CANCER DIAGNOSIS (I) / PRIOR HORMONAL CONTROL (I) BCD1/BHC1

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

INFORMED CONSENT

Date informed consent obtained: dd mm yyyy

CANCER DIAGNOSIS I

	Description
Primary Tumor Type	Prostate
Date of First Diagnosis:	dd mm yyyy
Histological Type (check (✓) one only)	☐1 Adenocarcinoma ☐94 Other, *specify*: _____

RADIOTHERAPY I

Did patient receive prior radiotherapy?
☐0 No ☐1 Yes

Stop Date of Last Radiotherapy: dd mm yyyy

Did the patient receive prior radiotherapy including more than 25% of the bone marrow? ☐0 No ☐1 Yes

PRIOR ESTRAMUSTINE THERAPY I

Did patient receive prior oral estramustine?
☐0 No ☐1 Yes ☐1 Monotherapy ☐2 Combination, specify:_____

Stop Date of Estramustine therapy: dd mm yyyy

PRIOR HORMONAL CONTROL I

Did the patient receive prior hormonal manipulation?
☐0 No ☐1 Yes

Method of castration:
☐1 Orchiectomy ☐2 ongoing LH-RH agonists*

Testosterone level: ___ . ___ ng/dL

Did the patient receive anti-androgens?
☐0 No ☐1 Yes

☐1 Flutamide / Nilutamide / Cyproterone acetate — Stop Date: dd mm yyyy

☐2 Bicalutamide — Stop Date: dd mm yyyy

*This treatment should be continued.

Investigator Name:	Investigator Number:

PROGRESSION AT STUDY ENTRY / PAIN EVALUATION BPSE/BPSA1/BPSA2/BPSA3/BPSA4/BPAE

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PROGRESSION AT STUDY ENTRY

☐1 Objective progression on (uni- or bidimensionally) MEASURABLE LESIONS:
Organ:_____ Subsite:_____
Date of progression: dd mm yyyy

☐2 Progression on NON MEASURABLE lesions (except bone):
Organ:_____ Subsite:_____
Date of progression: dd mm yyyy

☐3 Appearance of new lesions on BONE SCAN:
Date of progression: dd mm yyyy

☐4 Rising PSA (mandatory if no PD elsewhere)

BASELINE PSA

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.

Test	Recommended Units	Measure 1 Date of Sample: dd mm yyyy		Measure 2 Date of Sample: dd mm yyyy		Measure 3 Date of Sample: dd mm yyyy		Measure 4# Date of Sample: dd mm yyyy	
		Result	Actual units*	Result	Actual units*	Result**	Actual units*	Result**	Actual units*
PSA	ng/mL								

* Complete only if differs from recommended.

** 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.

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		●

BLOOD CHEMISTRY / HEMATOLOGY / VITAL SIGNS (I) BBC/BH/BVS1

Project No.	Protocol No.	Patient Initials	Patient Alloc. No.	Visit No. 0
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LAB NAME: _____

LAB ADDRESS _____

LABID: ____

BLOOD CHEMISTRY

To be performed within 14 days prior to randomization.

Test	Recommended units	Date of Sample: dd mm yyyy — Result	Actual units*
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

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.

HEMATOLOGY

To be performed within 14 days prior to randomization.

Test	Recommended units	Date of Sample: dd mm yyyy — Result	Actual units*
HEMOGLOBIN	g/dL		
PLATELETS	10^9/L		
WBC	10^9/L		
NEUTROPHILS	10^9/L		

* Complete only if differs from recommended

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 within 14 days prior to randomization. Please record below the assessment performed the closest to the date of randomization.

Date of Assessment: ____ ____ ____ (dd mm yyyy)

Karnofsky Performance Status

____

PATIENT WORKUP / LEFT VENTRICULAR EJECTION FRACTION

BPW/BLV

Project No.	Protocol No.	Patient Initials	Patient Alloc. No.	Visit No. 0
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PATIENT WORKUP
To be performed within 21 days prior to randomization.

	Type of Evaluation	Date Assessed (dd/mm/yyyy)	Tumor Involvement
1	Chest X-Ray	☐0 Not Done	☐0 No ☐1 Yes
2	Chest CT Scan	☐0 Not Done	☐0 No ☐1 Yes
3	Pelvic CT Scan	☐0 Not Done	☐0 No ☐1 Yes
4	Abdominal CT Scan	☐0 Not Done	☐0 No ☐1 Yes
5	Bone Scan (i.e., scintigraphy)	☐0 Not Done	☐0 No ☐1 Yes
94	Other, specify _____		☐0 No ☐1 Yes
94	Other, specify _____		☐0 No ☐1 Yes
94	Other, specify _____		☐0 No ☐1 Yes

LEFT VENTRICULAR EJECTION FRACTION
To be performed within 14 days prior to randomization. (check (✓) one only)

☐1 Radionuclide angiocardiography (MUGA scan)
Date of Assessment: dd mm yyyy
Value: ___ %
Lower limit of normal for the institution: ___ %

☐2 Echocardiography
Date of Assessment: dd mm yyyy
Value: ___ %
Lower limit of normal for the institution: ___ %

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STUDY ENTRY CRITERIA

EXCLUSION 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 ≥ 5 years.	☐ No ☐ Yes
5.	Known brain or leptomeningeal involvement.	☐ No ☐ Yes
6.	Symptomatic peripheral neuropathy ≥ 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

INCLUSION 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

PATIENT DEMOGRAPHICS

BPD

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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

Project No.	Protocol No.	Patient Initials	Patient Alloc. No.	Visit No. 0
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GENERAL MEDICAL / SURGICAL HISTORY AND CONCOMITANT MEDICAL CONDITIONS, OTHER THAN PROSTATE CANCER

☐0 NONE

Please enter any **significant and relevant** medical/surgical history and concomitant medical conditions of the patient other than prostate cancer.

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.

Description	Date of Onset (dd/mm/yyyy)	Date Ceased (dd/mm/yyyy) or ✓ if ongoing
		☐1 ongoing
		☐1 ongoing
		☐1 ongoing
		☐1 ongoing

PRIOR / CONCOMITANT MEDICATIONS – NON-ANTI-TUMOR

☐0 NONE

Please describe below any medications and / or therapies received by the patient **within 30 days prior to the first study drug infusion, excluding corticosteroids, chemo, immuno and hormonal therapy.** If drug is taken as per need **(PRN)** (as required), the approximate **Total Daily Dose** must be recorded.

Drug (Brand Name)	Route	Total Daily Dose		Start Date (dd/mm/yyyy)	Stop Date (dd/mm/yyyy) or ✓ if ongoing	Indication 5: Prophylaxis 6: Curative or symptomatic
		Dose	Unit			
					☐1 ongoing	
					☐1 ongoing	
					☐1 ongoing	
					☐1 ongoing	
					☐1 ongoing	
					☐1 ongoing	

CONCOMITANT MEDICATION (DIARY ANALGESICS ONLY) BPCM-DA

Project No.	Protocol No.	Patient Initials	Patient Alloc. No.	Visit No. 0
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CONCOMITANT MEDICATIONS

Only analgesics reported in the **Patient Pain Diary** should be recorded in this module.

