

LESN_001

Lesion #

00 11 22 33 44 55 66 77 88 99

LESN_002

Method of Assessment

1. MRI
2. CT
3. X-ray
4. Ultrasound
5. Physical Exam
6. Bone Scan
7. Whole Body Scan

LESN_003

Lesion Type

1. Target
2. Non-target

LESN_004

Location of Lesion (use codes below)

00 11 22 3 4 5 6 7 8 9

If 6, 16, 22 or 29 was chosen, please specify location:

_____

_____

_____

LESN_006

LESN_005

Lesion Identification Codes

Head/Neck
- 01 - Skull
- 02 - Brain
- 03 - Facial
- 04 - Sinus
- 05 - Neck
- 06 - Other head/neck

Abdominal
- 07 - Liver
- 08 - Spleen
- 09 - Adrenals
- 10 - Kidney
- 11 - Pancreas
- 12 - Lymph nodes
- 13 - Bowel
- 14 - Mesentery
- 15 - Abdominal wall
- 16 - Other abdominal

Chest
- 17 - Lung
- 18 - Mediastina
- 19 - Pleura
- 20 - Soft tissue/ chest wall
- 21 - Lymph nodes
- 22 - Other chest

Other areas
- 23 - Extremity
- 24 - Bone
- 25 - Breast
- 26 - Uterus
- 27 - Ovaries
- 28 - Cervix
- 29 - Other

Target Lesion Measurement Form (TARG)

Subject Code Number	

Subject Initials	

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Using the previously assigned lesion identification number, record the current size of the target lesions.

Evaluation Date

DAY	MONTH	YEAR
	Jan 1	
	Feb 2	
00	Mar 3	00
11	Apr 4	11
22	May 5	22
33	June 6	33
4	July 7	44
5	Aug 8	55
6	Sept 9	66
7	Oct 10	77
8	Nov 11	88
9	Dec 12	99

TARG_001

Lesion #

00 11 22 33 44 55 66 77 88 99

TARG_002

Target Lesion Size : Longest Diameter (mm)

. 00 11 22 33 44 55 66 77 88 99 0 1 2 3 4 5 6 7 8 9

TARG_003

Evaluation Date

DAY	MONTH	YEAR
	Jan 1	
	Feb 2	
00	Mar 3	00
11	Apr 4	11
22	May 5	22
33	June 6	33
4	July 7	44
5	Aug 8	55
6	Sept 9	66
7	Oct 10	77
8	Nov 11	88
9	Dec 12	99

TARG_001

Lesion #

00 11 22 33 44 55 66 77 88 99

TARG_002

Target Lesion Size : Longest Diameter (mm)

. 00 11 22 33 44 55 66 77 88 99 0 1 2 3 4 5 6 7 8 9

TARG_003

Non-Target Lesion Evaluation Form (NTLE)

Subject Code Number		

Subject Initials		

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Using the previously assigned lesion identification number, evaluate the change in size since last measurement of the non-target lesions.

Evaluation Date

DAY	MONTH	YEAR
	Jan 1	
	Feb 2	
00	Mar 3	00
11	Apr 4	11
22	May 5	22
33	June 6	33
4	July 7	44
5	Aug 8	55
6	Sept 9	66
7	Oct 10	77
8	Nov 11	88
9	Dec 12	99

NTLE_001

Lesion #

00
11
22
33
44
55
66
77
88
99

NTLE_002

Lesion Evaluation
(Change in Size)

1. Initial Evaluation
2. Lesion Disappeared Completely
3. Lesion Decreased in Size
4. No Change in Size
5. Lesion Increased in Size

NTLE_003

Evaluation Date

DAY	MONTH	YEAR
	Jan 1	
	Feb 2	
00	Mar 3	00
11	Apr 4	11
22	May 5	22
33	June 6	33
4	July 7	44
5	Aug 8	55
6	Sept 9	66
7	Oct 10	77
8	Nov 11	88
9	Dec 12	99

NTLE_001

Lesion #

00
11
22
33
44
55
66
77
88
99

NTLE_002

Lesion Evaluation
(Change in Size)

1. Initial Evaluation
2. Lesion Disappeared Completely
3. Lesion Decreased in Size
4. No Change in Size
5. Lesion Increased in Size

NTLE_003

Adverse Event (ADEX)

Subject Code Number		

Subject Initials		

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Fill out a section for each adverse event that occurs while on trial or during the follow up phase. Use the NCI Common Toxicity Criteria to grade the adverse events. If the CTC does not apply, use the following: 1=Mild 2=Moderate 3=Severe 4=Life Threatening.

