

CANCER DIAGNOSIS (I) / PRIOR HORMONAL CONTROL (I)

BCD1/BHC1

Project No.	Protocol No.	Patient Initials	Pat	tient Alloc. No.		Visit No. 0	
RP 56976V	327					Baseline	
		first middle I	ast			Registration Form	
INFORMED CONSENT							
Date informed consent obta	Date informed consent obtained: dd mm yyyy						
CANCER DIAGNOSIS I							
			De	escription			
Primary	Tumor Type		F	Prostate			
Date of F	irst Diagnosis:		dd	mm yyyy			
Histolo	ogical Type	□1 A	denoca	ırcinoma			
	(ν) one only)	□94 O	ther, sp	ecify:			
RADIOTHERAPY I							
Did patient receive prior rac ☐0 No ☐1 Yes	diotherapy?						
Stop Date of Last Radiothe	erapy: Lilling	уууу					
Did the patient receive prio	r radiotherapy including mor	re than 25%	of the b	one marrow?	□0 N	o □1 Yes	
PRIOR ESTRAMUSTINE	THERAPY I						
Did patient receive prior ora ☐0 No ☐1 Yes ☐		ination, spec	ify:				
Stop Date of Estramustine	therapy:	mm yyyy	<u></u>				
PRIOR HORMONAL CON	TROL I						
Did the patient receive prio ☐0 No ☐1 Yes	r hormonal manipulation?						
Method of cast □1 Orchie		-RH agonist	S*				
Testosterone le	evel: ng/o	dL					
Did the patient receive anti-androgens? ☐ No ☐ 1 Yes							
	☐1 Flutamide / Nilutamide Cyproterone acetate	e /	Stop D	Oate: dd	mm	уууу	
	☐2 Bicalutamide		Stop D		mm	уууу	
*This treatment should be c	ontinued.						
Investigator Name:			nvestig	gator Number:			



PROGRESSION AT STUDY ENTRY /

PAIN EVALUATION

☐3 Appearance of new lesions on BONE SCAN:

 \square 4 Rising PSA (mandatory if no PD elsewhere)

BPSE/BPSA1/BPSA2/BPSA3/BPSA4/BPAE

Project No.	Protocol No.	Patient Initials	Patient Alloc. No.	Visit No. 0
RP 56976V	327	first middle last		Baseline Registration Form
PROGRESSION AT STUD	Y ENTRY			
☐1 Objective progression of	on (uni- or bidimensionally)	MEASURABLE	LESIONS:	
Organ:		Subsite:		
Date of progression:	dd mm yyyy			
☐2 Progression on NON M	MEASURABLE lesions (exce	ept bone):		
Organ:		Subsite:		
Date of progression:	dd mm yyyy			

BASELINE PSA

Date of progression: L

In case of rising PSA at study entry, record as many PSA values as needed to evidence the protocol-defined rising PSA. In case of non-rising PSA, record the baseline PSA value as Measure 1 (the closest to randomization) and do not complete the other PSA values.

		Measure 1		Measure 2	Measure 2			Measure 4#	
	Ω	Date of Sample:							
	led Units	dd mm yyyy							
Test	Recommended	Result	Actual units*	Result	Actual units*	Result**	Actual units*	Result**	Actual units*
PSA	ng/mL								

^{*} Complete only if differs from recommended.

PAIN EVALUATION

To be averaged over 7 consecutive days. The 7th value should be obtained within 3 days prior to randomization.

Date of Assessment		Present Pain Intensity	Analgesics Score
1st day	dd mm yyyy		
2nd day			
3rd day			
4th day			
5th day			
6th day			
7th day	dd mm yyyy		

^{**} Should be > 5 ng/mL in case rising PSA is the only sign of progression at study entry.

[#] If Measure 3 not greater than Measure 2.



Project No.

BLOOD CHEMISTRY / HEMATOLOGY / VITAL SIGNS (I)

Protocol No.

BBC/BH/BVS1

Visit No. 0

RP 56976V		327		first mi	ddle last						Registratio		I										
LAB NAME:				7 1	HEMAT	ΤΟ	LO	GY															
LAB ADDRESS									vithin 14 d	ays	prior to rando	mization	٦.										
LABID:										D	ate of Sample												
BLOOD CHEMISTE To be performed wit		lays prior to randomizat	tion.						d units		dd mm	уууу	_										
Test	Recommended units	Date of Sample:			Test		Test		Test		Test		Test		Test		Test		Recommended units		Result	Actual units*	
1631	mend	Dec II	Actual units*		HEMOGLOE	BIN			g/dL														
	Сош	Result	ctual		PLATELETS	S			10 ⁹ /L														
	_ &		₹		WBC				10 ⁹ /L														
CREATININE	mg/dL				NEUTROPH	HILS			10 ⁹ /L				_										
TOTAL PROTEIN	g/dL																						
ALBUMIN	g/dL																						
ALKALINE PHOSPHATASE	IU/L																						
ASAT (SGOT)	IU/L				-				s from recon														
ALAT (SGPT)	IU/L										OR REPEAT TESTS . DRATORY PAGES SH												
TOTAL BILIRUBIN	mg/dL]	USED.																		
LDH	IU/L																						
SODIUM	mmol/L																						
POTASSIUM	mmol/L																						
CALCIUM	mmol/L																						
α1 ACID GLYCOPROTEIN#	g/L																						
* Complete only if differs f	rom recor	mmended																					
# Only in patients with PK	samples																						
IF ADDITIONAL TESTS (NOT SPECIFIED ABOVE) OR REPEAT TESTS ARE PERFORMED, ADDITIONAL PULL & INSERT LABORATORY PAGES SHOULD BE USED.																							
VITAL SIGNS I											□0	NOT done	∍										
To be performed wit the date of randomize		lays prior to randomizat	tion.	Please	erecord	be	elow	the a	assessme	nt p	erformed the	closest t	to										
Date of Assessmen	t: _																						

Patient Initials

Patient Alloc. No.

mm

Karnofsky Performance Status



PATIENT WORKUP / LEFT VENTRICULAR EJECTION FRACTION

$\mathbf{BPW/BLV}$

Proje	ect No. RP 56976V	Protocol No.	Patient Initials	Patient	t Alloc. No.	Visit 1	^{No. 0} Baseli	20
	first		first middle last			Re	egistratio	
PAT	TENT WORKUP							
To b	pe performed within 21	days prior to randomization.						
		Type of Evaluation			Date Assessed (dd/mm/yyyy)	b		mor /ement
1	Chest X-Ray				□o Not Done		□o No	□1 Yes
2	Chest CT Scan				□o Not Done		□o No	□1 Yes
3	Pelvic CT Scan			l	□0 Not Done		□o No	□1 Yes
4	Abdominal CT Scan				□0 Not Done		□o No	□1 Yes
5	Bone Scan (i.e., scintiç	graphy)			□0 Not Done		□o No	□1 Yes
94	Other, specify						□o No	□1 Yes
94	Other, specify						□o No	□1 Yes
94	Other, specify						□o No	□1 Yes
				•				
	T VENTRICULAR EJE be performed within 14	ECTION FRACTION days prior to randomization.	(check () one or	nly)				
□ 1	Radionuclide angiocard	diography (MUGA scan)	☐2 Echoca	ardiog	raphy			
	Date of Assessment:			Date of Assessment:				
	Value: / / %		Value:					
	Lower limit of normal for	or the institution:	% Lower	limit c	of normal for the in	stitutio	on:	%



BSEC STUDY ENTRY CRITERIA

Project No.	Protocol No. Patient Initials Patient Alloc. No.		Visit No. 0	
RP 56976V	327	first middle last		Baseline Registration Form

ST	UDY ENTRY CRITERIA			
EX	CLUSION CRITERIA			
1.	Prior cytotoxic chemotherapy, except monotherapy with oral estramustine.	No [] \	Yes
2.	Prior isotope therapy (e.g., strontium, samarium,)	No [] \	Yes
3.	Prior radiotherapy to > 25% of bone marrow (whole pelvic irradiation is not allowed).	No [] \	Yes
4.	Prior malignancy except the following: adequately treated basal cell or squamous cell skin cancer, or any other cancer from which the patient has been disease–free for \geq 5 years.	No [] \	Yes
5.	Known brain or leptomeningeal involvement.	No [] \	Yes
6.	Symptomatic peripheral neuropathy \geq grade 2 according to the NCI Common Toxicity Criteria.	No [] \	Yes
7.	Other serious illness or medical condition:			
	- congestive heart failure even if controlled. Previous history of myocardial infarction or angina pectoris within 1 year from study entry, uncontrolled hypertension or uncontrolled arrhythmias.	No [] \	Yes
	- active uncontrolled infection.	No [] \	Yes
	 peptic ulcer, unstable diabetes mellitus or other contraindications for the use of corticosteroids. 	No [] \	Yes
	- auto-immune disease (lupus, sclerodermia, rheumatoid polyarthritis).	No [] \	Yes
8.	Concurrent treatment with other experimental drugs. Participation in another clinical trial with any investigational drug within 30 days prior to study screening.	No [] \	Yes
9.	Concurrent treatment with any other anti-cancer therapy (except LHRH agonists).	No [] \	Yes
10.	Concomitant treatment with systemic corticosteroids used for reasons other than specified by the protocol.	No [] \	Yes
11.	Concomitant treatment with bisphosphonates.	No [] \	Yes
INC	CLUSION CRITERIA			
12.	Life expectancy ≥ 3 months.	No [] \	Yes
13.	Patients must be accessible for treatment and follow-up. Patients registered on this trial must be treated and followed at the participating center. Patients receiving weekly docetaxel who live distal to the center may receive treatments at weeks 2, 3 and 5 of each cycle locally, but under the advice and direction of a trial investigator.	No [] \	Yes



BPD PATIENT DEMOGRAPHICS

Project No.	Protocol No.	Patient Initials Patient Alloc. No.		Visit No. 0
RP 56976V	327			Baseline
		first middle last		

RANDOMIZATION		
Date of randomization:	dd mm yyyy	

DATE OF BIRTH / SEX	
Date of birth:	dd mm yyyy
Sex:	∑ 1 Male

RACE				
(check (✓) one only)				
☐1 Caucasian				
□2 Black				
☐3 Oriental				
☐4 Hispanic				
94 Other, specify				