☐0 NONE

				Dose of Analgesics (7-day period of the Pain Diary)							
Drug (Brand Name)	Route	Start Date (dd/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								
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CANCER DIAGNOSIS (II) / PRIOR SURGERY FOR CANCER / PRIOR RADIOTHERAPY

BCD2/BPS/BPR

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

CANCER DIAGNOSIS (II)

Record TNM stage and Gleason score at FIRST DIAGNOSIS

	Description
TNM/Stage (if not assessed, please enter X)	T: N: M: pT: pN: pM:
Histopathological Grade	☐1 G1 ☐2 G2 ☐3 G3 ☐4 G4 ☐5 GX
Staging	
Gleason Score (should be between 2 and 10)	☐1 Not Assessed

PRIOR SURGERY FOR CANCER, EXCLUDING ORCHIECTOMY, ADRENALECTOMY OR HYPOPHYSECTOMY

☐0 NONE

Please describe below any cancer-related surgery the patient has undergone

Date of Surgery (dd/mm/yyyy)	Operative procedure
	☐1 Prostatectomy
	☐5 Pelvic Lymphadenectomy
	☐94 Other, specify _____

PRIOR RADIOTHERAPY (II)

Please describe below any prior radiotherapy

☐0 NONE

Organ (check (✓) one only)	% Irradiated Bone Marrow	Estimated Total Dose (specify units) Dose	Estimated Total Dose (specify units) Units	Start Date (dd/mm/yyyy)	Stop Date (dd/mm/yyyy) *(Stop Date: date of last treatment)*
☐1 Prostate ☐2 Pelvic Lymph Nodes ☐3 Bone Palliation ☐94 Other, specify:_____			☐1 Gy ☐2 rads ☐3 cGy		
☐1 Prostate ☐2 Pelvic Lymph Nodes ☐3 Bone Palliation ☐94 Other, specify:_____			☐1 Gy ☐2 rads ☐3 cGy		
☐1 Prostate ☐2 Pelvic Lymph Nodes ☐3 Bone Palliation ☐94 Other, specify:_____			☐1 Gy ☐2 rads ☐3 cGy		

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

BST/BHCMT/BPEST

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PRIOR HORMONAL CONTROL (II): SURGICAL THERAPY

Please describe below any surgery for hormonal control the patient has undergone

☐0 NONE

Date of Surgery (dd/mm/yyyy)	Operative procedure
	☐1 Bilateral Orchiectomy
	☐2 Bilateral Adrenalectomy
	☐3 Hypophysectomy
	☐94 Other, specify _____

PRIOR HORMONAL CONTROL (II): MEDICAL THERAPY

☐0 NONE

Product Name (one line for each product if contained in a combination regimen)	Start Date (dd/mm/yyyy)	Stop Date (dd/mm/yyyy) or ✓ if ongoing
		☐1 ongoing
		☐1 ongoing
		☐1 ongoing
		☐1 ongoing
		☐1 ongoing

PRIOR ESTRAMUSTINE (II)

☐0 NONE

Drug (Brand Name)	Route	Total Daily Dose		Start Date (dd/mm/yyyy)	Stop Date (dd/mm/yyyy)
		Dose	Unit		

PRIOR CORTICOSTEROID THERAPY / VITAL SIGNS (II) / PHYSICAL EXAMINATION / ELECTROCARDIOGRAM BPCT/BVS/BPE/BECG

Project No.	Protocol No.	Patient Initials	Patient Alloc. No.	Visit No. 0
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PRIOR CORTICOSTEROID THERAPY

☐0 NONE

Drug (Brand Name)	Route	Total Daily Dose		Start Date (dd/mm/yyyy)	Stop Date (dd/mm/yyyy)
		Dose	Unit		

VITAL SIGNS (II)

☐0 NOT done

Date of Assessment: dd mm yyyy

Weight	Height
☐1 lb ☐2 kg	☐1 in ☐2 cm

PHYSICAL EXAMINATION, OTHER THAN CANCER

☐0 NOT done

Date Physical Exam Performed: dd mm yyyy

ELECTROCARDIOGRAM

☐0 NOT done

Date of Tracing: dd mm yyyy

Interpretation (check (✓) one only):

☐1 Within normal limits

☐2 Non-significant abnormalities

☐3 Significant abnormalities, complete ▶ *EXISTING SIGNS AND SYMPTOMS form.*

TUMOR ASSESSMENT

BTA

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TUMOR ASSESSMENT

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..)	Organ **a: Site** (enter the appropriate number) 1: Bone (complete also checklist) 2: Lymph Node 3: Liver 4: Lung 5: Other Soft Tissue, specify 94: Other Organ, specify **b: Subsite** (description)	Date of Assessment (dd/mm/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	Measurability *(Enter appropriate number)* 1: Bidimensionally measurable 2: Unidimensionally measurable 5: Non measurable	Measurement (mm x mm)
	a ☐ b _____				___ × ___
	a ☐ b _____				___ × ___
	a ☐ b _____				___ × ___
	a ☐ b _____				___ × ___
	a ☐ b _____				___ × ___
	a ☐ b _____				___ × ___
	a ☐ b _____				___ × ___

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BONE CHECK LIST ☐0 NONE

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	

EXISTING SIGNS AND SYMPTOMS

BESS

Project No.	Protocol No.	Patient Initials	Patient Alloc. No.	Visit No. 0
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EXISTING SIGNS AND SYMPTOMS

☐0 NONE

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)	OUTCOME (complete only ONE column)		Grade (1–4)
			Ongoing	Resolved date ceased (dd/mm/yyyy)	
CS-FAT	Fatigue		☐1	☐2 resolved	
PA-BON	Bone Pain		☐1	☐2 resolved	
GU-DYS	Dysuria (painful urination)		☐1	☐2 resolved	
GU-INC	Incontinence		☐1	☐2 resolved	
GU-RET	Urinary Retention		☐1	☐2 resolved	
MS-OTH	Pathological fracture		☐1	☐2 resolved	
OT-OTH	Spinal Cord Compression		☐1	☐2 resolved	
___ - ___			☐1	☐2 resolved	
___ - ___			☐1	☐2 resolved	
___ - ___			☐1	☐2 resolved	
___ - ___			☐1	☐2 resolved	
___ - ___			☐1	☐2 resolved	
___ - ___			☐1	☐2 resolved	
___ - ___			☐1	☐2 resolved	

In case of AE code is OT-OTH, grade severity as: 1=Mild, 2=Moderate, 3=Severe, 4=Life Threatening

Investigator Name:	Investigator Number:

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/m^2)	Total Dose Given (mg)
☐0 No ☐1 Yes ⇒ ___ _____	___ ___ ___ (dd mm yyyy)	☐17	Mitoxantrone	☐0 No ☐1 Yes ⇒ ___ _____		
		☐2	Docetaxel ☐1 q3w ☐2 qw			

Setting: ☐1 Outpatient Clinic ☐2 Inpatient Clinic *(fill in Inpatient Care form)*

* 1: Non-study drug related adverse experience(s)
Study Drug Related:
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) ☐1 ongoing	___ ___ ___ (dd mm yyyy) ☐1 ongoing	

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

STUDY MEDICATION ADMINISTRATION (II)

For weekly arm only (Arm C)

☐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)
☐0 No ☐1 Yes ⇒ ___ _____	2	___ ___ ___ dd mm yyyy	2	Docetaxel	☐0 No ☐1 Yes ⇒ ___ _____		
Setting: ☐1 Outpatient Clinic ☐2 Inpatient Clinic *(fill in Inpatient Care form)*							
☐0 No ☐1 Yes ⇒ ___ _____	3	___ ___ ___ dd mm yyyy	2	Docetaxel	☐0 No ☐1 Yes ⇒ ___ _____		
Setting: ☐1 Outpatient Clinic ☐2 Inpatient Clinic *(fill in Inpatient Care form)*							
☐0 No ☐1 Yes ⇒ ___ _____	4	___ ___ ___ dd mm yyyy	2	Docetaxel	☐0 No ☐1 Yes ⇒ ___ _____		
Setting: ☐1 Outpatient Clinic ☐2 Inpatient Clinic *(fill in Inpatient Care form)*							
☐0 No ☐1 Yes ⇒ ___ _____	5	___ ___ ___ dd mm yyyy	2	Docetaxel	☐0 No ☐1 Yes ⇒ ___ _____		
Setting: ☐1 Outpatient Clinic ☐2 Inpatient Clinic *(fill in Inpatient Care form)*							