ADEX_001

Adverse Experience:

START DATE DAY	START DATE MONTH	START DATE YEAR	END DATE DAY	END DATE MONTH	END DATE YEAR	Duration If < 24 hours
	1 Jan			1 Jan		
	2 Feb			2 Feb		
00	3 Mar	00	00	3 Mar	00	00
11	4 Apr	11	11	4 Apr	11	11
22	5 May	22	22	5 May	22	22
33	6 June	33	33	6 June	33	33
44	7 July	44	44	7 July	44	44
55	8 Aug	55	55	8 Aug	55	55
66	9 Sept	66	66	9 Sept	66	66
77	10 Oct	77	77	10 Oct	77	77
88	11 Nov	88	88	11 Nov	88	88
99	12 Dec	99	99	12 Dec	99	99

ADEX_002 ADEX_003 ADEX_004

ADEX_005 (1) **Bubble here if continuing at study exit**

Intensity ADEX_006

Refer to NCI Common Toxicity Criteria if appropriate

(1) (2) (3) (4)

Outcome ADEX_007

(1) Resolved, no residual effects
(2) Resolved, residual effects
(3) Unresolved
(4) Death

Action Taken ADEX_008

(1) None
(2) Dosage temporarily suspended
(3) Dosage Reduced
(4) Dosage stopped

Related to Study Treatment ADEX_009

(1) Not related
(2) Possibly related
(3) Probably related
(4) Definitely related

Medication Required ADEX_010

(1) Yes -- **complete CMED form**
(2) No

Serious Adverse Event ADEX_011

(1) Yes -- **complete SAE form**
(2) No

ADEX_012 (1) This AE is the **single most important** AE that led to discontinuation of study drug.

ADEX_001

Adverse Experience:

START DATE DAY | START DATE MONTH | START DATE YEAR | END DATE DAY | END DATE MONTH | END DATE YEAR | Duration If < 24 hours

1 Jan, 2 Feb, 3 Mar, 4 Apr, 5 May, 6 June, 7 July, 8 Aug, 9 Sept, 10 Oct, 11 Nov, 12 Dec

ADEX_002 ADEX_003 ADEX_004

ADEX_005 (1) **Bubble here if continuing at study exit**

Intensity ADEX_006

Refer to NCI Common Toxicity Criteria if appropriate

(1) (2) (3) (4)

Outcome ADEX_007

(1) Resolved, no residual effects
(2) Resolved, residual effects
(3) Unresolved
(4) Death

Action Taken ADEX_008

(1) None
(2) Dosage temporarily suspended
(3) Dosage reduced
(4) Dosage stopped

Related to Study Treatment ADEX_009

(1) Not related
(2) Possibly related
(3) Probably related
(4) Definitely related

Medication Required ADEX_010

(1) Yes -- **complete CMED form**
(2) No

Serious Adverse Event ADEX_011

(1) Yes -- **complete SAE form**
(2) No

ADEX_012 (1) This AE is the **single most important** AE that led to discontinuation of study drug.

Prior and Concomitant Medications (CMED)

Subject Code Number	

Subject Initials	

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Please record all medications taken by the subject during or 30 days prior to the study.

Drug Name:
(Generic Name preferred. Use brand name if combination product.)
CMED_001

Indication:
CMED_002

Total Daily Dose (include units)
CMED_003

Route
CMED_004

START DATE			END DATE		
DAY	MONTH	YEAR	DAY	MONTH	YEAR
	Jan (1)			Jan (1)	
	Feb (2)			Feb (2)	
00	Mar (3)	00	00	Mar (3)	00
11	Apr (4)	11	11	Apr (4)	11
22	May (5)	22	22	May (5)	22
33	June (6)	33	33	June (6)	33
4	July (7)	44	4	July (7)	44
5	Aug (8)	55	5	Aug (8)	55
6	Sept (9)	66	6	Sept (9)	66
7	Oct (10)	77	7	Oct (10)	77
8	Nov (11)	88	8	Nov (11)	88
9	Dec (12)	99	9	Dec (12)	99