MEDICAL HISTORY / PRIOR / CONCOMITANT MEDICATION

BMH/BPCM

MEDICAL HISTORY	FRIOR	/ CON	COMI	IANT MEDICA	4110 1	. 1)	DI CIVI
Project No. RP 56976V	Protocol No	327		Patient Initials	Patient	Alloc. No.	Visit N	o. 0 Baseline
GENERAL MEDICAL / SU CONDITIONS, OTHER TH					MEDIC	CAL		□0 NONE
Please enter any significant a prostate cancer.	and releva	nt medica	l/surgica	I history and concor	nitant m	edical conditions of	the pat	ient other than
Allergic history and cardiac history should be thoroughly documented. Any changes occurring during the study will be recorded on the Adverse Events form of the appropriate cycle.								
	Descrip	otion			С	Date of Onset (dd/mm/yyyy)		Pate Ceased (dd/mm/yyyy) or ✓ if ongoing
								1 ongoing
								1 ongoing
								1 ongoing
								1 ongoing
PRIOR / CONCOMITANT Please describe below any me infusion, excluding corticos the approximate Total Daily D	edications a	and / or the	erapies r nuno an	eceived by the patie				
Drug (Brand Name)	Route	Total Dose		Start Date (dd/mm/yyyy	<i>(</i>)	Stop Date (dd/mm/yyyy or ⊬ if ongoing	,	Indication 5: Prophylaxis 6: Curative or symptomatic
						☐1 ongoing		-,,,,
						☐1 ongoing		
						1 ongoing		
						☐1 ongoing		
						☐1 ongoing		
						☐1 ongoing		



CONCOMITANT MEDICATION (DIARY ANALGESICS ONLY)

RPCM_DA

CONCOMITANT MEDICATION (DIAKT ANALGESICS ONLI) Brem-DA							7					
Project No.			Protocol No.		Patient Initia	als	Patient Allo	c. No.		Visit No. 0		
RP 569	76V			327						В	aseline	
					first middl	e last						
CONCOMITAN	JT MF	DICAT	IONS									
				t Pain Diary sho	uld be re	cordec	l in this m	odule.			□0 N	ONE
						(Dose 7-day per	e of Analo iod of the	jesics Pain Di	ary)		
Drug (Brand Name)	Route		art Date mm/yyyy)	Stop Date (dd/mm/yyyy) or check if ongoing	1st Day	2nd Day	3rd Day	4th Day	5th Day	6th Day	7th Day	Unit
					_							
				□0 ongoing								
				□0 ongoing								
				□0 ongoing								
				□0 ongoing								
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				□0 ongoing								
				□ ongoing								



CANCER DIAGNOSIS (II) / PRIOR SURGERY FOR CANCER / PRIOR RADIOTHERAPY

BCD2/BPS/BPR

Project No.	Protocol No.		Patien	t Initials	Patient Alloc. No.	Visit No. 0		
RP 56976V	32	27				Baseline		
			first	middle last				
CANCER DIAGNOSIS (II)								
Record TNM stage and Glo	eason score a	t FIRST DI	AGNOSI	S				
					Description			
	T:		N:		M:			
TNM/Stage					_	_		
(if not assessed, please enter 2	X)							
	pT:		pN:	:	pM:			
Histopathological Grade	e	□2 G2	□з G	i3 □4 G	4 □5 GX			
Staging								
Gleason Score				1		☐1 Not Assessed		
(should be between 2 and 10)							
PRIOR SURGERY FOR C	ANCER, EXC	LUDING O	RCHIEC	TOMY, AD	RENALECTOMY OR	□o NONE		
	HYPOPHYSECTOMY Please describe below any cancer-related surgery the patient has undergone							
Date of Surgery	- Carloor Tolace		tile patie					
(dd/mm/yyyy)	Operative procedure							
	_ □1 Prostatectomy							
5 Pelvic Lymphadenectomy								
	94 Other, spec	ify						
PRIOR RADIOTHERAPY	(II)					□0 NONE		
Please describe below any	prior radiothe		F ::					
		% Irra-		mated Dose	a = .	Stop Date		
Organ (check (✓) one onl	v)	diated	(speci	fy units)	Start Date (dd/mm/yyyy)	(dd/mm/yyyy)		
	,,	Bone Marrow	Dose	Units		(Stop Date: date of last treatment)		
☐1 Prostate				П. о				
☐2 Pelvic Lymph Nodes				∐1 Gy				
☐3 Bone Palliation				∐2 rads				
□94 Other, specify:				∐з сGy				
☐1 Prostate								
								
☐2 Pelvic Lymph Nodes				□1 Gy				
□2 Pelvic Lymph Nodes□3 Bone Palliation				2 rads				
☐3 Bone Palliation ☐94 Other, specify:								
☐3 Bone Palliation ☐94 Other, specify: ☐1 Prostate				2 rads 3 cGy				
□3 Bone Palliation □94 Other, specify: □1 Prostate □2 Pelvic Lymph Nodes				2 rads 3 cGy				
☐3 Bone Palliation ☐94 Other, specify: ☐1 Prostate				2 rads 3 cGy				



PRIOR HORMONAL CONTROL (II) SURGICAL THERAPY/MEDICAL THERAPY / PRIOR ESTRAMUSTINE

BST/BHCMT/BPEST

RP 56976V	327		first mid		Patient Alloc. No.	Baseline		
PRIOR HORMONAL CO	ONTROL (II): SURGIC	AL THE	RAPY		s undergone	□0 NONE		
Date of Surgery (dd/mm/yyyy)					procedure			
	☐1 Bilateral Orchiecto	1 Bilateral Orchiectomy						
	☐2 Bilateral Adrenaled	2 Bilateral Adrenalectomy						
	☐3 Hypophysectomy							
	□94 Other, specify							
PRIOR HORMONAL CO	ONTROL (II): MEDICA	L THEF	RAPY					
	Product Name product if contained in a comb				Start Date (dd/mm/yyyy)	Stop Date (dd/mm/yyyy) or ⊬ if ongoing		
,			,					
						1 ongoing		
						1 ongoing		
						□1 ongoing		
PRIOR ESTRAMUSTIN	E (II)					□o NONE		
Dru (Brand N	_	Route	Total Do Dose		Start Date (dd/mm/yyyy)	Stop Date (dd/mm/yyyy)		



PRIOR CORTICOSTEROID THERAPY / VITAL SIGNS (II) / PHYSICAL EXAMINATION / ELECTROCARDIOGRAM

BPCT/BVS/BPE/BECG

Project No.	Protocol No.	Pati	ent Initials	Patient Alloc. No.	Visit No. 0			
RP 56976V	327				Baseline			
		fire	st middle last					
PRIOR CORTICOSTEROI	D THERAPY				□0 NONE			
Drug	Route	Total Dai	-	Start Date	Stop Date			
(Brand Name)	rioute	Dose	Unit	(dd/mm/yyyy)	(dd/mm/yyyy)			
NUTAL CIONO (II)								
VITAL SIGNS (II)					□0 NOT done			
Date of Assessment:	d mm yyyy							
V	Veight			Height				
	•							
]1 lb							
]2 kg			□2 cm				
PHYSICAL EXAMINATION	N, OTHER THAN	CANCER			□0 NOT done			
Date Physical Exam Perfor		1 1 11 1	1					
Date i flysiodi Exami i enoi	meu.	dd mm	уууу					
ELECTROCARDIOGRAM					□0 NOT done			
Date of Tracing:	mm yyyy							
Interpretation (check () one								
☐₁ Within normal lim								
2 Non-significant a	bnormalities							
☐3 Significant abnor	malities, complete	EXISTING SIGNS	S AND SYMPTOMS	form.				



Project No.

Protocol No.

BTA TUMOR ASSESSMENT

Patient Initials

Patient Alloc. No.

Visit No. 0

R	RP 56976V 327					Baseline		
TUMOR	ASSESSMENT							
N	laintain the same	numbering of les	ions (1, 2	rm using ALI) throughout t throughout	L DISEASE SITE the study and re the study.	ES. peat the sai	me me	ethods of
Lesion Number (Ex: 1, 2)	Orga a: Site (enter the appr 1: Bone (complete als 2: Lymph Node 3: Liver 4: Lung 5: Other Soft Tissue, s 94: Other Organ, spec b: Subsite (description	o checklist) specify ify	Asses	te of ssment ^{m/yyyy)}	Method of Measurement (Enter appropriate number) 1: Physical exam 2: X-Ray 4: CT scan 5: MRI 6: Ultrasound 7: Radionuclide (i.e. Bone Scan) 94: Other, specify	Measurak (Enter appropriment) 1: Bidimension measurable 2: Unidimension measurable 5: Non measu	oriate) nally e onally e	Measurement (mm x mm)
	a							×
	a							×
	a							×
	a							×
	a							×
	a							×
	a							×



BONE CHECK LIST BBCL

Project No.	Protocol No.	Patient Initials	Patient Alloc. No.	Visit No. 0
RP 56976V	327	first middle last		Baseline

BONE CHECK LIST To be completed in case of bone scan showing metastatic lesion						
Hot Spot Location	Number of Hot Spots					
□1 Skull/Head						
□2 Spine						
☐з Pelvis						
☐4 Ribs/Sternum/Clavicle/Shoulder Blade						
☐5 Upper Limbs						
☐6 Lower Limbs						



EXISTING SIGNS AND SYMPTOMS

BESS

Project No.	Protocol No.	Patient Initials	Patient A	Alloc. No.		Visit No. 0		
RP 56976V	327	first middle last				Baseline		
EXISTING SIGNS AND SYMPTOMS Please describe below any signs and symptoms reported at study entry whether related to previous or ongoing therapies or disease. Any relevant sign and symptom which occurred in the past two weeks should also be reported. During the study all ongoing signs and symptoms will be followed on the Adverse Event (AE) form at the appropriate cycle.								
Signs and Symptoms [Diagnosis if known or sign/symptom] (one term per row)		Date of Onset (dd/mm/yyyy)	((com	OUTCOME mplete only ONE column) Resolved date ceased (dd/mm/yyyy)		Grade (1-4)	
CS-FAT	Fatigue			□ 1		esolved		
PA-BON	Bone Pain			□ 1		esolved		
GU-DYS	Dysuria (painful urination)			□ 1		esolved		
GU-INC	Incontinence			□ 1		esolved		
GU-RET	Urinary Retention			□1		esolved		
MS-OTH	Pathological fracture			□ 1		esolved		
ОТ-ОТН	Spinal Cord Compression			□1		esolved		
				□1		esolved		
				□1		esolved		
				□ 1		esolved		
				□ 1		esolved		
				□1		esolved		
				□ 1		esolved		
				□ 1		esolved		
In case of AE code is 0	OT-OTH, grade severity as: 1=	Mild, 2=Moderate,	, 3=Sev	ere, 4	Life Threa	atening		
Investigator Name:		Inve	stigator	Numb	er:			



STUDY MEDICATION ADMINISTRATION

SMA1/SMA2

Project No.	Protocol No.	Patient Initials	Patient Alloc. No.	Visit No.
RP 56976V	327	first middle last		Cycle N°

STUDY MEDICATION ADMINISTRATION (I) First infusion of the cycle (Arm A, B or C) - Dose delayed / reduced is not applicable for cycle 1.								
Dose Delayed* (see definitions below)	Start Date	Study Drug	Dose Reduced* (see definitions below)	Intended Dose (mg/m²)	Total Dose Given (mg)			
□o No □1 Yes⇒□□□	dd mm yyyy	☐17 Mitoxantrone ☐2 Docetaxel☐1 q3w ☐2 qw	□ 0 No □ 1 Yes ⇒ □ □					
Setting: 1 Outpatient Clinic 2 Inpatient Clinic (fill in Inpatient Care form)								