* 1: Non-study drug related adverse experience(s)
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.
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HEMATOLOGY

To be performed on Day 1 before infusion and every 2 days in case of febrile neutropenia or infection up to fever < 38.0 °C and ANC ≥ 1.0 x 10^9/L. ☐0 NOT done

Test	Recommended units	Date of Sample: dd mm yyyy		Date of Sample: dd mm yyyy		Date of Sample: dd mm yyyy	
		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 only if differs from recommended*

HEMATOLOGY

Test	Recommended units	Date of Sample: dd mm yyyy		Date of Sample: dd mm yyyy		Date of Sample: dd mm yyyy	
		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 only if differs from recommended*

BLOOD CHEMISTRY

BC1/BC3

Project No.	Protocol No.	Patient Initials	Patient Alloc. No.	Visit No.
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To be performed every 3 weeks (Day 1 before infusion)

☐0 NOT done

	☐1 Check if laboratory is the same as baseline; otherwise complete below.	☐1 Check if laboratory is the same as baseline; otherwise complete below.	☐1 Check if laboratory is the same as baseline; otherwise complete below.
	LAB NAME	LAB NAME	LAB NAME
	LAB ADDRESS:	LAB ADDRESS:	LAB ADDRESS:
	LABID:	LABID:	LABID:
BLOOD CHEMISTRY			

Test	Recommended units	Date of Sample: dd mm yyyy		Date of Sample: dd mm yyyy		Date of Sample: dd mm yyyy	
		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 if differs from recommended*

\# *Only in patients with PK samples*

IF ADDITIONAL TESTS (NOT SPECIFIED ABOVE) OR REPEAT TESTS ARE PERFORMED, ADDITIONAL UNSCHEDULED LABORATORY PAGES SHOULD BE USED.

ADVERSE EVENTS

AE

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

ADVERSE EVENTS

☐0 NONE

AE TERM [Diagnosis if known or sign/symptom] (one code per row)			STATUS OF AE (check (✓) one only) 1=Ongoing without change [STOP]* 2=New or change to ongoing AE [continue]**	SERIOUS If serious, complete SAE form.	DATE OF ONSET (dd/mm/yyyy) or check (✓) if ongoing	OUTCOME (complete only ONE column)			GRADE (1-5)	ACTION TAKEN REGARDING STUDY MEDICATION (check (✓) one only) 0=None 1=Temporarily interrupted 2=Permanently discontinued*** 4=Regimen changed-dose reduced 5=Regimen changed-frequency changed 6=Regimen changed-other 7=Regimen changed-dose reduced and frequency changed	Other Action Taken Due To AE 0=None 1=Hospitalization	CAUSALITY Is there a reasonable possibility that the study medication caused the event? (check (✓) one only) 0=No 1=Unlikely 2=Possibly 3=Probably
	NCI CODE	DESCRIPTION				Ongoing	Resolved date ceased (dd/mm/yyyy)	Death				
NCI CRITERIA	AL-LER	Allergic Reaction	☐1 ☐2	☐ 0 No ☐ 1 Yes	☐1 ongoing	☐1	☐2 resolved	☐3		☐0 ☐1 ☐2 ☐4 ☐5 ☐6 ☐7	☐0 ☐1	☐0 ☐1 ☐2 ☐3
	GI-NAU	Nausea	☐1 ☐2	☐ 0 No ☐ 1 Yes	☐1 ongoing	☐1	☐2 resolved	☐3		☐0 ☐1 ☐2 ☐4 ☐5 ☐6 ☐7	☐0 ☐1	☐0 ☐1 ☐2 ☐3
	GI-VOM	Vomiting	☐1 ☐2	☐ 0 No ☐ 1 Yes	☐1 ongoing	☐1	☐2 resolved	☐3		☐0 ☐1 ☐2 ☐4 ☐5 ☐6 ☐7	☐0 ☐1	☐0 ☐1 ☐2 ☐3
	GI-STO	Stomatitis/Pharyngitis	☐1 ☐2	☐ 0 No ☐ 1 Yes	☐1 ongoing	☐1	☐2 resolved	☐3		☐0 ☐1 ☐2 ☐4 ☐5 ☐6 ☐7	☐0 ☐1	☐0 ☐1 ☐2 ☐3
	GI-DIA	Diarrhea	☐1 ☐2	☐ 0 No ☐ 1 Yes	☐1 ongoing	☐1	☐2 resolved	☐3		☐0 ☐1 ☐2 ☐4 ☐5 ☐6 ☐7	☐0 ☐1	☐0 ☐1 ☐2 ☐3

* Do not complete remainder of row. ** Complete remainder of row. *** Complete Discontinuation of Study Medication module.

Investigator Name: Investigator Number:

ADVERSE EVENTS

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

ADVERSE EVENTS

☐0 NONE

	AE TERM [Diagnosis if known or sign/symptom] (one code per row)		STATUS OF AE (check (✓) one only) 1=Ongoing without change [STOP]* 2=New or change to ongoing AE [continue]**	SERIOUS If serious, complete SAE form.	DATE OF ONSET (dd/mm/yyyy) or check (✓) if ongoing	OUTCOME (complete only ONE column)			GRADE (1-5)	ACTION TAKEN REGARDING STUDY MEDICATION (check (✓) one only) 0=None 1=Temporarily interrupted 2=Permanently discontinued*** 4=Regimen changed-dose reduced 5=Regimen changed-frequency changed 6=Regimen changed-other 7=Regimen changed-dose reduced and frequency changed	Other Action Taken Due To AE 0=None 1=Hospitalization	CAUSALITY Is there a reasonable possibility that the study medication caused the event? (check (✓) one only) 0=No 1=Unlikely 2=Possibly 3=Probably
	NCI CODE	DESCRIPTION				Ongoing	Resolved date ceased (dd/mm/yyyy)	Death				
NCI CRITERIA	IN-FEC	Infection, specify _____	☐1 ☐2	☐ 0 No ☐ 1 Yes	☐1 ongoing	☐1	☐2 resolved	☐3		☐0 ☐1 ☐2 ☐4 ☐5 ☐6 ☐7	☐0 ☐1	☐0 ☐1 ☐2 ☐3
	Febrile neutropenia		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.									
	CS-FEV	Fever	☐1 ☐2	☐ 0 No ☐ 1 Yes	☐1 ongoing	☐1	☐2 resolved	☐3		☐0 ☐1 ☐2 ☐4 ☐5 ☐6 ☐7	☐0 ☐1	☐0 ☐1 ☐2 ☐3
		Duration of fever ≥ 38.5°C			☐1 ongoing	☐1	☐2 resolved					
	SK-ALO	Alopecia	☐1 ☐2	☐ 0 No ☐ 1 Yes	☐1 ongoing	☐1	☐2 resolved	☐3		☐0 ☐1 ☐2 ☐4 ☐5 ☐6 ☐7	☐0 ☐1	☐0 ☐1 ☐2 ☐3
	NE-SEN	Neuropathy sensory	☐1 ☐2	☐ 0 No ☐ 1 Yes	☐1 ongoing	☐1	☐2 resolved	☐3		☐0 ☐1 ☐2 ☐4 ☐5 ☐6 ☐7	☐0 ☐1	☐0 ☐1 ☐2 ☐3
	NE-MOT	Neuropathy motor	☐1 ☐2	☐ 0 No ☐ 1 Yes	☐1 ongoing	☐1	☐2 resolved	☐3		☐0 ☐1 ☐2 ☐4 ☐5 ☐6 ☐7	☐0 ☐1	☐0 ☐1 ☐2 ☐3
	OT-OTH	Peripheral Edema	☐1 ☐2	☐ 0 No ☐ 1 Yes	☐1 ongoing	☐1	☐2 resolved	☐3		☐0 ☐1 ☐2 ☐4 ☐5 ☐6 ☐7	☐0 ☐1	☐0 ☐1 ☐2 ☐3

* Do not complete remainder of row. ** Complete remainder of row. *** Complete Discontinuation of Study Medication module.