CMED_005 CMED_006

CMED_007 (1) Bubble here if continuing at end of study

CMED_008 (1) Bubble here if this is a medication used for predosing the study drug

Drug Name:
(Generic Name preferred. Use brand name if combination product.)
CMED_001

Indication:
CMED_002

Total Daily Dose (include units)
CMED_003

Route
CMED_004

START DATE			END DATE		
DAY	MONTH	YEAR	DAY	MONTH	YEAR
	Jan (1)			Jan (1)	
	Feb (2)			Feb (2)	
00	Mar (3)	00	00	Mar (3)	00
11	Apr (4)	11	11	Apr (4)	11
22	May (5)	22	22	May (5)	22
33	June (6)	33	33	June (6)	33
4	July (7)	44	4	July (7)	44
5	Aug (8)	55	5	Aug (8)	55
6	Sept (9)	66	6	Sept (9)	66
7	Oct (10)	77	7	Oct (10)	77
8	Nov (11)	88	8	Nov (11)	88
9	Dec (12)	99	9	Dec (12)	99

CMED_005 CMED_006

CMED_007 (1) Bubble here if continuing at end of study

CMED_008 (1) Bubble here if this is a medication used for predosing the study drug

Concurrent Procedures (CPRO)

Subject Code Number		

Subject Initials		

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Please fill out one block for each procedure the subject underwent while on trial. Be sure to record the associated adverse events and medications on the appropriate CRF pages.

PROCEDURE DATE

DAY		MONTH		YEAR	
		Jan	1		
		Feb	2		
0	0	Mar	3	0	0
1	1	Apr	4	1	1
2	2	May	5	2	2
3	3	June	6	3	3
	4	July	7	4	4
	5	Aug	8	5	5
	6	Sept	9	6	6
	7	Oct	10	7	7
	8	Nov	11	8	8
	9	Dec	12	9	9

CPRO_001

Procedure Performed

CPRO_002

Reason for Procedure

CPRO_003

PROCEDURE DATE

DAY		MONTH		YEAR	
		Jan	1		
		Feb	2		
0	0	Mar	3	0	0
1	1	Apr	4	1	1
2	2	May	5	2	2
3	3	June	6	3	3
	4	July	7	4	4
	5	Aug	8	5	5
	6	Sept	9	6	6
	7	Oct	10	7	7
	8	Nov	11	8	8
	9	Dec	12	9	9

CPRO_001

Procedure Performed

CPRO_002

Reason for Procedure

CPRO_003

PROCEDURE DATE

DAY		MONTH		YEAR	
		Jan	1		
		Feb	2		
0	0	Mar	3	0	0
1	1	Apr	4	1	1
2	2	May	5	2	2
3	3	June	6	3	3
	4	July	7	4	4
	5	Aug	8	5	5
	6	Sept	9	6	6
	7	Oct	10	7	7
	8	Nov	11	8	8
	9	Dec	12	9	9

CPRO_001

Procedure Performed

CPRO_002

Reason for Procedure

CPRO_003

PROCEDURE DATE

DAY		MONTH		YEAR	
		Jan	1		
		Feb	2		
0	0	Mar	3	0	0
1	1	Apr	4	1	1
2	2	May	5	2	2
3	3	June	6	3	3
	4	July	7	4	4
	5	Aug	8	5	5
	6	Sept	9	6	6
	7	Oct	10	7	7
	8	Nov	11	8	8
	9	Dec	12	9	9

CPRO_001

Procedure Performed

CPRO_002

Reason for Procedure

CPRO_003

PROCEDURE DATE

DAY		MONTH		YEAR	
		Jan	1		
		Feb	2		
0	0	Mar	3	0	0
1	1	Apr	4	1	1
2	2	May	5	2	2
3	3	June	6	3	3
	4	July	7	4	4
	5	Aug	8	5	5
	6	Sept	9	6	6
	7	Oct	10	7	7
	8	Nov	11	8	8
	9	Dec	12	9	9