- 2: Hematological toxicity (including infection, or fever with neutropenia)
- 3: Non-hematological toxicity
- 4: Both

94: Other, specify

PREDNISONE ADMINISTRATION								
Study Drug	Route	Start Date or ⊬ if ongoing	Stop Date or ⊬ if ongoing	Total Daily Dose (mg)				
□18 Prednisone		dd mm yyyy	dd mm yyyy					

^{1:} Non-study drug related adverse experience(s) Study Drug Related:



o No

]ı Yes⇒

STUDY MEDICATION ADMINISTRATION

2

SMA3/SMA6

o No

☐1 Yes ⇒

Project No.	Pr	otocol No.	Patient Initials	Patient Alloc. No.	Visit No.	
RP 56976V		327	first middle last		Cycle	N° L
STUDY MEDICATION For weekly arm only		NISTRATION (II)			□1 NOT	APPLICABLE
Dose Delayed* (see definitions below)	Infusion Number	Start Date	Study Drug	Dose Reduced* (see definitions below)	Intended Dose (mg/m²)	Total Dose Given (mg)

Setting:	∐₁ Out	tpatient Cli	nic ∐2	Inpatient C	linic (fill in Inpatie	ent Care form)	
0 No 1 Yes =	*	3	dd mm yyy	уу 2	Docetaxel	0 No 1 Yes ⇒	
Setting:	□1 Out	tpatient Cli	nic \square_2	Inpatient C	Clinic (fill in Inpatie	ent Care form)	

2

Docetaxel

□0 No □1 Yes⇒□□	4	dd mm yyyy	2	Docetaxel	□0 No □1 Yes⇒□□	
Setting: 🗆 1 Out	tpatient Cl	inic 🗆 2 Inpa	atient C	Clinic (fill in Inpatio	ent Care form)	

□0 No □1 Yes⇒□□□	5	dd mm yyyy	2	Docetaxel	□0 No □1 Yes⇒□□□	
G. III. G				NI da ann a an an		

Setting: □1 Outpatient Clinic ☐2 Inpatient Clinic (fill in Inpatient Care form) 1: Non-study drug related adverse experience(s)

mm

уууу

Study Drug Related: 2: Hematological toxicity (including infection, or fever with neutropenia)

3: Non-hematological toxicity

4: Both

94: Other, specify



HEMATOLOGY H1/H6

Project No.	Protocol No.	Patient Initials	Patient Alloc. No.	Visit No.
RP 56976V	327	first middle last		Cycle Nº

HEMATOLOGY ☐0 NOT done To be performed on Day 1 before infusion and every 2 days in case of febrile neutropenia or infection up to fever < 38.0 $^{\circ}$ C and ANC \geq 1.0 x 10⁹/L. Date of Sample: Date of Sample: Date of Sample: dd mm yyyy Recommended units Test Actual units* Result Actual units* Result Actual Result HEMOGLOBIN g/dL 10⁹/L **PLATELETS** 10⁹/L WBC 10⁹/L NEUTROPHILS

* Complete only if differs from recommended

		Date of Sample:		Date of Sample:		Date of Sample:	
	d units	dd mm yy	уу	dd mm yy	уу	dd mm yyy	УУ
Test	Recommended units	Result	Actual units*	Result	Actual units*	Result	Actual units*
HEMOGLOBIN	g/dL						
PLATELETS	10 ⁹ /L						
WBC	10 ⁹ /L						
NEUTROPHILS	10 ⁹ /L						
* Complete on	ly if differe f	rom recommended					



BLOOD CH	HEMIS	ΓRY						BC1/B	SC3
Project No.		Protocol No.		Patient Initials	Patient All	loc. No.		Visit No.	
RP 56	976V	327		first middle last				Cycle No	
		To be performed e	very 3 w	eeks (Day 1 befo	ore infus	sion)		□0	NOT done
		The check if laboratory is the same otherwise complete below. LAB NAME LAB ADDRESS: LABID:	e as baseline;	1 Check if laboratory is otherwise complete below LAB NAME_ LAB ADDRESS: LABID:		baseline;			e as baseline;
BLOOD CHEMISTRY									
		Date of Sample:		Date of Sample	e:		Date o	f Sample:	
	d units	dd mm yy	уу	dd mm	уууу		dd	mm y	ууу
Test	Recommended units	Result	Actual units*	Result		Actual units*		Result	Actual units*
PSA	ng/ml								
CREATININE	mg/dL								
TOTAL PROTEIN	g/dL								
ALBUMIN	g/dL								
ALKALINE PHOSPHATASE	IU/L								
ASAT (SGOT)	IU/L								
ALAT (SGPT)	IU/L								
TOTAL BILIRUBIN	mg/dL								
LDH	IU/L								
SODIUM	mmol/L								
POTASSIUM	mmol/L								
CALCIUM	mmol/L								
α1 ACID GLYCO- PROTEIN#	g/L								
* Complete only it	f differs froi	m recommended	•						·
# Only in patients	with PK sa	amples							
IF ADDITIONAL TEST	TS (NOT SPE	CIFIED ABOVE) OR REPEAT TESTS	S ARE PERFOR	RMED, ADDITIONAL UNSC	CHEDULED LA	ABORATOR'	Y PAGES SHO	OULD BE USED.	



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₹	ADVERSE EVENTS	VENTS											AE	
Δ.	Project No.	Pr	Protocol No.			Patient Initials	ials	Pa	Patient Alloc. No.	loc. No	Visit No.			
	RP 56	RP 56976V		327			first mi	middle last			Cyc	Cycle N°		
◀	ADVERSE EVE	EVENTS											□0 NONE	
<u> </u>	AE · [Diagnosis if knov	AE TERM [Diagnosis if known or sign/symptom]	*{4018	SERIOUS	DATE OF		00)	OUTCOME (complete only ONE column)		(G-t)	ACTION TAKEN REGARDING STUDY MEDICATION		Is there a reasonable possibility that the study medication caused the event, (A) one only)	Φ 3
	oo euo)	(one code per row)	OF AE (check (vg without change [i	If serious, complete SAE form.	(dd/mm/yyyy) or check (~) if ongoing	7 7 3 m	gniognO	Resolved date ceased (dd/mm/yyyy)	Death	GRADE	0=None 1=Temporarily interrupted 2=Permanently discontinued*** 4=Regimen changed- dose reduced 5=Regimen changed- frequency changed-	ər Action Taken Due 0=None 1=Hospitalization		`
	NCI CODE	DESCRIPTION	uio6u∩=L								6=Regimen changed-other 7=Regimen changed-dose reduced and frequency changed	эч 1 О		
	AL-LER	Allergic Reaction		0 No	1 ongoing			2 resolved	<u>8</u>		□0 □1 □2 □4 □5 □6 □7	□0 □1]1 0 0 1 2 3	
C.5	GI-NAU	Nausea		0 No	☐☐☐☐1 ongoing			2 resolved	3		□0 □1 □2 □4 □5 □6 □7	Ĝ	□1 □0 □1 □2 □3	
, L F	R GI-VOM	Vomiting		O No	☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐		- _		3		□0 □1 □2 □4 □5 □6 □7	0 🗆	□1 □0 □1 □2 □3	
ш	R GI-STO	Stomatitis/Pharyngitis		0 No				2 resolved	3		□0 □1 □2 □4 □5 □6 □7	°	□1 □0 □1 □2 □3	
	A GI-DIA	Diarrhea		0 No					3		□0 □1 □2 □4 □5 □6 □7	□0 □1]1 0 0 02 03	
*	Do not complete re	* Do not complete remainder of row. ** Complete remainder of row.	plete rema	inder of rov	*** Complete	Discontinue	ation of	Discontinuation of Study Medication module.						
=	Investigator Name	me:							Inve	stiga	Investigator Number:			



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AL	ADVERSE EVENTS	VENTS												AE	
Proj	Project No.	ш.	Protocol No.			Patient Initials	<u>s</u>	<u>a. </u>	Patient Alloc. No.	oc. No	Visit No.	lo.			
	RP 56976V	79260		327		first	t middle	lle last			S	Cycle Nº	•		
AD	ADVERSE EVE	EVENTS												□0 NONE	
11	AE ⁻ Diagnosis if knov	AE TERM [Diagnosis if known or sign/symptom]	*[GOTS]	SERIOUS			(соп	OUTCOME (complete only ONE column)		(3-1)	ACTION TAKEN REGARDING STUDY MEDICATION (check (~) one only)	∃A oT ər		CAUSALITY Is there a reasonable possibility that the study medication caused the event?	
	oue euo)	(one code per row)	OF AE (check (no ongoing	If serious, complete SAE form.	(dd/mm/yyy) or check (~) if ongoing		gniognO	Resolved date ceased (dd/mm/yyyy)	Death	GHADE ####################################	0=None 1=Temporarily interrupted 2=Permanently discontinued*** 4=Regimen changed- dose reduced 5=Regimen changed- frequency changed-	her Action Taken Di	enoM=0 bitszilstiqsoH=f	0=No 1=Unlikely 2=Possibly 3=Probably	
	NCI CODE	DESCRIPTION	niognO= f							9 2= 7	6=Regimen changed-other 7=Regimen changed-dose reduced and frequency changed	10			
	IN-FEC	Infection, specify		0 No	s			2 resolved	° = 1		□0 □1 □2 □4 □5 □6 □	0	0 0	0	1
	Febril	Febrile neutropenia	If the patient fever below.	atient exper	iences fever in abse	nce of micr	obiolog	jically or clinically docun	nented in	fection	If the patient experiences fever in absence of microbiologically or clinically documented infection, report blood counts in Hematology (page C.3) and report fever below.	logy (pag	ge C.3) an	d report	
z 0 –	CS-FEV	Fever	<u></u>	0 No	s			2 resolved	33		□0 □1 □2 □4 □5 □6 □	0	0 1 0	0	
ပ	!	Duration of fever ≥ 38.5°C			1 ongoing										
r — — ı	SK-ALO	Alopecia	<u></u>	0 No	s			2 resolved	33		□0 □1 □2 □4 □5 □6 □	0	0	0	
u сс — «	NE-SEN	Neuropathy sensory		0 No			-	2 resolved	33		□0 □1 □2 □4 □5 □6 □	0	0 0	0	
∢	NE-MOT	Neuropathy motor		0 No	s Tongoing			2 resolved	33	Ш	□0 □1 □2 □4 □5 □6 □	0	0 0	0 1 2 3	
	от-отн	Peripheral Edema		0 No	s				3	Ш	□0 □1 □2 □4 □5 □6 □	0 2		□0 □1 □2 □3	
* Dc	* Do not complete remainder of row.	1 1	mplete rem	** Complete remainder of row.	*** Complete	scontinuati	on of S	Discontinuation of Study Medication module	0.			-	-		-
Ž	Investigator Name:	ne:							Inves	stigat	Investigator Number:				