Investigator Name: Investigator Number:

Revised 02JUN00

Released (V#7) 08FEB00

ADVERSE EVENTS

AE

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

ADVERSE EVENTS

☐0 NONE

AE TERM [Diagnosis if known or sign/symptom] (one code per row)			STATUS OF AE (check (✓) one only) 1=Ongoing without change [STOP]* 2=New or change to ongoing AE [continue]**	SERIOUS If serious, complete SAE form.	DATE OF ONSET (dd/mm/yyyy) or check (✓) if ongoing	OUTCOME (complete only ONE column)			GRADE (1-5)	ACTION TAKEN REGARDING STUDY MEDICATION (check (✓) one only) 0=None 1=Temporarily interrupted 2=Permanently discontinued*** 4=Regimen changed-dose reduced 5=Regimen changed-frequency changed 6=Regimen changed-other 7=Regimen changed-dose reduced and frequency changed	Other Action Taken Due To AE 0=None 1=Hospitalization	CAUSALITY Is there a reasonable possibility that the study medication caused the event? (check (✓) one only) 0=No 1=Unlikely 2=Possibly 3=Probably
	NCI CODE	DESCRIPTION				Ongoing	Resolved date ceased (dd/mm/yyyy)	Death				
NCI CRITERIA	CD-LVF	Cardiac Left Ventricular Function	☐1 ☐2	☐ 0 No ☐ 1 Yes	☐1 ongoing	☐1	☐2 resolved	☐3		☐0 ☐1 ☐2 ☐4 ☐5 ☐6 ☐7	☐0 ☐1	☐0 ☐1 ☐2 ☐3
	CS-FAT	Fatigue	☐1 ☐2	☐ 0 No ☐ 1 Yes	☐1 ongoing	☐1	☐2 resolved	☐3		☐0 ☐1 ☐2 ☐4 ☐5 ☐6 ☐7	☐0 ☐1	☐0 ☐1 ☐2 ☐3
	PA-BON	Bone Pain	☐1 ☐2	☐ 0 No ☐ 1 Yes	☐1 ongoing	☐1	☐2 resolved	☐3		☐0 ☐1 ☐2 ☐4 ☐5 ☐6 ☐7	☐0 ☐1	☐0 ☐1 ☐2 ☐3
	GU-DYS	Dysuria (painful urination)	☐1 ☐2	☐ 0 No ☐ 1 Yes	☐1 ongoing	☐1	☐2 resolved	☐3		☐0 ☐1 ☐2 ☐4 ☐5 ☐6 ☐7	☐0 ☐1	☐0 ☐1 ☐2 ☐3
	GU-INC	Incontinence	☐1 ☐2	☐ 0 No ☐ 1 Yes	☐1 ongoing	☐1	☐2 resolved	☐3		☐0 ☐1 ☐2 ☐4 ☐5 ☐6 ☐7	☐0 ☐1	☐0 ☐1 ☐2 ☐3
	GU-RET	Urinary Retention	☐1 ☐2	☐ 0 No ☐ 1 Yes	☐1 ongoing	☐1	☐2 resolved	☐3		☐0 ☐1 ☐2 ☐4 ☐5 ☐6 ☐7	☐0 ☐1	☐0 ☐1 ☐2 ☐3
	MS-OTH	Pathological fracture	☐1 ☐2	☐ 0 No ☐ 1 Yes	☐1 ongoing	☐1	☐2 resolved	☐3		☐0 ☐1 ☐2 ☐4 ☐5 ☐6 ☐7	☐0 ☐1	☐0 ☐1 ☐2 ☐3
	OT-OTH	Spinal cord compression	☐1 ☐2	☐ 0 No ☐ 1 Yes	☐1 ongoing	☐1	☐2 resolved	☐3		☐0 ☐1 ☐2 ☐4 ☐5 ☐6 ☐7	☐0 ☐1	☐0 ☐1 ☐2 ☐3

* Do not complete remainder of row. ** Complete remainder of row. *** Complete Discontinuation of Study Medication module.

Investigator Name: Investigator Number:

Released (V#7) 08FEB00

ADVERSE EVENTS

AE

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

BULK

C.8

ADVERSE EVENTS

☐0 NONE

	AE TERM [Diagnosis if known or sign/symptom] (one code per row): NCI CODE	DESCRIPTION	STATUS OF AE (check (✓) one only) 1=Ongoing without change [STOP]* 2=New or change to ongoing AE [continue]**	SERIOUS If serious, complete SAE form.	DATE OF ONSET (dd/mm/yyyy) or check (✓) if ongoing	OUTCOME (complete only ONE column): Ongoing	OUTCOME: Resolved date ceased (dd/mm/yyyy)	OUTCOME: Death	GRADE (1-5)	ACTION TAKEN REGARDING STUDY MEDICATION (check (✓) one only) 0=None 1=Temporarily interrupted 2=Permanently discontinued*** 4=Regimen changed-dose reduced 5=Regimen changed-frequency changed 6=Regimen changed-other 7=Regimen changed-dose reduced and frequency changed	Other Action Taken Due To AE 0=None 1=Hospitalization	CAUSALITY Is there a reasonable possibility that the study medication caused the event? (check (✓) one only) 0=No 1=Unlikely 2=Possibly 3=Probably
NCI CRITERIA	-		☐1 ☐2	☐0 No ☐1 Yes	☐1 ongoing	☐1	☐2 resolved	☐3		☐0 ☐1 ☐2 ☐4 ☐5 ☐6 ☐7	☐0 ☐1	☐0 ☐1 ☐2 ☐3
	-		☐1 ☐2	☐0 No ☐1 Yes	☐1 ongoing	☐1	☐2 resolved	☐3		☐0 ☐1 ☐2 ☐4 ☐5 ☐6 ☐7	☐0 ☐1	☐0 ☐1 ☐2 ☐3
	-		☐1 ☐2	☐0 No ☐1 Yes	☐1 ongoing	☐1	☐2 resolved	☐3		☐0 ☐1 ☐2 ☐4 ☐5 ☐6 ☐7	☐0 ☐1	☐0 ☐1 ☐2 ☐3
	-		☐1 ☐2	☐0 No ☐1 Yes	☐1 ongoing	☐1	☐2 resolved	☐3		☐0 ☐1 ☐2 ☐4 ☐5 ☐6 ☐7	☐0 ☐1	☐0 ☐1 ☐2 ☐3
	-		☐1 ☐2	☐0 No ☐1 Yes	☐1 ongoing	☐1	☐2 resolved	☐3		☐0 ☐1 ☐2 ☐4 ☐5 ☐6 ☐7	☐0 ☐1	☐0 ☐1 ☐2 ☐3
	-		☐1 ☐2	☐0 No ☐1 Yes	☐1 ongoing	☐1	☐2 resolved	☐3		☐0 ☐1 ☐2 ☐4 ☐5 ☐6 ☐7	☐0 ☐1	☐0 ☐1 ☐2 ☐3
	-		☐1 ☐2	☐0 No ☐1 Yes	☐1 ongoing	☐1	☐2 resolved	☐3		☐0 ☐1 ☐2 ☐4 ☐5 ☐6 ☐7	☐0 ☐1	☐0 ☐1 ☐2 ☐3
	-		☐1 ☐2	☐0 No ☐1 Yes	☐1 ongoing	☐1	☐2 resolved	☐3		☐0 ☐1 ☐2 ☐4 ☐5 ☐6 ☐7	☐0 ☐1	☐0 ☐1 ☐2 ☐3

* Do not complete remainder of row. ** Complete remainder of row. *** Complete Discontinuation of Study Medication module.