CPRO_001

Procedure Performed

CPRO_002

Reason for Procedure

CPRO_003

PROCEDURE DATE

DAY		MONTH		YEAR	
		Jan	1		
		Feb	2		
0	0	Mar	3	0	0
1	1	Apr	4	1	1
2	2	May	5	2	2
3	3	June	6	3	3
	4	July	7	4	4
	5	Aug	8	5	5
	6	Sept	9	6	6
	7	Oct	10	7	7
	8	Nov	11	8	8
	9	Dec	12	9	9

CPRO_001

Procedure Performed

CPRO_002

Reason for Procedure

CPRO_003

Vital Signs (VITL)

Subject Code Number

Subject Initials

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Bubble the correct visit number:

①	Baseline	③	Week 3 / Cycle 2	⑧	Week 9 / Cycle 4	⑫	Week 15 / Cycle 6
②	Week 0 / Cycle 1	⑥	Week 6 / Cycle 3	⑩	Week 12 / Cycle 5	⑭	30 Day Follow-up

Date and Time of Vitals

DAY	MONTH	YEAR	00:00 - 23:59
	Jan ①		
	Feb ②		
00	Mar ③	00	00 : 00
11	Apr ④	11	11 : 11
22	May ⑤	22	22 : 22
33	June ⑥	33	33 : 33
	July ⑦	44	44 : 44
	Aug ⑧	55	55 : 55
	Sept ⑨	66	66 : 66
	Oct ⑩	77	77 : 77
	Nov ⑪	88	88 : 88
	Dec ⑫	99	99 : 99

VITL_000 VITL_001

Temp. (C)

00 . 0
11 . 1
22 . 2
33 . 3
44 . 4
55 . 5
66 . 6
77 . 7
88 . 8
99 . 9

VITL_002

Blood Pressure (mmHG)

Systolic	Diastolic
000	000
111	111
222	222
333	333
444	444
555	555
666	666
777	777
888	888
999	999

VITL_003 VITL_004

Pulse (beats/min)

000
111
222
333
444
555
666
777
888
999

VITL_005

Respiration (breaths/min)

000
111
222
333
444
555
666
777
888
999

VITL_006

Bubble the correct visit number:

①	Baseline	③	Week 2 / Cycle 2	⑧	Week 9 / Cycle 4	⑫	Week 15 / Cycle 6
②	Week 0 / Cycle 1	⑥	Week 6 / Cycle 3	⑩	Week 12 / Cycle 5	⑭	30 Day Follow-up

Date and Time of Vitals

DAY	MONTH	YEAR	00:00 - 23:59
	Jan ①		
	Feb ②		
00	Mar ③	00	00 : 00
11	Apr ④	11	11 : 11
22	May ⑤	22	22 : 22
33	June ⑥	33	33 : 33
	July ⑦	44	44 : 44
	Aug ⑧	55	55 : 55
	Sept ⑨	66	66 : 66
	Oct ⑩	77	77 : 77
	Nov ⑪	88	88 : 88
	Dec ⑫	99	99 : 99

VITL_000 VITL_001

Temp. (C)

00 . 0
11 . 1
22 . 2
33 . 3
44 . 4
55 . 5
66 . 6
77 . 7
88 . 8
99 . 9

VITL_002

Blood Pressure (mmHG)

Systolic	Diastolic
000	000
111	111
222	222
333	333
444	444
555	555
666	666
777	777
888	888
999	999

VITL_003 VITL_004

Pulse (beats/min)

000
111
222
333
444
555
666
777
888
999

VITL_005

Respiration (breaths/min)

000
111
222
333
444
555
666
777
888
999

VITL_006

Pre-Treatment Signs and Symptoms (PTSS)

Subject Code Number

Subject Initials

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Please record any relevant conditions (i.e., clinically significant or requiring medication) that occurred within thirty days prior to the subject's randomization date. If the NCI CTC does not apply, use the following: 1=Mild 2=Moderate 3=Severe 4=Life Threatening.

