EFC6546 | AVE0005 VENICE

CASE REPORT FORM



A MULTICENTER, RANDOMIZED, DOUBLE-BLIND STUDY COMPARING THE EFFICACY AND SAFETY OF AFLIBERCEPT VERSUS PLACEBO ADMINISTERED EVERY 3 WEEKS IN PATIENTS TREATED WITH DOCETAXEL / PREDNISONE FOR METASTATIC ANDROGEN-INDEPENDENT PROSTATE CANCER

Country number:	Centre number:	
Subject number:	SUBJECT INITIALS:	

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BIOCHEMISTRY

Investigator:	Country No: LILL Centre No: LILL
Laboratory Name: Address:	Effective date:

TESTS	Unit	IF OTHER	Sex	Ac		Normai	RANGES
		UNIT, SPECIFY	M = male F = female B = both	(Unit: Y Low	′ear 図) High	Lower limit	Upper limit
Sodium	mmol/L						
Calcium	mmol/L						
Potassium	mmol/L						
Phosphorus	mmol/L						
Blood Urea Nitrogen	mg/dL						
Urea	mmol/L						
Magnesium	mg/dL						
Creatinine	μmol/L						
Glucose	mmol/L						
AST	IU/L						
ALT	IU/L						
Alkaline Phosphatase	IU/L						
Total Bilirubin	mg/dL						
Total Protein	g/dL						
Albumin	g/dL						
LDH	IU/L						
Haptoglobin	g/L						
Orosmucoïd	g/L						
Testosterone	ng/dL						

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HEMATOLOGY

Investigator:				Cou	ıntry No: L	JULU C	Centre No: L	
Laboratory Name: _				⊏ff.o.	ativo data.		L	
Address:				ЕПЕ	ctive date:		month	year
TESTS	Unit	IF OTHER	SE	x	Ac	GE	Normai	RANGES
		UNIT, SPECIFY	M = m F = fe		(Unit: \	∕ear 図)	Lower	Upper
		SPECIFY	B = b		Low	High	limit	limit
INR	Ratio							

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URINALYSIS

Investigator:	Country No: LILL Centre No: LILL
Laboratory Name: Address:	Effective date:

TESTS	Unit	IF OTHER	SEX	Ac	GE	Normal	RANGES
		UNIT, SPECIFY	M = male F = female B = both	(Unit: \ Low	′ear 図) High	Lower limit	Upper limit
Protein	g/L						
Creatinine	g/L						

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ELECTROPHORESIS

Investigator:	Country No: LILL Centre No: LILL
Laboratory Name: Address:	Effective date:

TESTS	Unit	IF OTHER UNIT, SPECIFY	SEX M = male F = female B = both	AGE (Unit: Year 図) Low High		NORMAL Lower limit	RANGES Upper limit
Albumin	g/L						
Alpha 1 Globulin	g/L						
Alpha 2 Globulin	g/L						
Beta Globulin	g/L						
Gamma Globulin	g/L						

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SCREENING	V 00			Date of visi	t: day	month	/ Dear
							_
NFORME	D CONSENT		INFCN	<u> _01</u>			
Date o	consent obtained:						
DEMOGR <i>A</i>	month year	OG_01					
	\PHY DEMO	0G_01					
DEMOGR <i>A</i>	APHY DEMO	<u> 9</u>					
DEMOGR Date of birth:	LILI LILI L 1 day month	1 					
DEMOGR Date of birth:	APHY DEMO	1 					
DEMOGRA Date of birth: Sex:	DEMO APHY DEMO day month Male Female Caucasian/White Black	year					
DEMOGRA Date of birth: Sex:	DEMO day DEMO day month Male Female Caucasian/White	year		r, specify: _			

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SCREENING	V 00					

CANCER DIAGNOSIS CDIAG_01

Date of initial diagnosis:	(Date of histological diagnosis) day month year
LOCATION (tick one box only	:
☐ 18 Prostate	
☐ 30 Other, <i>specify</i> :	
HISTOLOGY TYPE (tick one bo	only): Other, specify:
HISTOPATHOLOGY (tick one bo	x only):
☐ Unknown	☐ Poorly differentiated
☐ Moderately differentiated	☐ Well differentiated
• Staging: T 📖	N L M L

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• **Gleason Score** (2-10):