In case of AE code is OT-OTH, grade severity as: 1=Mild, 2=Moderate, 3=Severe, 4=Life Threatening

Investigator Name:

Investigator Number:

CONCOMITANT MEDICATION

PCM

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

CONCOMITANT MEDICATIONS ☐0 NONE

If drug is **PRN**, the approximate **Total Daily Dose** must be recorded.

Drug (Brand Name)	Status of Conc. Med. (check (✓) one only) 1=Ongoing without change [STOP] * 2=New or change to ongoing medication [continue] **	Route	Total Daily Dose		Start Date (dd/mm/yyyy) or ✓ if ongoing	Stop Date (dd/mm/yyyy) or ✓ if ongoing	Indication 5: Prophylaxis 6: Curative or Symptomatic
			Dose	Unit			
	☐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 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	

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

CONCOMITANT MEDICATION (DIARY ANALGESICS ONLY) PCM-DA

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

CONCOMITANT MEDICATIONS

Only analgesics reported in the **Patient Pain Diary** should be recorded in this module.

☐0 NONE

				Dose of Analgesics (7-day period of the Pain Diary)							
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								
		☐0 ongoing	☐0 ongoing								
		☐0 ongoing	☐0 ongoing								
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		☐0 ongoing	☐0 ongoing								
		☐0 ongoing	☐0 ongoing								
		☐0 ongoing	☐0 ongoing								

TUMOR ASSESSMENT

TA

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

TUMOR ASSESSMENT

☐0 NOT done

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 ...)	Organ **a: Site** (enter the appropriate number) 1:Bone (complete also checklist) 2:Lymph Node 3:Liver 4:Lung 5:Other Soft Tissue, specify 94:Other Organ, specify **b: Subsite (description)**	Date of Assessment (dd/mm/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	Measurement (mm x mm)	Response of Non-Measurable 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 ☐ b _____	☐0 Not Done		×	
	a ☐ b _____	☐0 Not Done		×	
	a ☐ b _____	☐0 Not Done		×	
	a ☐ b _____	☐0 Not Done		×	
	a ☐ b _____	☐0 Not Done		×	
	a ☐ b _____	☐0 Not Done		×	
	a ☐ b _____	☐0 Not Done		×	

Overall Tumor Response at end of this cycle:

☐1 CR ☐2 PR ☐3 NC/SD ☐4 PD ☐5 NE, specify _____

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 bone scan showing metastatic lesion

☐0 NONE

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: dd mm yyyy

Karnofsky:

Weight

☐1 lb

☐2 kg

LEFT VENTRICULAR EJECTION FRACTION (check (✓) one method only)

In Arm A: to be completed after cycles 5, 8 and 10
In each arm: to be completed at end of study

☐0 NOT done

☐1 Radionuclide angiocardiography (MUGA scan)

Date of Assessment: dd mm yyyy

Value: %

Lower limit of normal for the institution: %

☐2 Echocardiography

Date of Assessment: dd mm yyyy

Value: %

Lower limit of normal for the institution: %

PAIN EVALUATION

To be averaged over 7 consecutive days. To be performed every 3 weeks.

☐0 NOT done

	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		•

INPATIENT CARE

IPC

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

INPATIENT ADMISSION DURING CYCLE

Since the last visit, has the patient been admitted for overnight stay to hospital?

☐0 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 ☐1 Ongoing	dd mm yyyy ☐1 Ongoing	☐1 Study drug administration ☐2 Tumor related Adverse Event** ☐3 Study drug related Adverse Event** ☐94 Other, *specify:* ______	☐2 Surgery ☐3 Internal Medicine ☐4 ICU* ☐94 Other, *specify:* ______
dd mm yyyy ☐1 Ongoing	dd mm yyyy ☐1 Ongoing	☐1 Study drug administration ☐2 Tumor related Adverse Event** ☐3 Study drug related Adverse Event** ☐94 Other, *specify:* ______	☐2 Surgery ☐3 Internal Medicine ☐4 ICU* ☐94 Other, *specify:* ______
dd mm yyyy ☐1 Ongoing	dd mm yyyy ☐1 Ongoing	☐1 Study drug administration ☐2 Tumor related Adverse Event** ☐3 Study drug related Adverse Event** ☐94 Other, *specify:* ______	☐2 Surgery ☐3 Internal Medicine ☐4 ICU* ☐94 Other, *specify:* ______

During those hospitalizations, have any major procedures been performed? ☐0 None

☐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

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

*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

Patient's status as of end of follow-up

(check (✓) one only):

☐1 Alive

☐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 (patient's progression has been already reported or patient has not progressed yet)

☐2 Protocol-defined progression on tumor lesions

☐3 Protocol-defined PSA progression

☐4 Protocol-defined 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 THERAPY (I)

If the patient has received any therapy listed below which may affect the tumor since discontinuing the study chemotherapy, please specify below. ☐0 NONE

Type of Therapy C: Chemotherapy Cs: Corticosteroids (please specify regimen)	Regimen/Drug	Dose	Unit	Start Date (dd/mm/yyyy) or ✓ if ongoing	Stop Date (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	☐1 ongoing	☐1 ongoing
C 1	☐2 Docetaxel ☐2 qw		mg/m^2	☐1 ongoing	☐1 ongoing

ANTI-TUMOR THERAPY (II)

If the patient has received any other therapy than listed above which may affect the tumor since discontinuing the study treatment, please specify below. ☐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