Complaint/Condition:
Please enter diagnosis only
PTSS_001

START DATE — DAY / MONTH / YEAR — PTSS_005

END DATE — DAY / MONTH / YEAR — PTSS_006

Frequency	Maximum Intensity	Medication Required
PTSS_002	PTSS_003	PTSS_004
1 Single episode 2 Intermittent 3 Continuous	Refer to NCI Common Toxicity Criteria (Protocol Appendix A) 1 2 3 4	1 Yes 2 No ***If YES, complete CMED form***

PTSS_007 (1) **Bubble here if continuing at start of study**

Complaint/Condition:
Please enter diagnosis only
PTSS_001

START DATE — DAY / MONTH / YEAR — PTSS_005

END DATE — DAY / MONTH / YEAR — PTSS_006

Frequency	Maximum Intensity	Medication Required
PTSS_002	PTSS_003	PTSS_004
1 Single episode 2 Intermittent 3 Continuous	Refer to NCI Common Toxicity Criteria (Protocol Appendix A) 1 2 3 4	1 Yes 2 No ***If YES, complete CMED form***

PTSS_007 (1) **Bubble here if continuing at start of study**

INVESTIGATOR/SITE NUMBER	PATIENT INITIALS	PATIENT NUMBER
___ ___ ___	___ ___ ___	___ ___ ___

CRF PTX Prior Therapies

☐ **Baseline**

Please circle or complete the information appropriately. If patient received multiple prior therapies, please complete this form for each line of prior treatment accordingly.

Prior Therapy

Type of Chemotherapy used:	Treatment Dates:	Line of Treatment:	Response Observed?	Progression Observed?
(Please specify) **Specify:** _____	**Start date:** ___ ___/___ ___ ___/___ ___ ___ ___ dd / mmm / yyyy **Stop date:** ___ ___/___ ___ ___/___ ___ ___ ___ dd / mmm / yyyy	*(Circle response)* **1 Adjuvant** **2 1st Line** **3 2nd Line** **4 3rd Line** **5 4th Line** **6 5th Line** **7 Other** **Specify:** _____	*(Circle response)* **1 Yes** **2 No** **3 N/A**	*(Circle response)* **1 Yes** **2 No**
Dose (mg/m²) ___ ___ ___			**Date Response Observed? (if applicable)** ___ ___/___ ___ ___/___ ___ ___ ___ dd / mmm / yyyy	**Date Progression Observed? (if applicable)** ___ ___/___ ___ ___/___ ___ ___ ___ dd / mmm / yyyy
Frequency _____			**Type of Response:** **1 Complete** **2 Partial** **3 Stable Disease**	**Resistance** **Did the patient progress during treatment?** **1 Yes** **2 No**
Total Number of Cycles _____				

CONFIDENTIAL		
INVESTIGATOR/SITE NUMBER	**PATIENT INITIALS**	**PATIENT NUMBER**
___ ___ ___	___ ___ ___	___ ___ ___

CRF (PTX1) Prior Therapies – Page 1 of 2

Indicate which chemotherapy agents (or other treatment i.e. hormonal therapy) were used in either the adjuvant and/or metastatic settings at any time for this cancer.

LINE	AGENT(S) Name / Dose / Frequency	Name / Dose / Frequency	Start Date dd/mmm/yyyy	End Date dd/mmm/yyyy
Adjuvant:	_____/_____/____ _____/_____/____	_____/_____/_____ _____/_____/_____	dd: _____ mmm: _____ yyyy:_____	dd: _____ mmm: _____ yyyy:_____
1st Line:	_____/_____/____ _____/_____/____	_____/_____/_____ _____/_____/_____	dd: _____ mmm: _____ yyyy:_____	dd: _____ mmm: _____ yyyy:_____
2nd Line:	_____/_____/____ _____/_____/____	_____/_____/_____ _____/_____/_____	dd: _____ mmm: _____ yyyy:_____	dd: _____ mmm: _____ yyyy:_____
3rd Line:	_____/_____/____ _____/_____/____	_____/_____/_____ _____/_____/_____	dd: _____ mmm: _____ yyyy:_____	dd: _____ mmm: _____ yyyy:_____
4th Line: (if more than 4 lines enter last prior chemotherapy, and indicate line of therapy: _____)	_____/_____/_____ _____/_____/_____	_____/_____/_____ _____/_____/_____	dd: _____ mmm: _____ yyyy:_____	dd: _____ mmm: _____ yyyy:_____

CONFIDENTIAL		
INVESTIGATOR/SITE NUMBER	**PATIENT INITIALS**	**PATIENT NUMBER**
___ ___ ___	___ ___ ___	___ ___ ___

CRF (PTX2) Prior Therapies – Page 2 of 2

Continuing from PTX1 (refer page 1 of 2) please circle clinical response corresponding to the appropriate line of treatment.