Released (V#7) 08FEB00



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AD	ADVERSE EVENTS	VENTS										AE
Proje	Project No.	<u>a</u>	Protocol No.	Ċ	Patien	Patient Initials	<u>a</u>	Patient Alloc. No.	c. No.	Visit No.		
	RP 5(RP 56976V		327		first	middle last			Cycle Nº	o N	
AD	ADVERSE EVENTS	ENTS										□0 NONE
	AE Jiagnosis if kno	AE TERM [Diagnosis if known or sign/symptom]	*[GOTS]	SERIOUS	DATE OF ONSET		OUTCOME (complete only ONE column)		ACTION TAKEN REGARDING STUDY MEDICATION (check (~) one only)	(Áluc		CAUSALITY Is there a reasonable possibility that the study medication caused the event?
	oo euo)	(one code per row)	OF AE (check (vg without change l	If serious, complete SAE form.	(dd/mm/yyyy) or check (✓) if ongoing	gniognO	Resolved date ceased (dd/mm/yyyy)	Death	O=None 1=Temporarily interrupted 2=Permanently discontinued*** 4=Regimen changed-dose reduced 5=Regimen changed-frequency changed-frequency changed	****P\$	her Action Taken Dr 6-00 on 7 = Hospitalizatio	(accord (b)) accord (c)) according to the control of the control
	NCI CODE	DESCRIPTION	niognO= f						6=Regimen changed-other 7=Regimen changed-dose reduced and frequency changed	changed	ŀΟ	
	CD-LVF	Cardiac Left Ventricular Function		0 No	1 ongoing	<u>-</u>	2 resolved	£ □	□0 □1 □2 □4 □5	2 □6 □7	0	□0 □1 □2 □3
	CS-FAT	Fatigue		0 No				3	□0 □1 □2 □4 □5	2	□ □ □	□0 □1 □2 □3
z 0 –	PA-BON	Bone Pain		0 No				3	□ 0 □ 1 □ 2 □ 4 □	2		□0 □1 □2 □3
OΕ	GU-DYS	Dysuria (painful urination)		0 No	1 ongoing	<u>-</u>		3	0 0 0 0 0 0	2 6 7	□0 □1	□0 □1 □2 □3
— — ш	GU-INC	Incontinence	2	0 No	1 ongoing			8	□ 0 □ 1 □ 2 □ 4 □	5 6 7	0 01	□0 □1 □2 □3
œ – ∢	GU-RET	Urinary Retention		0 No	1 ongoing	<u>-</u>		3	□0 □1 □2 □4 □5	2 □ 6 □7	□0 □1	□0 □1 □2 □3
	MS-OTH	Pathological fracture		0 No			Z resolved		□0 □1 □2 □4 □5	2	□0 □1	□0 □1 □2 □3
	от-отн	Spinal cord compression		0 No				3	□ 0 □ 1 □ 2 □ 4 □	2 □6 □7	□0 □1	□0 □1 □2 □3
°D*	not complete re	Do not complete remainder of row. ** Cor	nplete ren	** Complete remainder of row.		tinuation	*** Complete Discontinuation of Study Medication module					
<u>I</u>	Investigator Name:	ıme:						Inves	Investigator Number:			
										Release	Released (V#7) 08FEB00	FEB00



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⋖	ADVERSE EVENTS	LS														\mathbf{AE}
ď	Project No.	Protocol No.	ol No.			Patient Initials	Initials			Patient Alloc. No.	S. No.		Visit No.			
	RP 56976V			327			first m	middle	last				Cycle Nº	No (
⋖	ADVERSE EVENTS														0 🗆	□o NONE
BULK	AE TERM [Diagnosis if known or sign/symptom]	M rsign/symptom]	*[40T8]	SERIOUS	Snc	DATE OF		(con	OUTCOME (complete only ONE column)	olumn)	(3-1)	ACTION TAKEN REGARDING STUDY MEDICATION (check (~) one only)	NE Ne Ne Vano;			CAUSALITY Is there a reasonable possibility that the study medication caused the event? (check (r/) one only)
	(one code per row)	ər row)	OF AE (check () outhout change onsonge to ongoing	If serious, complete SAE form.	ous, orm.	(ad/mm/yyy) or check (~) if ongoing		gniognO	Resolved date ceased (dd/mm/yyyy)	Death	GRADE	0=None 1=Temporarily interrupted 2=Permanently discontinued*** 4=Regimen changed- dose reduced 5=Regimen changed- frequency changed	pe peq****	er Action Taken Due 0=None 1=15 Publisation		ikely ssibly bably
	NCI CODE	DESCRIPTION	ılogn∪= Γ								<u> </u>	6=Regimen changed-other 7=Regimen changed-dose reduced and frequency changed	ther ose y changed	ЧЮ		
	-				0 No	1 ongoing		-	2 resolved			□0 □1 □2 □4	2 □6 □7	7 🗆 0	1 0 01	23
C.8					0 No 1 Yes	1 ongoing		<u>-</u>	2 resolved	3		□0 □1 □2 □4	2 □6 □7	7 🗆 0	1 0 01	23
O –	-				0 No	1 ongoing		-	2 resolved	E		□0 □1 □2 □4	_5 □6 □7	7 🗆 0	1 00 1	□2 □3
OE			1		0 No 1 Yes	1 ongoing					_	□0 □1 □2 □4	□5 □6 □7	7 🗆 0	1 00 1	□2 □3
— н ш	-		1	0	0 No							□0 □1 □2 □4	□5 □6 □7	□ 0□ 2	1 00 1	□2 □3
ı œ — ·			1 2	0	0 No	1 ongoing						□0 □1 □2 □4	□2 □6 □	7 	1 🗆 0	□2 □3
4	-		1 2	0	0 No 1 Yes	1 ongoing						□0 □1 □2 □4	□5 □6 □7	□ 0□ 2	1 🗆 0 🗆 1	□2 □3
	-				Oñ	1 ongoing						□0 □1 □2 □4	□5 □6 □7	7 🗆 0 🗆 1	1 00 1	_2 □3
<u>* =</u>	* Do not complete remainder of row. ** Complete remainder of row. *** Complete In case of AE code is OT-OTH, grade severity as: 1=Mild, 2=Moderate, 3=Severe,	er of row. ** Complete remainder of row. OTH, grade severity as: 1=Mild, 2=Moder	e remaind s: 1=Mild	er of rov , 2=Moc	w. *** C derate, 3=	*** Complete Disconti tte, 3=Severe, 4=Life ⁻	Discontinuation of S 4=Life Threatening	f Study ng	Discontinuation of Study Medication module.	σί						
	Investigator Name:									Invest	igator	Investigator Number:				

Released (V#7) 08FEB00



Project No.

CONCOMITANT MEDICATION

Protocol No.

PCM

Visit No.

RP 56976V			327		fire	st middle last	C ₃	ycle Nº
CONCOMITANT MEDI			Dose r	nust be	record	ed.		□0 NONE
Drug (Brand Name)	Cor (ch or 1=Ong withou [STOF	out change or the change	Route	Total Dose		Start Date (dd/mm/yyyy) or ⊬ if ongoing	Stop Date (dd/mm/yyyy) or ⊬ if ongoing	Indication 5: Prophylaxis 6: Curative or Symptomatic
		1				□ 1 ongoing	□ 1 ongoing	
		1				□ 1 ongoing	□ 1 ongoing	
		1 🗆2				☐1 ongoing	☐1 ongoing	
		1				☐1 ongoing	☐1 ongoing	
		1				□ 1 ongoing	☐1 ongoing	
		1 🗆2				□ 1 ongoing	☐1 ongoing	
		1 🗆2				☐1 ongoing	☐1 ongoing	
		1 🗆2				☐1 ongoing	☐1 ongoing	
		1 🗆2				☐1 ongoing	☐1 ongoing	
		1				☐1 ongoing	☐1 ongoing	
		1 🗆2				☐1 ongoing	☐1 ongoing	
*Do not complete remai						1 ongoing	□ 1 ongoing	

Patient Initials

Patient Alloc. No.

^{*}Do not complete remainder of row. **Complete remainder of row.



CONCOMITANT MEDICATION (DIARY ANALGESICS ONLY)

PCM-DA

Project No.		Protocol No.		Patient Init	als	Patient Allo	c. No.		Visit No.		
RP 569	76V		327	first midd	le last				Cycle	No	
CONCOMITAN	NT ME	DICATIONS									
Only analgesic	s repo	rted in the Patien	t Pain Diary sho	ould be re	ecorde	d in this m	odule.			□0 N	IONE
						Dose (7-day per	of Analo iod of the		iary)		
Drug (Brand Name)	Route	Start Date (dd/mm/yyyy) Or check if ongoing	Stop Date (dd/mm/yyyy) or check if ongoing	1st Day	2nd Day	3rd Day	4th Day	5th Day	6th Day	7th Day	Unit
		□0 ongoing	□0 ongoing								
		□0 ongoing	□ ongoing								
		□0 ongoing	□0 ongoing								
		□0 ongoing	□0 ongoing								
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			□0 ongoing								



TA TUMOR ASSESSMENT

Project No.		Protocol No.		Patient Initials	Pati	ient Alloc. No.		Visit	No.	
RP	56976V	327						_	I- NO	
				first middle last	<u>ا</u> ا			C	ycle Nº	
								1		
TUMOR AS	SSESSMENT								□0 NG	OT done
		Please comp	lete the fo	rm using ALL	DISE	ASE SITES	3			
Mai	intain the same i	numbering of lesio						ame r	nethods o	of
77762	man the came i	me	asuremen	t throughout th	ne stu	dy.			,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	
				<u> </u>					Respo	nse of
	Oı	rgan				ethod of				asurable
	a: Site (enter the ap	=				surement			Lesion	s Only
Lesion						er appropriate number)			(Enter ap	
Number	1:Bone (complete a 2:Lymph Node	lso checklist)	D	ate of		sical exam	Magaziran			nber)
· tarriso.	3:Liver		Asse	essment	2:X-F	Ray	Measurer (mm x m		1:CR (Comple 2:PR (Partial	ete Response)
(F ₁ , 1, 0,)	4:Lung	if.	(dd/i	mm/yyyy)	4:CT s		,	,	3:NC/SD (N	o Change/
(Ex: 1, 2)	5:Other Soft Tissue 94:Other Organ, sp	, specify ecifv			6:Ultra	asound			Stable Diseas 4:PD (Progre	
		-				lionuclide Bone scan)			Disease)	
	b: Subsite (descrip	ption)				her, specify			5:New lesion	
									6:NE (Not eva	aluable)
	a						X			
	b			at Done						
				DOILE .						
	a									
							X	,		
	b		\Box_0 No	ot Done						
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	a									
							$ \cdot \times $			
	b		∐o No	ot Done						
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	a		1 . 11 .							
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	b		□0 No	t Done						
	a						X			
	b		∐o No	ot Done				=		
	a						X			
	b			at Done						
				, Done						
	a									
							X	,		
	b		\Box_0 No	ot Done						
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Overall Tur	nor Response a	t end of this cycle:								
		. —								
			n	VIC aposify						I



BONE CHECK LIST / VITAL SIGNS / LEFT VENTRICULAR EJECTION FRACTION / PAIN EVALUATION

BCL/VS/LVEF/PAE

Project No.	Protocol No.	Patient Initials	Patient Alloc. No.	Visit No.
RP 56976V	327	first middle last		Cycle Nº

BONE CHECK LIST To be completed in case of the showing metastatic lesion	pone scan
Hot Spot Location	Number of Hot Spots
□1 Skull/Head	
□2 Spine	
□3 Pelvis	
☐4 Ribs/Sternum/Clavicle/ Shoulder Blade	
☐5 Upper Limbs	
☐6 Lower Limbs	

VITAL SIGNS To be performed at end of cycle.	□0 NOT done
Date of Assessment: Kar	rnofsky:
Weight	
□1 lb □2 kg	

LEFT VENTRICULAR EJECTION FRACTION (check (✓) one In Arm A: to be completed after cycles 5, 8 and 10 In each arm: to be completed at end of study	e method only)
☐1 Radionuclide angiocardiography (MUGA scan)	☐2 Echocardiography
Date of Assessment:	Date of Assessment:
Value:	Value:
Lower limit of normal for the institution: \(\) %	Lower limit of normal for the institution: %

PAIN EVALUATO be averaged	TION I over 7 consecutive days. To be	e performed every 3 weeks.	□0 NOT done
Da	ate of Assessment	Present Pain Intensity	Analgesics Score
1st Day	dd mm yyyy		•
2nd Day			•
3rd Day			•
4th Day			•
5th Day			•
6th Day			
7th Day	dd mm yyyy		



RP 56976V

Protocol No.