FOLLOW-UP ADVERSE EVENTS

FAE

PULL & INSERT

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

ADVERSE EVENTS

☐0 NONE

	AE TERM [Diagnosis if known or sign/symptom] (one code per row)		STATUS OF AE (check (✓) one only) 1=Ongoing without change [STOP]* 2=New or change to ongoing AE [continue]**	SERIOUS If serious, complete SAE form.	DATE OF ONSET (dd/mm/yyyy) or check (✓) if ongoing	OUTCOME (complete only ONE column)			GRADE (1-5)	Other Action Taken Due To AE 0=None 1=Hospitalization	CAUSALITY Is there a reasonable possibility that the study medication caused the event? (check (✓) one only) 0=No 1=Unlikely 2=Possibly 3=Probably
	NCI CODE	DESCRIPTION				Ongoing	Resolved date ceased (dd/mm/yyyy)	Death			
NCI CRITERIA	GI-STO	Stomatitis/Pharyngitis	☐1 ☐2	☐ 0 No ☐ 1 Yes	☐1 ongoing	☐1	☐2 resolved	☐3		☐0 ☐1	☐0 ☐1 ☐2 ☐3
	SK-ALO	Alopecia	☐1 ☐2	☐ 0 No ☐ 1 Yes	☐1 ongoing	☐1	☐2 resolved	☐3		☐0 ☐1	☐0 ☐1 ☐2 ☐3
	NE-SEN	Neuropathy sensory	☐1 ☐2	☐ 0 No ☐ 1 Yes	☐1 ongoing	☐1	☐2 resolved	☐3		☐0 ☐1	☐0 ☐1 ☐2 ☐3
	NE-MOT	Neuropathy motor	☐1 ☐2	☐ 0 No ☐ 1 Yes	☐1 ongoing	☐1	☐2 resolved	☐3		☐0 ☐1	☐0 ☐1 ☐2 ☐3
	OT-OTH	Peripheral Edema	☐1 ☐2	☐ 0 No ☐ 1 Yes	☐1 ongoing	☐1	☐2 resolved	☐3		☐0 ☐1	☐0 ☐1 ☐2 ☐3
	CD-LVF	Cardiac Left Ventricular Function	☐1 ☐2	☐ 0 No ☐ 1 Yes	☐1 ongoing	☐1	☐2 resolved	☐3		☐0 ☐1	☐0 ☐1 ☐2 ☐3

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

Investigator Name: Investigator Number:

FOLLOW-UP ADVERSE EVENTS

FAE

PULL & INSERT

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

ADVERSE EVENTS

☐0 NONE

	NCI CODE	DESCRIPTION	STATUS OF AE (check (✓) one only) 1=Ongoing without change [STOP]* 2=New or change to ongoing AE [continue]**	SERIOUS If serious, complete SAE form.	DATE OF ONSET (dd/mm/yyyy) or check (✓) if ongoing	OUTCOME (complete only ONE column) Ongoing	Resolved date ceased (dd/mm/yyyy)	Death	GRADE (1-5)	Other Action Taken Due To AE 0=None 1=Hospitalization	CAUSALITY Is there a reasonable possibility that the study medication caused the event? (check (✓) one only) 0=No 1=Unlikely 2=Possibly 3=Probably
	CS-FAT	Fatigue	☐1 ☐2	☐0 No ☐1 Yes	☐1 ongoing	☐1	☐2 resolved	☐3		☐0 ☐1	☐0 ☐1 ☐2 ☐3
NCI CRITERIA	PA-BON	Bone Pain	☐1 ☐2	☐0 No ☐1 Yes	☐1 ongoing	☐1	☐2 resolved	☐3		☐0 ☐1	☐0 ☐1 ☐2 ☐3
	GU-DYS	Dysuria (painful urination)	☐1 ☐2	☐0 No ☐1 Yes	☐1 ongoing	☐1	☐2 resolved	☐3		☐0 ☐1	☐0 ☐1 ☐2 ☐3
	GU-INC	Incontinence	☐1 ☐2	☐0 No ☐1 Yes	☐1 ongoing	☐1	☐2 resolved	☐3		☐0 ☐1	☐0 ☐1 ☐2 ☐3
	GU-RET	Urinary Retention	☐1 ☐2	☐0 No ☐1 Yes	☐1 ongoing	☐1	☐2 resolved	☐3		☐0 ☐1	☐0 ☐1 ☐2 ☐3
	MS-OTH	Pathological fracture	☐1 ☐2	☐0 No ☐1 Yes	☐1 ongoing	☐1	☐2 resolved	☐3		☐0 ☐1	☐0 ☐1 ☐2 ☐3
	OT-OTH	Spinal Cord Compression	☐1 ☐2	☐0 No ☐1 Yes	☐1 ongoing	☐1	☐2 resolved	☐3		☐0 ☐1	☐0 ☐1 ☐2 ☐3

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

Investigator Name: Investigator Number:

PULL & INSERT

FOLLOW-UP ADVERSE EVENTS

FAE

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

ADVERSE EVENTS

☐0 NONE

AE TERM [Diagnosis if known or sign/symptom] (*one code per row*) — NCI CODE	DESCRIPTION	STATUS OF AE (check (✓) one only) 1=Ongoing without change [STOP]* 2=New or change to ongoing AE [continue]**	SERIOUS If serious, complete SAE form.	DATE OF ONSET (dd/mm/yyyy) or check (✓) if ongoing	OUTCOME (complete only ONE column): Ongoing	OUTCOME: Resolved date ceased (dd/mm/yyyy)	OUTCOME: Death	GRADE (1-5)	Other Action Taken Due To AE 0=None 1=Hospitalization	CAUSALITY Is there a reasonable possibility that the study medication caused the event? (check (✓) one only) 0=No 1=Unlikely 2=Possibly 3=Probably
___ - ___		☐1 ☐2	☐0 No ☐1 Yes	☐1 ongoing	☐1	☐2 resolved	☐3		☐0 ☐1	☐0 ☐1 ☐2 ☐3
___ - ___		☐1 ☐2	☐0 No ☐1 Yes	☐1 ongoing	☐1	☐2 resolved	☐3		☐0 ☐1	☐0 ☐1 ☐2 ☐3
___ - ___		☐1 ☐2	☐0 No ☐1 Yes	☐1 ongoing	☐1	☐2 resolved	☐3		☐0 ☐1	☐0 ☐1 ☐2 ☐3
___ - ___		☐1 ☐2	☐0 No ☐1 Yes	☐1 ongoing	☐1	☐2 resolved	☐3		☐0 ☐1	☐0 ☐1 ☐2 ☐3
___ - ___		☐1 ☐2	☐0 No ☐1 Yes	☐1 ongoing	☐1	☐2 resolved	☐3		☐0 ☐1	☐0 ☐1 ☐2 ☐3
___ - ___		☐1 ☐2	☐0 No ☐1 Yes	☐1 ongoing	☐1	☐2 resolved	☐3		☐0 ☐1	☐0 ☐1 ☐2 ☐3
___ - ___		☐1 ☐2	☐0 No ☐1 Yes	☐1 ongoing	☐1	☐2 resolved	☐3		☐0 ☐1	☐0 ☐1 ☐2 ☐3
___ - ___		☐1 ☐2	☐0 No ☐1 Yes	☐1 ongoing	☐1	☐2 resolved	☐3		☐0 ☐1	☐0 ☐1 ☐2 ☐3
___ - ___		☐1 ☐2	☐0 No ☐1 Yes	☐1 ongoing	☐1	☐2 resolved	☐3		☐0 ☐1	☐0 ☐1 ☐2 ☐3

NCI CRITERIA

* Do not complete remainder of row. ** Complete remainder of row.
In case of AE code is OT-OTH, grade severity as: 1=Mild, 2=Moderate, 3=Severe, 4=Life Threatening

Investigator Name:

Investigator Number:

FOLLOW-UP CONCOMITANT THERAPY

FPCM

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

CONCOMITANT THERAPY

If drug is **PRN**, the approximate Total Daily Dose must be recorded.

☐0 NONE

Drug (Brand Name)	Status of Conc. Med. (check (✓) one only) 1=Ongoing without change [STOP] * 2=New or change to ongoing medication [continue] **	Route	Total Daily Dose		Start Date (dd/mm/yyyy) or ✓ if ongoing	Stop Date (dd/mm/yyyy) or ✓ if ongoing
			Dose	Unit		
	☐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 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

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

CONCOMITANT MEDICATION (DIARY ANALGESICS ONLY) FPCM-DA

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

CONCOMITANT MEDICATIONS

Only analgesics reported in the **Patient Pain Diary** should be recorded in this module.