LINE (contd. from PTX1)	RESPONSE OBSERVED Yes / No / n/a	TYPE OF RESPONSE Complete /Partial/Stable (CR) (PR) (SD)	Date of Response (if applicable) dd/mmm/yyyy	Date of Progression (if applicable) dd/mmm/yyyy	RESISTANCE Did patient progress during treatment – Yes/No
Adjuvant:	YES NO N/A	CR PR SD	dd: _____ mmm: _____ yyyy: _____	dd: _____ mmm: _____ yyyy: _____	YES NO
1st Line:	YES NO N/A	CR PR SD	dd: _____ mmm: _____ yyyy: _____	dd: _____ mmm: _____ yyyy: _____	YES NO
2nd Line:	YES NO N/A	CR PR SD	dd: _____ mmm: _____ yyyy: _____	dd: _____ mmm: _____ yyyy: _____	YES NO
3rd Line:	YES NO N/A	CR PR SD	dd: _____ mmm: _____ yyyy: _____	dd: _____ mmm: _____ yyyy: _____	YES NO
4th Line: (if more than 4 lines enter last prior chemotherapy)	YES NO N/A	CR PR SD	dd: _____ mmm: _____ yyyy: _____	dd: _____ mmm: _____ yyyy: _____	YES NO

Initials / Date
Study Monitor: _____ / _____
Data Mgmt Review: _____ / _____

SUBJECT CODE NUMBER ___ ___ ___

SUBJECT INITIALS ___ ___ ___

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

CBC and Differential Panel

Visit
□ **Baseline Visit**
□ Week 0/Cycle 1 Visit
□ Week 3/Cycle 2 Visit
□ Week 5 Visit
□ Week 6/Cycle 3 Visit
□ Week 9/Cycle 4 Visit
□ Week 12/Cycle 5 Visit
□ Week 15/Cycle 6/End of Study visit
□ 30 Day follow Up Visit
□ Six Month Follow Up Visit
□ Survival Endpoint
□ Unscheduled Visit

Date Sample Collected: __ __/__ __ __/__ __ __ __ dd mmm yyyy	Time Sample Collected: _____:_____ (00:00-23:59)

Test name (units)	Value	Clinically significant Yes	Clinically significant No	Comment *Please indicate whether any clinically significant abnormalities since baseline are to be reported as adverse events.*
Hemoglobin (g/dL)		[ ]	[ ]	
Hematocrit (%)		[ ]	[ ]	
RBC ($X10^6$)		[ ]	[ ]	
Mean Cell Volume (μ^3)		[ ]	[ ]	
Mean Cell Hemoglobin (pg)		[ ]	[ ]	
Mean Cell Hemoglobin Conc. (%)		[ ]	[ ]	
Platelet Count ($X10^3$)		[ ]	[ ]	
WBC ($X10^3$)		[ ]	[ ]	
Neutrophils-Segs (%)		[ ]	[ ]	
Neutrophils-Bands (%)		[ ]	[ ]	
Lymphocytes (%)		[ ]	[ ]	
Monocytes (%)		[ ]	[ ]	
Eosinophils (%)		[ ]	[ ]	
Basophils (%)		[ ]	[ ]	
Neutrophils Absolute		[ ]	[ ]	
Monocyte Absolute		[ ]	[ ]	
Lymphs Absolute		[ ]	[ ]	
Eos Absolute Value		[ ]	[ ]	
Other (Specify): _____		[ ]	[ ]	

SUBJECT CODE NUMBER
___ ___ ___

SUBJECT INITIALS
___ ___ ___

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Clinical Chemistry Panel

Visit
□ **Baseline Visit**
□ Week 0/Cycle 1 Visit
□ Week 3/Cycle 2 Visit
□ Week 5 Visit
□ Week 6/Cycle 3 Visit
□ Week 9/Cycle 4 Visit
□ Week 12/Cycle 5 Visit
□ Week 15/Cycle 6/End of Study visit
□ 30 Day follow Up Visit
□ Six Month Follow Up Visit
□ Survival Endpoint
□ Unscheduled Visit