327

94 Other, specify in Other Procedures Form in the Extra Forms Section

Project No.

IPC

Visit No.

Cycle No

INPATIENT ADMISSIO				
	•	ted for overnight stay to hospital?		
∐₀ No	s, Complete section belo	ow:		
Admission/Transfer Date or Ongoing	Discharge/Transfer Date or Ongoing	Reason for admission (check ()) one only)	(ched	Unit ck () one only)
dd mm yyyy 1 Ongoing	dd mm yyyy 1 Ongoing	☐ 1 Study drug administration ☐ 2 Tumor related Adverse	□2 Surgery	☐3 Internal Medicine ☐94 Other, specify:
dd mm yyyy 1 Ongoing	dd mm yyyy 1 Ongoing	☐ 1 Study drug administration ☐ 2 Tumor related Adverse	□2 Surgery	☐3 Internal Medicine ☐94 Other, specify:
dd mm yyyy 1 Ongoing	dd mm yyyy 1 Ongoing	☐ 1 Study drug administration ☐ 2 Tumor related Adverse	□2 Surgery	☐3 Internal Medicine ☐94 Other, specify:
		jor procedures been performed? orm in the Extra Forms section	□o None	
☐2 Imaging (CT S	can, MRI, Bone Scan),	specify in Other Procedures form in	the Extra Forn	ns Section

Patient Initials

first middle last

Patient Alloc. No.

^{*}ICU = Intensive Care Unit

^{**}Please complete an SAE form.



FOLLOW-UP STATUS

FUS/FVS/FDS

Project No.	Protocol No.	Patient Initials	Patient Alloc. No.	Visit No.			
RP 56976V	327	first middle last		Follow-Up Nº			
PATIENT FOLLOW	-UP STATUS						
Date of last contact:	dd mm yyyy						
(1) 1 (1) 1 1 1 1	Pat	ient's status as of	ena ot tollow-up				
(check (✓) one only): ☐1 Alive							
	e Death Report Form						
☐2 Dead : Complete Death Report Form ☐3 Lost to follow-up							
PERFORMANCE STATUS							
☐1 Not Applicable (further anti-tumor therapy administration)							
Performance Status: Karnofsky:							
DISEASE STATUS							
Record the progression criteria observed during the follow-up period. Please attach the follow-up pages (Tumor Assessment, PSA, Pain Evaluation) unless the patient's progression has already been reported.							
(check (✓) all that apply)							
☐1 Not applicable (p	oatient's progression ha	s been already rep	orted or patient has	not progressed yet)			
☐2 Protocol-defined	d progression on tumor	lesions					
☐3 Protocol-defined	□₃ Protocol-defined PSA progression						
☐4 Protocol-defined	d pain progression						



FURTHER THERAPY

FT/FTHERA

Project No.	Protocol No.	Patient Initials	Patient Alloc. No.	Visit No.
RP 56976V	327	first middle last		Follow-Up No

ANTI-TUMOR THERAP	Y (I)				
	d any therapy listed below hemotherapy, please spec		y affect th	e tumor since	□o NONE
Type of Therapy				Start Date	Stop Date
C: Chemotherapy Cs: Corticosteroids (please specify regimen)	Regimen/Drug	Dose	Unit	(dd/mm/yyyy) or ✓ if ongoing	(dd/mm/yyyy) or ✓ if ongoing
Cs 8	specify:		mg	□1 ongoing	□1 ongoing
Cs 8	specify:		mg	□ 1 ongoing	□ 1 ongoing
C 1	□17 Mitoxantrone q3w		mg/m ²	☐1 ongoing	□1 ongoing
C 1	☐2 Docetaxel ☐1 q3w		mg/m ²		
01			1119/111	☐1 ongoing	☐1 ongoing
C 1	☐2 Docetaxel ☐2 qw		mg/m ²	□1 ongoing	□1 ongoing

ANTI-TUMOR T	HERAPY (II)				
		nerapy than listed ab nt, please specify bel		y affect the tumor	□0 NONE
Type of Therapy C: Chemotherapy H: Hormonal I: Immunotherapy R: Radiotherapy S: Surgery G: Gene Therapy	Regimen/Drug	Site/Procedure (for radiotherapy and surgery)	Dose (for chemotherapy, hormonal and corticosteroids)	Start Date (dd/mm/yyyy) or ⊭ if ongoing	Stop Date (dd/mm/yyyy) or ⊭ if ongoing
C ₁ I ₃ S ₅ H ₂ R ₄ G ₆				☐1 ongoing	□1 ongoing
C ₁ I ₃ S ₅ H ₂ R ₄ G ₆				1 ongoing	☐1 ongoing
C ₁ I ₃ S ₅ H ₂ R ₄ G ₆				□1 ongoing	□1 ongoing
C ₁ I ₃ S ₅ H ₂ R ₄ G ₆				□1 ongoing	□1 ongoing
C ₁ I ₃ S ₅ H ₂ R ₄ G ₆				□1 ongoing	□1 ongoing
C ₁ I ₃ S ₅ H ₂ R ₄ G ₆				□ 1 ongoing	□1 ongoing

FAE

□0 NONE

CAUSALITY

Follow-Up Nº

Visit No.

Is there a reasonable possibility that the study medication caused the event? (check (~) one only)

0=No 1=Unlikely 2=Possibly 3=Probably



					er Action Taken Due 0=Mone 1=Hospitalizatio	ou1O	□0 □1	□0 □1	□0 □1	□0 □1	□0 □1	□0 □1
					GRADE	-110]					
					Death		3	3	3	3	3	3
	Patient Alloc. No.			OUTCOME (complete only ONE column)	Resolved date ceased (dd/mm/yyyy)				2 resolved			
				Ú	gniognO				1	<u></u>	<u></u>	
	Patient Initials	first middle last		DATE OF	90							
				SERIOUS	If serious, complete SAE form.		0 No	0 No	0 No	0 No	0 No	% 0 N°
		2:		*{90TS]	oF AE (check (; yowithout change change to ongoing	iiognO= f	1		1	1		1 🗆
DVERSE EVENTS	Protocol No.	327		AE TERM [Diagnosis if known or sign/symptom]	(one code per row)	DESCRIPTION	Stomatitis/Pharyngitis	Alopecia	Neuropathy sensory	Neuropathy motor	Peripheral Edema	Cardiac Left Ventricular Function
FOLLOW-UP ADVERS	Project No.	RP 56976V	ADVERSE EVENTS	A Diagnosis if k	(one	NCI CODE	GI-STO	SK-ALO	NE-SEN	NE-MOT	от-отн	CD-LVF C
FO	Proje							z 0 –	υœ	— — ш	œ – ∢	
		PULL	& INSE	RT								

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Investigator Number:

☐2 resolved

☐1 ongoing

2

* Do not complete remainder of row. ** Complete remainder of row.

Investigator Name:

Released (V#7) 08FEB00



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Proj	Project No.	Protocol No			Patient Initials	Patient Alloc. No.	No.		Visit No.
	RP 5(RP 56976V	327		first middle last				Follow-Up N°
AD	ADVERSE EVE	EVENTS							□0 NONE
	[Diagno:	AE TERM [Diagnosis if known or sign/symptom]	(γlno əno (∖ν *[qOT2]	SERIOUS	DATE OF	OUTCOME (complete only ONE column)		∃A oT əu	CAUSALITY Is there a reasonable possibility that the study medication caused the event?
		(one code per row)	s OF AE (check ()	If serious, complete SAE form.	0 0	Resolved date ceased dd/mm/yyyy)	GRADE	her Action Taken Dr 0=None 1=Hospitalizatio	(Crieco (P.) Orle Orily) 0=No 1=Unlikely 2=Possibly 3=Probably
	NCI CODE	DESCRIPTION	SUTATS niognO=1					#O	
	CS-FAT	Fatigue		0 No		□1	E	0 0	
	PA-BON	Bone Pain		0 No		□1		□0 □1	1 0 0 1 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0
z 0 –	GU-DYS	Dysuria (painful urination)		0 No		1	E	0	1
OE	GU-INC	Incontinence		0 No	1 ongoing	1	<u> </u>	□0 □1	1
— — ш	GU-RET	Urinary Retention		0 No		1	° = 1	0	
œ – ∢	MS-OTH	Pathological fracture		0 No		□1	<u> </u>	0 0	□0 □1 □2 □3
	от-отн	Spinal Cord Compression		0 No		□1	©	0 0	0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0
	not complete re	Do not complete remainder of row. ** Complete remainder of row.	ainder of row.				-	_	
<u>ک</u>	Investigator Name:	me:				Investigator Number:	· Number:		

Released (V#7) 08FEB00



OLLOW-UP ADVERSE EVENTS	ADVERSE	EVENTS									FAE
roject No.		Protocol No.		Pati	Patient Initials		Patient Alloc. No.			Visit No.	
RP 56976V	. 6V	327			first middle last						Follow-Up No
DVERSE EVENTS	TS										□0 NONE
[Diagnosis	AE TERM [Diagnosis if known or sign/symptom]	/symptom]	*[GOTS]	SERIOUS	DATE OF	Ö)	OUTCOME (complete only ONE column)		(G-t) 3A oT e		CAUSALITY Is there a reasonable possibility that the study medication caused the event?
))	(one code per row)	(w	OF AE (check (v g without change change to ongoing	If serious, complete SAE form.	90	gniognO	Resolved date ceased (dd/mm/yyyy)	Death	r Action Taken Due	eNoM=0 noitszilstiqsoH=1	(check (ν) one only) 0=No 1=Unlikely 2=Possibly 3=Probably
NCI CODE	ā	DESCRIPTION	g n iognO=1						Othe		
·				0 No			2 resolved	ε 	°	<u>-</u>	□0 □1 □2 □3
-				0 No		_	2 resolved	33	ů		0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0
-				0 No	1 ongoing	_	2 resolved	3	°	<u></u>	0 0 0 0 0
				0 No		_		33	°		0 0 0 0 0
<u></u>				0 No			2 resolved	33	°	<u></u>	0 0 0 0 0
- 111 6				0 No				33	°	<u></u>	□0 □1 □2 □3
- 1				0 No	1 ongoing		2 resolved	33	°		□0 □1 □2 □3
-				0 No			2 resolved	33	°		0 0 0 0 0
-			□1 □2	O No	1 ongoing	1		3	0 0		□0 □1 □2 □3
Do not complete rema case of AE code is O	inder of row. **)T-OTH, grade s	Do not complete remainder of row. ** Complete remainder of row. case of AE code is OT-OTH, grade severity as: 1=Mild, 2=Moderate,	3=	Severe, 4=L	Severe, 4=Life Threatening						
vestigator Name:	••						Investigator Number:	er:			
							_			Rele	Released (V#7) 08FEB00



Project No.