☐0 NONE

				Dose of Analgesics (7-day period of the Pain Diary)							
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								
		☐0 ongoing	☐0 ongoing								
		☐0 ongoing	☐0 ongoing								
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		☐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 EVALUATION

To be averaged over 7 consecutive days. To be performed every month until patient's progression or further anti-tumor therapy.

☐0 NOT done

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		•

FOLLOW-UP PSA

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

☐0 NOT done

PSA

Test	Recommended Units	Date of Sample: dd mm yyyy — Result	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?

☐0 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 ☐1 Ongoing	dd mm yyyy ☐1 Ongoing	☐2 Tumor related Adverse Event** ☐3 Study drug related Adverse Event** ☐94 Other, *specify:* ______	☐2 Surgery ☐3 Internal Medicine ☐4 ICU* ☐94 Other, *specify:* ______
dd mm yyyy ☐1 Ongoing	dd mm yyyy ☐1 Ongoing	☐2 Tumor related Adverse Event** ☐3 Study drug related Adverse Event** ☐94 Other, *specify:* ______	☐2 Surgery ☐3 Internal Medicine ☐4 ICU* ☐94 Other, *specify:* ______
dd mm yyyy ☐1 Ongoing	dd mm yyyy ☐1 Ongoing	☐2 Tumor related Adverse Event** ☐3 Study drug related Adverse Event** ☐94 Other, *specify:* ______	☐2 Surgery ☐3 Internal Medicine ☐4 ICU* ☐94 Other, *specify:* ______

During those hospitalizations, have any major procedures been performed? ☐0 None

☐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

☐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

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

TUMOR ASSESSMENT

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

☐0 NOT done

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 ...)	Organ **a: Site** (enter the appropriate number) 1:Bone (complete checklist) 2:Lymph Node 3:Liver 4:Lung 5:Other Soft Tissue, specify 94:Other Organ, specify **b: Subsite (description)**	Date of Assessment (dd/mm/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	Measurement (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 ☐ b _____	☐0 Not Done		×	
	a ☐ b _____	☐0 Not Done		×	
	a ☐ b _____	☐0 Not Done		×	
	a ☐ b _____	☐0 Not Done		×	
	a ☐ b _____	☐0 Not Done		×	
	a ☐ b _____	☐0 Not Done		×	
	a ☐ b _____	☐0 Not Done		×	

Overall Tumor Response:

☐1 CR ☐2 PR ☐3 NC/SD ☐4 PD ☐5 NE, specify _____

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 ☐0 NONE

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	first middle last		End of Study

RESPONSE PATTERNS AT END OF STUDY

Best Overall Tumor Response:

☐1 CR ☐2 PR ☐3 NC/SD ☐4 PD ☐5 NE, specify: _____

PSA Response:

Did the patient achieve a protocol-defined PSA response? ☐1 Yes ☐0 No ☐2 Not Applicable

Pain Response:

Did the patient achieve a protocol-defined pain response? ☐1 Yes ☐0 No ☐2 Not Applicable

DISCONTINUATION OF STUDY MEDICATION

Indicate the primary reason for discontinuation of study medication (check (✓) one only):

☐0 Completed study medication

☐1 Adverse event *(complete appropriate adverse event form)*

☐2 Death *(complete DEATH REPORT module)*

☐13 Progressive disease

☐21 Patient required therapy / procedure not permitted

☐22 Other major protocol violation, *specify* _____

☐31 Lost to follow-up ▶ Date of last contact: ___ ___ ___ (dd mm yyyy)

☐91 Consent withdrawn, *specify* _____

☐94 Other, *specify* _____

PROGRESSION CRITERIA AT END OF STUDY

(check (✓) all that apply)

☐1 Not applicable (patient has not progressed yet)

☐2 Protocol-defined progression on tumor lesions

☐3 Protocol-defined PSA progression

☐4 Protocol-defined pain progression

CASE REPORT FORM REVIEW

I have reviewed all data contained in this case report form and verified that the contents are consistent with observations and source records. They accurately reflect the condition of the patient before, during, and at the completion of the study.

_____

Primary Investigator's or Sub-Investigator's Signature

___ ___ ___ (dd mm yyyy)

DEATH REPORT FORM

DR

Project No.	Protocol No.	Patient Initials	Patient Alloc. No.	
RP 56976V	327	first middle last		Death Report Form

DEATH REPORT FORM

Date of Death: dd mm yyyy

Cause of death – indicate MOST probable cause (check (✓) one only):

- ☐ 1 Septic (with at least one possibly or probably related **AE** at the last cycle, such as infection, sepsis or fever with outcome: **Died**).
- ☐ 2 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.	Visit No.
RP 56976V	327	___ ___ ___ (first middle last)	___ ___ ___ ___ ___	☐ Cycle Nº: ___ ☐ Follow-Up Nº: ___

OTHER PROCEDURES

Please note any additional assessment whether related to tumor or not e.g.: radiological assessment, bacteriological examination, myelogram, etc.

Type of Procedure **a: Procedure** (enter the appropriate number) 3: Cultures 4: Imaging 5: Puncture/Drainage 6: Biopsy 7: Surgery 8: Test 94: Other, specify procedure **b: Description**	Date assessed (dd/mm/yyyy)	Comments* (if applicable)
a ☐ b _____	__/__/____	
a ☐ b _____	__/__/____	
a ☐ b _____	__/__/____	
a ☐ b _____	__/__/____	
a ☐ b _____	__/__/____	
a ☐ b _____	__/__/____	
a ☐ b _____	__/__/____	
a ☐ b _____	__/__/____	

*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.

BLOOD CHEMISTRY - UNSCHEDULED

ZBC1/ZBC3

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

	☐1 Check if laboratory is the same as baseline; otherwise complete below.	☐1 Check if laboratory is the same as baseline; otherwise complete below.	☐1 Check if laboratory is the same as baseline; otherwise complete below.
	LAB NAME LAB ADDRESS: LABID:	LAB NAME LAB ADDRESS: LABID:	LAB NAME LAB ADDRESS: LABID:

BLOOD CHEMISTRY

Test	Date of Sample: dd mm yyyy		Date of Sample: dd mm yyyy		Date of Sample: dd mm yyyy	
	Result	Actual units	Result	Actual units	Result	Actual units

IF ADDITIONAL TESTS (NOT SPECIFIED ABOVE) OR REPEAT TESTS ARE PERFORMED, ADDITIONAL UNSCHEDULED LABORATORY PAGES SHOULD BE USED.

HEMATOLOGY - UNSCHEDULED

ZH1/ZH6

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

HEMATOLOGY

Test	Date of Sample: dd mm yyyy		Date of Sample: dd mm yyyy		Date of Sample: dd mm yyyy	
	Result	Actual units	Result	Actual units	Result	Actual units

HEMATOLOGY

Test	Date of Sample: dd mm yyyy		Date of Sample: dd mm yyyy		Date of Sample: dd mm yyyy	
	Result	Actual units	Result	Actual units	Result	Actual units

CONCOMITANT RADIOTHERAPY - UNSCHEDULED

ZCR

Project No.	Protocol No.	Patient Initials	Patient Alloc. No.	Visit No.
RP 56976V	327	___ ___ ___ (first middle last)	___ ___ ___ ___ ___	☐ Cycle Nº: ___ ☐ Follow-Up Nº: ___

CONCOMITANT RADIOTHERAPY

Please describe below all concomitant radiotherapy received by the patient during the study.