Date Sample Collected: ___ ___/__ __ __/__ __ __ __ (dd mmm yyyy)	Time Sample Collected: _____:_____ (00:00-23:59)

Test name (units)	Value	Clinically significant Yes	Clinically significant No	Comment *Please specify whether any clinically significant abnormalities since baseline are to be reported as adverse events.*
AST (SGOT) (U/L)		[ ]	[ ]	
ALT (SGPT) (U/L)		[ ]	[ ]	
Alkaline Phosphatase (U/L)		[ ]	[ ]	
BUN (mg/dL)		[ ]	[ ]	
Creatinine (mg/dL)		[ ]	[ ]	
T. Bilirubin (mg/dL)		[ ]	[ ]	
Albumin (g/dL)		[ ]	[ ]	
Uric Acid (mg/dL)		[ ]	[ ]	
Sodium (mEq/L)		[ ]	[ ]	
Potassium (mEq/L)		[ ]	[ ]	
Chloride (mEq/L)		[ ]	[ ]	
Glucose (mEq/L)		[ ]	[ ]	
Calcium (mg/dL)		[ ]	[ ]	
Phosphorus (mg/dL)		[ ]	[ ]	
Total Protein (g/dL)		[ ]	[ ]	
Other (Specify): _____		[ ]	[ ]	
Other (Specify): _____		[ ]	[ ]	

SUBJECT CODE NUMBER
___ ___ ___

SUBJECT INITIALS
___ ___ ___

An Open Label Study of ABI-007 and TAXOL® in Subjects with Metastatic Breast Cancer.

Protocol CA012-0

Serum β-hCG Pregnancy Test

Visit
□ Baseline
□ Week 15/Cycle 6/EOS

Date Sample Collected: __ __/__ __ __/__ __ __ __ dd mmm yyyy	Test Result: [ ] Positive [ ] Negative

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INVESTIGATOR/SITE NUMBER	PATIENT INITIALS	PATIENT NUMBER
___ ___ ___	___ ___ ___	___ ___ ___

PK Hematology Collection

All whole blood samples (~5 ml) in EDTA containing tubes will be obtained during and after the 30 minute IV infusion at the following time points: 0, 15 30 (end of infusion), 45 minute; 1 hour, 1.25, 1.5, 2, 3, 4, 6, 9, 12, 15, 24, 36, 48, 60, and 72 hours post dose (n = 19 samples/dose). Blood samples should be collected once for each period after the initial infusion of the study medication. Record the exact time period that the blood samples were collected.

Dates of Blood Collection	__ __/__ __ __/__ __ __ __ **to** __ __/__ __ __/__ __ __ __ dd mmm yyyy dd mmm yyyy

Sample Collected	Time Collected (0:00 – 23:59)	Comments
0 Minutes start of study medication infusion	_____:_____	
15 Minutes during study medication infusion	_____:_____	
30 Minutes end of study medication infusion	_____:_____	
45 minutes post study drug infusion	_____:_____	
1 Hour post study drug infusion	_____:_____	
1.25 Hours post study drug infusion	_____:_____	
1.5 Hours post study drug infusion	_____:_____	
2 Hours post study drug infusion	_____:_____	
3 Hours post study drug infusion	_____:_____	
4 Hours post study drug infusion	_____:_____	
6 Hours post study drug infusion	_____:_____	
9 Hours post study drug infusion	_____:_____	
12 Hours post study drug infusion	_____:_____	
15 Hours post study drug infusion	_____:_____	
24 Hours post study drug infusion	_____:_____	
36 Hours post study drug infusion	_____:_____	
48 Hours post study drug infusion	_____:_____	
60 Hours post study drug infusion	_____:_____	
72 Hours post study drug infusion	_____:_____	

INVESTIGATOR/SITE NUMBER	PATIENT INITIALS	PATIENT NUMBER
___ ___ ___	___ ___ ___	___ ___ ___

PK Urine Collection

All urine samples must be obtained for the following time periods following ABI-007 administration: pre-dose, 0-6, 6-12, 12-24, 24-48, 48-72, 72-96, and 96-120 hours post dose (n = 8 samples/dose). Urine should be collected in eight separate containers. Record the exact time period the urine samples were collected.