FOLLOW-UP CONCOMITANT THERAPY

Protocol No.

FPCM

Visit No.

RP 56976V	327	first middle la	ast			Follo	ow-Up Nº
CONCOMITANT THER If drug is PRN, the approxi		ust be recorded	i.				□0 NONE
_	Status of Conc. Med	-1.		Daily ose	Start Date Stop		Stop Date
Drug (Brand Name)	1=Ongoing without of [STOP] * 2=New or change to ongoing medication [continue] **	change Mod	Dose	Unit	(dd/mm/y or ⊬ if ong	ууу)	(dd/mm/yyyy) or ⊬ if ongoing
	□1 □2				□ 1 ongoing		□1 ongoing
	□1 □2				□ □ □ □ □ □ □ □ 1 ongoing		□ 1 ongoing
	□1 □2				□ □ □ □ □ □ □ □ 1 ongoing		☐1 ongoing
	□1 □2				1 ongoing		□1 ongoing
	□1 □2				1 ongoing		□1 ongoing
	□1 □2				1 ongoing		□1 ongoing
	□1 □2				1 ongoing		□1 ongoing
	□1 □2				1 ongoing	1 1 1	□ 1 ongoing
	□1 □2				1 ongoing		□1 ongoing
	□1 □2				1 ongoing		□1 ongoing
	□1 □2				1 ongoing		☐1 ongoing
	□1 □2				□ l l l l l l l l l l l l l l l l l l l		1 ongoing
	□1 □2				□ □ 1 ongoing		☐1 ongoing

Patient Initials

Patient Alloc. No.

^{*}Do not complete remainder of row. **Complete remainder of row.



CONCOMITANT MEDICATION (DIARY ANALGESICS ONLY)

FPCM-DA

Project No.		Protocol No.	Patient Initia	als	Patient Allo	c. No.		Visit No.			
RP 56976	6V	327	first middle	e last				Follo	ow-Up I	/l o	
CONCOMITAN	NT MEI	DICATIONS									
		rted in the Patien	t Pain Diary shoւ	ıld be r	ecorded i	n this m	odule.			□0 N	IONE
					(7		of Ana iod of th	lgesics e Pain Dia	ry)		
Drug (Brand Name)	Route	Start Date (dd/mm/yyyy) or check if ongoing	Stop Date (dd/mm/yyyy) or check if ongoing	1st Day	2nd Day	3rd Day	4th Day	5th Day	6th Day	7th Day	Unit
		□0 ongoing									
		□0 ongoing	□0 ongoing								
		□ 0 ongoing	□ 0 ongoing								
		□ 0 ongoing	□ O ongoing								
		□ □ 0 ongoing	□ O ongoing								
			□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□								
		□ 0 ongoing	□0 ongoing								
		□0 ongoing	□ 0 ongoing								
		□ 0 ongoing	□ 0 ongoing								
		□0 ongoing	□0 ongoing								
			□ 0 ongoing								
		□0 ongoing	□0 ongoing								
		□0 ongoing	□ 0 ongoing								
		□ 0 ongoing	□ 0 ongoing								
			□ 0 ongoing								
		□0 ongoing	□0 ongoing								



FOLLOW-UP PAIN EVALUATION / FOLLOW-UP PSA

FPAE/FPSA

Project No.	Protocol No.	Patient Initials	Patient Alloc. No.	Visit No.
RP 56976V	327	first middle last		Follow-Up Nº

PAIN EVALUATO be averaged or further anti-t	d over 7 consecutive days. To be	e performed every month until pa	atient's progression
Da	ate of Assessment	Present Pain Intensity	Analgesics Score
1st Day	dd mm yyyy		
2nd Day			•
3rd Day			
4th Day			
5th Day			
6th Day			
7th Day	dd mm yyyy		

FOLLOW-UP PSA To be performed every month until patient's progression or further anti-tumor therapy. □ NOT done							
PSA							
Test	Recommended Units	Date of Sample:	Actual units*				
PSA	ng/mL						



FOLLOW-UP INPATIENT CARE

FIPC

Project No.	Protocol No.	Patient Initials Patient Alloc. No.		Visit No.	
RP 56976V	327	first middle last		Follow-Up Nº	

INPATIENT ADMISSION DURING FOLLOW-UP							
Since the last visit, has the patient been admitted for overnight stay to hospital?							
□ No □ 1 Yes, Complete section below:							
Admission/Transfer Date or Ongoing	Discharge/Transfer Date or Ongoing	Reason for admission (check () one only)	Unit (check (⊬) one only)				
dd mm yyyy dc	dd mm yyyy 1 Ongoing	☐2 Tumor related Adverse Event** ☐3 Study drug related Adverse	☐2 Surgery	☐3 Internal Medicine			
		Event** 94 Other, specify:	□4 ICU*	94 Other, specify:			
,,,,,	dd mm yyyy 1 Ongoing	2 Tumor related Adverse Event**	☐2 Surgery	☐3 Internal Medicine			
		☐3 Study drug related Adverse Event** ☐94 Other, specify:	□4 ICU*	94 Other, specify:			
dd mm yyyy 1 Ongoing	dd mm yyyy 1 Ongoing	2 Tumor related Adverse Event**	☐2 Surgery	☐3 Internal Medicine			
		☐3 Study drug related Adverse Event** ☐94 Other, specify:	□4 ICU*	94 Other, specify:			
During those hospitalizations, have any major procedures been performed?							
\square 1 Surgery, specify in Other Procedures form in the Extra Forms section							
☐₂ Imaging (CT Scan, MRI, Bone Scan), specify in Other Procedures form in the Extra Forms Section							
\square 94 Other, specify in Other Procedures Form in the Extra Forms Section							

^{*}ICU = Intensive Care Unit

^{**}Please complete an SAE form.



FOLLOW-UP TUMOR ASSESSMENT

FTA

I OLLO	V-OI ION	TOR ADDEDDINE!	■					1 1/1				
Project No.		Protocol No.	Patient Initials	Patient A	Alloc. No.	V	isit No.					
RP 56	6976V	327	first middle last				Follow-	Up Nº				
TUMOR A	SSESSMEN	IT						□0 NOT done				
(To be perf	ormed every	y 2 months until patien	t's progression or	further	anti-tumor t	therapy	.)	□0 NO1 done				
Mai	Please complete the form using ALL DISEASE SITES. Maintain the same numbering of lesions (1, 2) throughout the study and repeat the same methods of measurement throughout the study.											
Lesion Number (Ex: 1, 2)	a: Site (enter to the state of	issue, specify an, specify	Date of Assessment (dd/mm/yyyy)		Method o Measureme (Enter appropria number) 1:Physical exar 2:X-Ray 4:CT scan 5:MRI 6:Ultrasound 7:Radionuclide (i.e., Bone sca 94:Other, speci	m Me	easurement mm x mm)	Response of Evaluable and Non-evaluable Lesions Only (Enter appropriate number) 1:CR (Complete Response) 2:PR (Partial Response) 3:NC/SD (No Change/ Stable Disease) 4:PD (Progressive Disease) 5:New lesion 6:NE (Not evaluable)				
	a		0 Not Done									
	a		0 Not Done				X					
	a b		0 Not Done				×					
	a		0 Not Done									
	a		0 Not Done				×					
	a		0 Not Done									
	a		0 Not Done				X					
Overall Tur	mor Respon	se:										
1 CR	2 PR	3 NC/SD 4 P	D 5 NE, spe	cify								



FOLLOW-UP BONE CHECK LIST

FBCL

Project No.	Protocol No.	Patient Initials	Patient Alloc. No.	Visit No.
RP 56976V	327	first middle last		Follow-Up Nº

BONE CHECK LIST To be completed in case of bone scan showing metastatic lesion							
Hot Spot Location	Number of Hot Spots						
□1 Skull/Head							
□2 Spine							
□3 Pelvis							
☐4 Ribs/Sternum/Clavicle/Shoulder Blade							
☐5 Upper Limbs							
☐6 Lower Limbs							



BEST OVERALL RESPONSE / DISCONTINUATION OF STUDY MEDICATION

BR/TSM/PCE

Project No.	Protocol No.	Patient Initials	Patient Alloc. No.							
RP 56976V	327			End of Study						
		first middle last								
RESPONSE PATTERNS A										
Best Overall Tumor Resp										
	3 NC/SD ☐4 PD	_5 NE, specify: ₋								
PSA Response:	wateral defined DOA was a		□ a Nia □ □ a Nia 4	A						
Pain Response:	protocol-defined PSA respo	onse?1 Yes	□0 No □2 Not	Applicable						
<u>-</u>	orotocol-defined pain respo	nse? □1 Yes	□o No □2 Not	Applicable						
DISCONTINUATION OF S	STUDY MEDICATION									
Indicate the <u>primary</u> reason for discontinuation of study medication (check (✓) one only):										
	☐o Completed study m	edication								
	1 Adverse event (com	nplete appropriate adv	erse event form)							
	2 Death (complete DEATH	н REPORT module)								
	☐ ₁₃ Progressive disease	е								
	☐ ₂₁ Patient required the	erapy / procedure	not permitted							
	☐22 Other major protoco	ol violation, specify	·							
	☐31 Lost to follow-up ▶	Date of last con	tact:							
	□ ₉₁ Consent withdrawn	, specify								
	94 Other, specify									
PROGRESSION CRITERI	A AT END OF STUDY									
(check () all that apply)										
☐1 Not applicable (patient	has not progressed yet)									
☐2 Protocol-defined progr	ression on tumor lesions									
☐3 Protocol-defined PSA	progression									
☐4 Protocol-defined pain	progression									
CASE REPORT FORM RE	EVIEW									
I have reviewed all data observations and source the completion of the stu	records. They accurately									
Primary Investigator's or	r Sub-Investigator's Sigr	– nature	L dd	mm yyyy						



Project No.