Organ 1 = Site 2 = Subsite (description)	Total Dose (specify units)		Start Date (dd/mm/yyyy)	Stop Date (dd/mm/yyyy) *or indicate if ongoing*
	Dose	Units		
1_____ 2_____		☐1 Gy ☐2 rads ☐3 cGy	__/__/____	__/__/____ ☐1 ongoing
1_____ 2_____		☐1 Gy ☐2 rads ☐3 cGy	__/__/____	__/__/____ ☐1 ongoing
1_____ 2_____		☐1 Gy ☐2 rads ☐3 cGy	__/__/____	__/__/____ ☐1 ongoing

STUDY MEDICATION RE-ADMINISTRATION

ZSMA1/ZSMA3

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

STUDY MEDICATION RE-ADMINISTRATION - DOCETAXEL

☐0 NONE

Study Drug		Route	Date of Administration	Stop Date	Total Daily Dose Given	
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 MEDICATION RE-ADMINISTRATION - MITOXANTRONE

☐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

☐0 NONE

Study Drug		Route	Start Date	Stop Date or ✓ if ongoing	Total Daily Dose Given	
Prednisone	18		dd mm yyyy	dd mm yyyy ☐1 ongoing		mg

LEFT VENTRICULAR EJECTION FRACTION / ELECTROCARDIOGRAM- UNSCHEDULED

ZLV/ZECG

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

LEFT VENTRICULAR EJECTION FRACTION (check (✓) one method only)

☐0 NOT done

☐1 Radionuclide angiocardiography (MUGA scan)

Date of Assessment: dd mm yyyy

Value: %

Lower limit of normal for the institution: %

☐2 Echocardiography

Date of Assessment: dd mm yyyy

Value: %

Lower limit of normal for the institution: %

ELECTROCARDIOGRAM

☐0 NOT done

Date of Tracing: dd mm yyyy

Interpretation (check (✓) one only):

☐1 Within normal limits

☐2 Non-significant abnormalities

☐3 Significant abnormalities ▶ *COMPLETE THE ADVERSE EVENT FORM.*

FACT P COMPLETION STATUS

QOLS

Project No.	Protocol No.	Patient Initials	Patient Alloc. No.	Visit No.
RP 56976V	327	___ ___ ___ (first middle last)	___ ___ ___ ___ ___	☐ Baseline: ☐ Cycle Nº: ___ ☐ Follow-Up Nº: ___

Date Questionnaire Completed: ___ ___ ___ ___ ___ ___ ___ ___ (dd mm yyyy)

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 cycle, at end of study and then every month until initiation of further anti-tumor therapy)

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) ☐0 No ☐1 Yes ☐2 Not Applicable

Was the questionnaire completed prior to corticosteroid premedication? (only for patients treated in Arm B or C) ☐0 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? ☐0 No ☐1 Yes ☐2 Not Applicable

☐0 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
- ☐94 Other, specify _____

LOT NUMBERS

LN

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

Cycle No.	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 last	

Investigator Name:	Investigator Number:

CONTACTS:

[redacted]

*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.

INTRODUCTION

Dictionary: – NCI Common Toxicity Criteria (Version 2)

CRF SECTIONS:

- BASELINE
- CYCLE N^{O} |____|
- END OF STUDY
- FOLLOW-UP
- DEATH REPORT FORM
- LOT NUMBERS

EXTRA CYCLE (cycle n^{o}) |____|

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.

EXTRA FORMS

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.

URGENT TRANSMISSION NEEDED

FAX NUMBER: [redacted]
FROM: [redacted]

STUDY RP56976-V-327 / PATIENT REGISTRATION FORM

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

TO BE FILLED OUT BY THE INVESTIGATOR TOGETHER WITH CASE REPORT FORM PAGES B.1 TO B.5
(TO BE INSERTED IN THE CASE REPORT FORM AFTER STUDY NUMBER ALLOCATION)

TO: **INVESTIGATOR'S NAME:** Dr._____

INSTITUTION: _____

_____

Name of person completing this form: _____

Direct FAX Number:_____ **COUNTRY:** _____

PATIENT INITIALS	DATE OF BIRTH	DATE TREATMENT PLANNED
first middle last	dd mm yyyy	dd mm yyyy

TO BE FILLED OUT BY RPR IN CASE OF PATIENT NOT ELIGIBLE

THE PATIENT IS NOT ELIGIBLE

Reason:

_____

_____

_____

Date of Registration Form receipt: dd mm yyyy

Study Manager's signature:_____ Date: dd mm yyyy

IN CASE THE PATIENT IS ELIGIBLE, THE CONFIRMATION OF RANDOMIZATION WITH THE TREATMENT ARM AND THE PATIENT NUMBER ASSIGNED WILL BE FAXED THROUGH THE INTERACTIVE VOICE RESPONSE SYSTEM

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	327	___ ___ ___ (first middle last)	___ ___ ___ ___ ___	**Cycle Nº** ___

PHARMACOKINETIC DATA – DOCETAXEL

Day (check (✓) one only)	Date of Administration: (dd/mm/yyyy)	Start Time (hr/min)	Stop Time (hr/min)
☐1 Day 1 ☐2 Day 22	___ ___ ___ ___ ___	___:___	___:___

7 mL of whole blood will be drawn in heparinized tubes. Centrifuge within 30 minutes of collection.

Time	Sample Number	Theoretical time of samples (Hr/min)	Actual time of samples (Hr/min)	Comments
Time 0 before infusion	T0	___:___	___:___	
15 min before the end of infusion	T1	___:___	___:___	
15 min post infusion	T2	___:___	___:___	
45 min post infusion	T3	___:___	___:___	
2 hours post infusion	T4	___:___	___:___	
5 hours post infusion	T5	___:___	___:___	

Matrix: Plasma Anticoagulant: Sodium Heparin

Temperature of Sample Storage: _____ ° C (Reminder: Should be –20°C or below)

Date Samples Shipped: ___ ___ ___ (dd mm yyyy)

For Clinical Drug Disposition Department Use Only

Date Samples Received: ___ ___ ___ (dd mm yyyy) Received by: _____ *(print name)*

Comments: _____

NOTE: Green copy of form must accompany pharmacokinetic samples sent to RPR.

Investigator Name:	Investigator Number: ___ ___ ___ ___ ___ ___ ___

LABORATORY REFERENCE RANGES

LABRR

Project No.	Protocol No.
RP 56976V	327

INVESTIGATOR NAME:	LAB NAME:
INVESTIGATOR NUMBER:	LAB ADDRESS:
	LABID:

Effective Start Date : dd mm yyyy

Effective Stop Date : dd mm yyyy

TEST	UNIT		SEX	NORMAL VALUE RANGE		AGE RANGE			
	Recommended	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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BASELINE VISIT - REGISTRATION

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BASELINE VISIT

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GENERIC CYCLE

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END OF STUDY VISIT

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FOLLOW-UP VISIT

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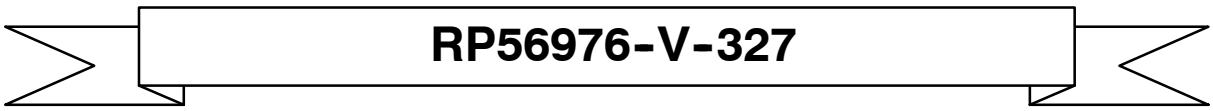
Complete the following as per protocol or as needed:



DEATH REPORT FORM

CASE REPORT FORM NAME	FORM ID	PAGE #

LOT NUMBERS

CASE REPORT FORM NAME	FORM ID