Dates of Urine Collection	__ __/__ __ __ /__ __ __ __ **to** __ __/__ __ __/__ __ __ __ dd mmm yyyy dd mmm yyyy

Sample Collected	Time Collected (0:00-23:59)	Comments
Pre-dose – before study medication infusion	_____:_____	
0 – 6 Hours post study medication infusion	_____:_____	
6 – 12 Hours post study medication infusion	_____:_____	
12 – 24 Hours post study medication infusion	_____:_____	
24 – 48 Hours post study medication infusion	_____:_____	
48 – 72 Hours post study medication infusion	_____:_____	
72 – 96 Hours post study medication infusion	_____:_____	
96 - 120 Hours post study medication infusion	_____:_____	

CONFIDENTIAL

INVESTIGATOR/SITE NUMBER	PATIENT INITIALS	PATIENT NUMBER
___ ___ ___	___ ___ ___	___ ___ ___

PK Fecal Collection

All feces should be collected following ABI-007 administration from 0 – 5 days (120 hours); if the patient does not have a bowel movement on day 5, feces should be collected at the next bowel movement. Please record the exact day and date the fecal sample was collected.

Sample Collected	Day Collected (Please circle)	Date Collected	Time (0:00 – 23:59)	Comments
0 – 5 Days (120 hours) post study medication infusion	1 2 3 4 5	__ __/__ __ __/_ _ _ _ dd mmm yyyy	______:______	
0 – 5 Days (120 hours) post study medication infusion	1 2 3 4 5	__ __/__ __ __/_ _ _ _ dd mmm yyyy	______:______	
0 – 5 Days (120 hours) post study medication infusion	1 2 3 4 5	__ __/__ __ __/_ _ _ _ dd mmm yyyy	______:______	
0 – 5 Days (120 hours) post study medication infusion	1 2 3 4 5	__ __/__ __ __/_ _ _ _ dd mmm yyyy	______:______	
0 – 5 Days (120 hours) post study medication infusion	1 2 3 4 5	__ __/__ __ __/_ _ _ _ dd mmm yyyy	______:______	
0 – 5 Days (120 hours) post study medication infusion	1 2 3 4 5	__ __/__ __ __/_ _ _ _ dd mmm yyyy	______:______	
0 – 5 Days (120 hours) post study medication infusion	1 2 3 4 5	__ __/__ __ __/_ _ _ _ dd mmm yyyy	______:______	
0 – 5 Days (120 hours) post study medication infusion	1 2 3 4 5	__ __/__ __ __/_ _ _ _ dd mmm yyyy	______:______	
0 – 5 Days (120 hours) post study medication infusion	1 2 3 4 5	__ __/__ __ __/_ _ _ _ dd mmm yyyy	______:______	
Next bowel movement post study medication, but beyond 0 -5 days	________	__ __/__ __ __/_ _ _ _ dd mmm yyyy	______:______	

Initials / Date
ABI Monitor: ______ /_______
Data Review: _______ /_______

INVESTIGATOR/SITE NUMBER	PATIENT INITIALS	PATIENT NUMBER
___ ___ ___	___ ___ ___	___ ___ ___

Protocol Deviation Form

When a protocol deviation has occurred it must be confirmed by the monitor and signed off on by the PI.

Date of deviation: ___ ___ / ___ ___ ___ / ___ ___ ___ ___
dd mmm yyyy

Monitor's signature: _____.
Monitor's printed name: _____.

Specify and comment on deviation(s):

_____

_____

_____

_____

_____

Investigator's Statement: *I am aware that the protocol deviation listed above has occurred and feel that it is justified due to the following circumstances:*

_____

_____

_____

_____

Investigator's Signature: _____.

Date: ___ ___ / ___ ___ ___ / ___ ___ ___ ___
dd mmm yyyy

CONFIDENTIAL

INVESTIGATOR/SITE NUMBER	PATIENT INITIALS	PATIENT NUMBER
___ ___ ___	___ ___ ___	___ ___ ___

Comments Page

Reference CRF Page	Comments

Siganture: ______________________________	__ __/__ __ __/__ __ __ __ dd mmm yyyy

AMERICAN BIOSCIENCE, INC
Protocol: CA012-0
ABI-007 Phase III

Initials / Date
ABI Monitor: ______ /_______
Data Review: _______ /_______