DEATH REPORT FORM

RP 56976V

FOF	RM			DR
	Protocol No.	Patient Initials	Patient Alloc. No.	
	327	first middle last		Death Report Form

DEATH REPORT FORM	
Date of Death: dd mm yyyy	
Cause of death - indicate MOST probable cause	e (check ($ u$) one only):
	Septic (with at least one possibly or probably related AE at the last cycle, such as infection, sepsis or fever with outcome: Died).
	Non-Septic (with at least one possibly or probably related AE except the one listed for septic, with outcome: Died).
	☐₃ Progressive Disease
	994 Other, specify
Source of information (check () all that apply):	☐₁ Death certificate
	□ ₂ Autopsy
	☐3 Hospital chart notes and/or other medical report
	☐4 Physician contact
	☐ ₅ Family contact
	94 Other, specify



OTHER PROCEDURES - UNSCHEDULED

ZOP

Project No.	Protocol No.	Patient Initials	Patient Alloc. No.	1	Visit No.
RP 56976V	327				☐ Cycle Nº:
		first middle last			
					☐ Follow-Up Nº: ☐ ☐
OTHER PROCEDI Please note any a examination, myelo	dditional assessm	ent whether relate	ed to tumor or	not e.g.: ra	adiological assessment, bacteriological
Type of Pr	ocedure				
a: Procedure (enter the a	appropriate number)				
3: Cultures 4: Imaging 5: Puncture/Drainage 6: Biopsy 7: Surgery 8: Test 94: Other, specify proce	dure	Date asse (dd/mm/y			Comments* (if applicable)
b: Description					
a			1 1 1		
b					
a					
D	_				
a					
b					
a					
b					
a					
b					
а					
b					
a					
b					
а					
b	as repeated sever	al times a day ple	ase note how	many time	es it was performed. When relevant,

^{*}If the procedure was repeated several times a day, please note how many times it was performed. When relevant please note the result of the procedure.



Project No.

BLOOD CHEMISTRY - UNSCHEDULED

Patient Initials

Protocol No.

ZBC1/ZBC3

Visit No.

RP 56976V		327	first midd	dle last			Cycle Nº	
		The control of the control of the control of the complete complete complete control of the contr	below.	s baseline;	1 Check if laboratory is the same otherwise complete below. LAB NAME LAB ADDRESS: LABID:	as baseline;	1 Check if laboratory is the san otherwise complete below. LAB NAME LAB ADDRESS: LABID:	ne as baseline;
BLOOD CHEMIST	ΓRY							
		Date of San	nple:			ryy	Date of Sample:	
Test		Res	ult	Actual units	Result	Actual units	Result	Actual units
IF ADDITIONAL TESTS (NOT	SPECIF	FIED ABOVE) OR RE	PEAT TESTS ARE	PERFORME	ED, ADDITIONAL UNSCHEDULED LA	BORATORY F	PAGES SHOULD BE USED.	- '

Patient Alloc. No.



HEMATOLOGY	- UN	SCHEDULED						ZH	1/ZH6
Project No.		Protocol No.		Patient Initials	Patient A	Alloc. No.		Visit No.	
RP 56976V		327		first middle last				Cycle Nº	
HEMATOLOGY									
	Date of	of Sample:		Date of Sample:			Date of	Sample:	
	dd mm yyyy		dd mm	уууу	<u></u> y	dd mm yyyy			
Test		Result	Actual units	Result		Actual units		Result	Actual units

Date of Sample:		Date of Sample:		Date of Sample:	
dd mm yyyy		dd mm yyy	 y	dd mm yyyy	
Result	Actual units	Result	Actual units	Result	Actual units
	dd mm yyy	dd mm yyyy Result Actual	dd mm yyyy dd mm yyyy: Result Actual Result	Result Actual Result Actual	Result Actual Result Actual Result



CONCOMITANT RADIOTHERAPY - UNSCHEDULED

ZCR

CONCOMITA	INI KADIOTI	ILIKAI I - UN	OCHEDO					
Project No.	Protocol No.	Patient Initials	Patient	Alloc. No.		Visit No.		
RP 56976V	327	first middle I	ast			☐ Cycle Nº:		
CONCOMITANT	RADIOTHERAF	ΡΥ						
Ple	ase describe belo	ow all concomita	nt radiothe	rapy receive	ed by the p	atient during	the study.	
1 = S 2 = S	Organ Site Subsite			Dose y units)		urt Date nm/yyyy)	Stop Date (dd/mm/yyyy)	
2 - 0	(description)		Dose	Units	(44/11	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	or indicate if ongoing	
2				□1 Gy □2 rads □3 cGy			□ 1 ongoing	
2				□1 Gy □2 rads □3 cGy			□ 1 ongoing	
2				□1 Gy □2 rads □3 cGy			□ I ongoing	



STUDY MEDICATION RE-ADMINISTRATION

ZSMA1/ZSMA3

Project No.	Protocol No.	Patient Initials	Patient Alloc. No.	Visit No.
RP 56976V	327			Cycle Nº
		first middle last		- ,

STUDY MEDICATION RE-ADMINISTRATION - DOCETAXEL								
Study Drug		Route	Date of Administration	Stop Date	Total Daily Dose Giver	1		
Docetaxel	2	IV	dd mm yyyy			mg		
Docetaxel	2	IV	dd mm yyyy			mg		
Docetaxel	2	IV	dd mm yyyy			mg		
Docetaxel	2	IV	dd mm yyyy			mg		
Docetaxel	2	IV	dd mm yyyy			mg		

STUDY MEDICATIO	N RE-	ADMIN	NISTRATION - MITOXANTRO	ONE	□0 NONE	
Study Drug		Route	Date of Administration Stop Date		Total Daily Dose Given	
Mitoxantrone	17	IV	dd mm yyyy		mg	

STUDY MEDICATION RE-ADMINISTRATION - PREDNISONE						
Study Drug		Route	Start Date	Stop Date or ⊬ if ongoing	Total Daily Dose Giver	1
Prednisone 18			dd mm yyyy	dd mm yyyy		mg





LEFT VENTRICULAR EJECTION FRACTION / ELECTROCARDIOGRAM- UNSCHEDULED

ZLV/ZECG

ELECTROCA	KDIOGKAMI-	UNSCHEDULE	U		
Project No.	Protocol No.	Patient Initials	Patient Alloc. No.	Visit No.	
RP 56976V	327			☐ Cycle Nº:	
		first middle last		☐ Follow-Up Nº:	
LEFT VENTRICU	JLAR EJECTION	FRACTION (check ((one method only)		□0 NOT done
	angiocardiograph	y (MUGA scan)	2 Echocardiogra	ıphy	
Date of Asse	ssment: L_L	mm yyyy	Date of Asses	sment:	уууу
Value:	%	ини уууу	Value:	%	уууу
value.			value.		
Lower limit o	f normal for the in	stitution:	│ % Lower limit of	normal for the institution:	%
ELECTROCARD	IOGRAM				□0 NOT done
Date of Tracing:					
Interpretation (cl	mm yyyy				
	• • • • • • • • • • • • • • • • • • • •				
1 Within I	normal limits				
2 Non−sig	gnificant abnormal	ities			
☐з Signific	ant abnormalities	COMPLETE THE ADVERSE	E EVENT FORM.		



FACT P COMPLETION STATUS

QOLS

Project No.	Protocol No.	Patient Initials	Patient Alloc. No.	Visit No.
RP 56976V	327			☐ Baseline:
		first middle last		☐ Cycle Nº:
				☐ Follow-Up Nº: ☐
Date Questionnai	re Completed:			
		dd mm yy	уу	

FACT-P COMPLETION STATUS

TO BE COMPLETED BY THE PERSON RESPONSIBLE FOR QOL QUESTIONNAIRE ADMINISTRATION.
(THIS FORM SHOULD NOT BE GIVEN TO THE PATIENT.)

FACT P (To be completed within 3 days prior to randomization, at end of every month until initiation of further anti-tumor therapy)	cycle, at end of study and then every
Was the FACT P questionnaire completed?	
☐1 Yes, Complete below:	
Was the questionnaire self-administered?	□0 No □1 Yes
Was the questionnaire completed prior to patient's knowledge of the treatment assigned? (only for Baseline)	□o No □1 Yes □2 Not Applicable
Was the questionnaire completed prior to corticosteroid premedication? (only for patients treated in Arm B or C)	□o No □1 Yes □2 Not Applicable
Was the questionnaire completed before the patient was told that he is progressive or that he will receive further anti-tumor treatment?	□o No □1 Yes □2 Not Applicable
□ No, Indicate the primary reason:	
☐₁ Translation not available	
2 Patient refused, specify reason:	
☐3 Patient did not show up, specify	·
☐4 Staff unavailable	
☐5 Patient not given form by staff	
94Other, specify	



LOT NUMBERS LN

Project No.	Protocol No.	Patient Initial	3	Patient	Alloc.	No.	
RP 56976V	327	first midd	le last				

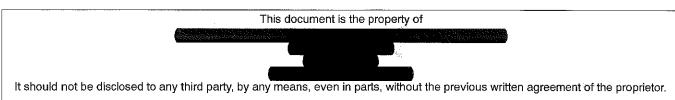
Cycle No.	D	Drug Name Batch Number		Drug Name		Batch Number	Drug Name		Batch Number
	2	DOCETAXEL		17	MITOXANTRONE		18	PREDNISONE	
	2	DOCETAXEL		17	MITOXANTRONE		18	PREDNISONE	
	2	DOCETAXEL		17	MITOXANTRONE		18	PREDNISONE	
	2	DOCETAXEL		17	MITOXANTRONE		18	PREDNISONE	
	2	DOCETAXEL		17	MITOXANTRONE		18	PREDNISONE	
	2	DOCETAXEL		17	MITOXANTRONE		18	PREDNISONE	
	2	DOCETAXEL		17	MITOXANTRONE		18	PREDNISONE	
	2	DOCETAXEL		17	MITOXANTRONE		18	PREDNISONE	
	2	DOCETAXEL		17	MITOXANTRONE		18	PREDNISONE	
	2	DOCETAXEL		17	MITOXANTRONE		18	PREDNISONE	
	2	DOCETAXEL		17	MITOXANTRONE		18	PREDNISONE	
	2	DOCETAXEL		17	MITOXANTRONE		18	PREDNISONE	
	2	DOCETAXEL		17	MITOXANTRONE		18	PREDNISONE	
	2	DOCETAXEL		17	MITOXANTRONE		18	PREDNISONE	
	2	DOCETAXEL		17	MITOXANTRONE		18	PREDNISONE	
	2	DOCETAXEL		17	MITOXANTRONE		18	PREDNISONE	



A MULTICENTER PHASE III RANDOMIZED TRIAL COMPARING DOCETAXEL ADMINISTERED EITHER WEEKLY OR EVERY THREE WEEKS, IN COMBINATION WITH PREDNISONE VERSUS MITOXANTRONE IN COMBINATION WITH PREDNISONE FOR METASTATIC HORMONE REFRACTORY PROSTATE CANCER

Project No.	Protocol No.	Patient Initials	Patient Alloc. No.
RP 56976V	327	first middle fast	
Investigator Name:		Investigator Number:	
CONTACTS:			
			······································
			•
		•	
	W		Ng.
		,	

The case report form must be completed in **black ball point pen or typewritten**. Any correction of the data must be initialed and dated, and must leave the initial entry readable.



Released (V#7) 08FEB00

INTRODUCTION

Dictionary: - NCI Common Toxicity Criteria (Version 2)
CRF SECTIONS:
- BASELINE
- CYCLE NO
- END OF STUDY
- FOLLOW-UP
- DEATH REPORT FORM
- LOT NUMBERS
EXTRA CYCLE (cycle nº)
Only 3 cycles are included in this binder, if more cycles are needed for a patient, Extra Cycles are available, kept separate from the CRF and can be added into the CRF.

If more forms are needed for examinations already described in cycles or for supplementary examinations, forms are available among the Pull In Forms provided, separate from the CRF. They should be inserted into the Baseline, Cycle or Follow-up sections wherever needed.

EXTRA FORMS

	JRGENT TRANSMISSION NEED	ED
FAX NUMBER: FROM:)	
A MULTICENTER PHASE III RANDO OR EVERY THREE WEEKS, IN COM		XEL ADMINISTERED EITHER WEEKLY US MITOXANTRONE IN COMBINATION
	NVESTIGATOR TOGETHER WITH CASE R THE CASE REPORT FORM AFTER STUD	
TO: INVESTIGATOR'S N	AME: Dr	
INSTITUTION:		,
Name of person completing this form:		
Direct FAX Number:		7:
PATIENT INITIALS	DATE OF BIRTH	DATE TREATMENT PLANNED
first middle last	dd mm yyyy	dd mm yyyy
TO BE FILI	LED OUT BY RPR IN CASE OF PATIENT	NOT ELIGIBLE
	THE PATIENT IS NOT ELIGIBLE	
Reason:		
Date of Registration Form receipt:	i l yyyy	
Study Manager's signature:		Date: dd mm yyyy
AND THE PAT	E, THE CONFIRMATION OF RANDOM IENT NUMBER ASSIGNED WILL BE F E INTERACTIVE VOICE RESPONSE S	

FOLLOW-UP INSTRUCTIONS

TUMOR ASSESSMENT / BONE CHECKLIST

To be performed every 2 months until patient's progression or further anti-tumor therapy.

Attach Follow-Up Tumor Assessment and Bone Checklist forms (Pull & Insert), if applicable.

PAIN EVALUATION

To be performed every month until patient's progression or further anti-tumor therapy.

Attach Follow-Up Pain Evaluation form (Pull & Insert), if applicable.

PSA

To be performed every month until patient's progression or further anti-tumor therapy.

Attach Follow-Up PSA form (Pull & Insert), if applicable.

QUALITY OF LIFE QUESTIONNAIRE

To be performed every month until further anti-tumor therapy.

Attach FACT P Completion Status and QOL Questionnaire, if applicable.

ADVERSE EVENTS

To be performed only for ongoing AE at time of end of study until further anti-tumor therapy.

Attach Follow-Up Adverse Event form (Pull & Insert), if applicable.

CONCOMITANT THERAPY

To be completed only for those medications given for:

- AE related to study drug ongoing at time of End of Study
- Tumor related symptoms ongoing at time of End of Study

Attach Follow-Up Concomitant Therapy form (Pull & Insert), if applicable.

INPATIENT CARE

To be completed until patient's death.

Attach Follow-Up Inpatient Care form (Pull & Insert), if applicable.



PHARMACOKINETICS - BLOOD COLLECTION FORM

PKBCF

Project No. Protocol No.		Patient Initials			Patient Alloc. No.		Visit No.		
RP 56976V	32	327				Cycle Nº			
				first middle last			Oycie II		
PHARMACOKINE	TIC DATA - DO	CETAXEL							
Day		te of		Sta	art Time		Stop Time		
(check (✓) one only)		istration: m/yyyy)			nr/min)		(hr/min)		
	(dd/III	···/ y y y y /							
☐1 Day 1			_						
☐2 Day 22									
	I.					•			
7 mL of whole blood	will be drawn in	heparinize	ed tube	s. Centrifuge	within 30 minutes of	of collection	n.		
		Sample	Thec	retical time	Actual time of				
Time		Number		samples	samples		Comments		
			- '	(Hr/min)	(Hr/min)				
Time 0 before infus	ion	T0							
			 						
15 min before the e	nd of infusion	T1							
				1	1 1-1				
15 min post infusior	1	T2							
				1-1	1 1-1				
45 min post infusior	1	Т3							
					. • .				
2 hours post infusio	n	T4							
C become most infrais				, • ,	•				
5 hours post infusio	ın	T5							
Matrix: Plasma			Δnt	icoagulant: <u>So</u>	dium Henarin				
				_	·				
Temperature of Sar	nple Storage:		C (Rer	minder: Shoul	d be -20°C or belo	w)			
Date Samples Ship	ned·		ıl						
Date Gampies Gmp	dd r	nm yyyy							
	<u>For Clii</u>	<u>nical Dru</u>	g Dis	position D	<u>epartment Use</u>	<u>Only</u>			
Date Samples Rece	eived: Lullu	nm yyyy			Received by:				
Comments:	uu i	іші уууу				(pr	int name)		
			-			200			
NOTE: Green copy	ot torm must	accompar	iy pna	rmacokinetic	samples sent to I	RPH.			
Incomplied to All					Investigator Numbe)r:			
Investigator Name:					iiivesiiyaitii Nullibe	1.			



LABORATORY REFERENCE RANGES

LABRR

LABORATORY REFERENCE RANGES	LADIK
Project No.	Protocol No.
RP 56976V	327
INVESTIGATOR NAME:	LAB NAME:
INVESTIGATOR NUMBER:	LAB ADDRESS:
	LABID:
Effective Start Date :	Effective Stop Date :
LINIT	NORMAL VALUE

Effective Start Date :		m yy	ууу	Effective S		 dd	mm	уууу	
	UN	IIT	SEX	NORMA RAN	L VALUE NGE		AGE R	ANGE	
TEST	Recom mended	Actual *	1=Male 2=Female 3=Both	Low Limit (ie. 1.0)	Upper Limit (ie. 5.6)	Low Age	Units (ie. years, months, days)	High Age	Units (ie. years, months, days)
PSA	ng/ml								
CREATININE	mg/dL								
TOTAL PROTEIN	g/dL								
ALBUMIN	g/dL								
ALKALINE PHOSPHATASE	IU/L								
ASAT (SGOT)	IU/L								
ALAT (SGPT)	IU/L								
TOTAL BILIRUBIN	mg/dL								
LDH	IU/L								
SODIUM	mmol/L								
POTASSIUM	mmol/L								
CALCIUM	mmol/L								
α1 ACID GLYCOPROTEIN	g/L								

^{*} Complete only if differs from recommended units.

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PROGRESSION AT STUDY ENTRY /	BCD1/BHC1	 D. I
PAIN EVALUATION BPSE/BPSA1/BPSA2/BPSA3/B	3PSA4/BPAE	 B.2
BLOOD CHEMISTRY / HEMATOLOGY / VITAL SIGNS (I)		
PATIENT WORKUP / LEFT VENTRICULAR EJECTION FRACTION	-	
STUDY ENTRY CRITERIA	BSEC	 B.5
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PATIENT DEMOGRAPHICS	BPD	 B.6
MEDICAL HISTORY / PRIOR / CONCOMITANT MEDICATION	BMH/BPCM	 B.7
CANCER DIAGNOSIS (II) / PRIOR SURGERY FOR CANCER / PRIOR RADIOTHERAPYBC	D2/BPS/BPR	 B.8
PRIOR HORMONAL CONTROL (II) SURGICAL THERAPY/ MEDICAL THERAPY / PRIOR ESTRAMUSTINE BST/BH	ICMT/BPEST	 B.9
PRIOR CORTICOSTEROID THERAPY / VITAL SIGNS (II) / PHYSICAL EXAMINATION / ELECTROCARDIOGRAM BPCT/BVS	S/BPE/BECG	 B.10
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STUDY MEDICATION ADMINISTRATION	SMA3/SMA6	 C.2
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BLOOD CHEMISTRY	•	
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ADVERSE EVENTS		
ADVEDOE EVENTO	^ _	\sim 7

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CONCOMITANT MEDICATION		
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	IA	 C.10
BONE CHECK LIST / VITAL SIGNS / LEFT VENTRICULAR EJECTION FRACTION / PAIN EVALUATION	BCL/VS/LVEF/PAE	 C.11
INPATIENT CARE		
END OF OTHERWING		
END OF STUDY VISIT		
BEST OVERALL RESPONSE /		
DISCONTINUATION OF STUDY MEDICATION	BR/TSM/PCE	 E.O.S.1
FOLLOW-UP VISIT		
FOLLOW-UP STATUS	FUS/FVS/FDS	 F.U.1
FURTHER THERAPY	FT/FTHERA	 F.U.2
Complete the following on pay mystered as an accorded:		
Complete the following as per protocol or as needed:		
FOLLOW-UP ADVERSE EVENTS	FAE	
FOLLOW-UP ADVERSE EVENTS	FAE	
FOLLOW-UP ADVERSE EVENTS	FAE	
FOLLOW-UP CONCOMITANT THERAPY	FPCM	
FOLLOW-UP PAIN EVALUATION / FOLLOW-UP PSA	FPAE/FPSA	
FOLLOW-UP INPATIENT CARE	FIPC	
FOLLOW-UP TUMOR ASSESSMENT	FTA	
FOLLOW-UP BONE CHECK LIST	FBCL	

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LOT NUMBERS		
LOT NUMBERS	I N	

BASELINE VISIT - REGISTRATION

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BLOOD CHEMISTRY / HEMATOLOGY	/ VITAL SIGNS (I) BBC	C/BH/BVS1	B.3
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STUDY ENTRY CRITERIA		BSEC	B 5

BASELINE VISIT

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GENERIC CYCLE

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ADVERSE EVENTS	AE	 C.8
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END OF STUDY VISIT

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FOLLOW-UP VISIT

CASE REPORT FORM NAME	FORM ID	PAGE #
FOLLOW-UP STATUS	FUS/FVS/FDS	F.U.1
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Complete the following as per protocol or as needed:		
FOLLOW-UP ADVERSE EVENTS	FAE	
FOLLOW-UP ADVERSE EVENTS	FAE	
FOLLOW-UP ADVERSE EVENTS	FAE	
FOLLOW-UP CONCOMITANT THERAPY	FPCM	
FOLLOW-UP PAIN EVALUATION / FOLLOW-UP PSA	FPAE/FPSA	
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DEATH REPORT FORM

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LOT NUMBERS

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