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	CREENING JRGERY SURG	V 00			
PRI	OR SURGERY FOR PI		RCINOMA E	KCLUDING ANDRO	GEN ABLATION
	Su	RGERY		Surgery Date of Day Month	R NOT PERFORMED Year
1	Prostatectomy				」
2	Pelvic lymphadenecto	omy		□□ □□□ □ Not	」
3					
4					
	JRGERY SURG		20051	ADI ATION	
	ONE	FOR ANI	DROGEN	ABLATION	
	Su	RGERY		Surgery Date of Day Month	R NOT PERFORMED Year
1	Bilateral Orchiectomy				 performed
2	Bilateral Adrenalector	ny			」
3	Hypophysectomy				 performed
4					

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*LOCATION:

03	Bone			
11.01	Regional Lymph Nodes			
11.02	Distant Lymph Nodes			
18	Prostate			
99	Other			



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RADIATION THERAPY RADIX_01

PRIOR RADIATION THERAPY



PLEASE RECORD ALL THE PRIOR RADIATION THERAPY RELATED TO PROSTATE CANCER

NONE

	SITE LOCATION*	START DATE day month year	STOP DATE day month year	TOTAL DOSE	Units	Intent
1	<u></u>					Palliative Curative
2						☐ Palliative☐ Curative
3						☐ Palliative☐ Curative
4					☐ Grays☐ Rads	☐ Palliative☐ Curative☐
5	<u></u>				☐ Grays☐ Rads	☐ Palliative☐ Curative☐
6					☐ Grays☐ Rads	☐ Palliative☐ Curative☐
7	<u></u>				☐ Grays☐ Rads	☐ Palliative☐ Curative☐
8					☐ Grays☐ Rads	☐ Palliative☐ Curative☐
9	LJLJ.LJLJ				☐ Grays☐ Rads	☐ Palliative☐ Curative
10					☐ Grays☐ Rads	☐ Palliative☐ Curative

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_			
IN	T	N	т•

1 - Neoadjuvant

2 - Adjuvant

3 - Advanced

** THERAPY TYPE:

HO - Hormonotherapy

OT - Other

CH - Chemotherapy

BI - Biologicals

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ANTI-CANCER THERAPY CANTX_02

PRIOR TREATMENT

None	П



PLEASE RECORD ALL THE PRIOR MEDICAL HORMONAL THERAPIES AND ALL ESTRAMUSTINE THERAPY AND CHEMOTHERAPY RELATED TO PROSTATE CANCER.

REGIMEN NO.	NTENT*	Drug per Regimen	THERAPY Type**	START DATE DAY MONTH YEAR DAY MONTH YEAR DAY MONTH YEAR	ONGOING
		1			ב
1.		2			
		3			_
		4			د
		1			_
2.		2			د
		3			ے
		4			_
		1			_
3.		2			_
3.		3			ے
		4			_

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Sc	REENING	V 00		
MI	EDICAL HIST	ORY 1/2	MHX_02	
□ Re	None cord relevant medical	history for thro	ombovascular events and ca	ardiovascular risk factors.
	MEDICAL / SURGIO	CAL HISTORY	START DATE OR NOT OCCURRED Month Year	Ongoing
1	Angina Pectoris		□ Not Occurred	☐ Yes ☐ No If yes, disease/symptoms controlled ☐ Yes ☐ No
2	Unstable Angina		□ Not Occurred	☐ Yes ☐ No If yes, disease/symptoms controlled ☐ Yes ☐ No
3	Myocardial Infarction		□ Not Occurred	☐ Yes ☐ No If yes, disease/symptoms controlled ☐ Yes ☐ No
	Atrial Fibrillation			☐ Yes ☐ No

5

6

7

8

Stroke

Disease

NO

Transient Ischemic Attack

Peripheral Arterial Thrombotic

Deep Venous Thrombosis

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☐ No

If yes, disease/symptoms controlled:

If yes, disease/symptoms controlled:

If yes, disease/symptoms controlled:

If yes, disease/symptoms controlled:

☐ Yes

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■ Not Occurred

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Not Occurred

Not Occurred

Not Occurred

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Sc	REENING	V 00					
ME	EDICAL HIST	FORY 2/2	№ MHX_02				
Re	cord relevant medica MEDICAL / SURG		Star	T DATE OR NOT OCCURRED			r risk factors. NGOING
9	Pulmonary Embolisn	n		UUUU Not Occurred	∟ If y	Yes yes, disease, Yes	□ No /symptoms controlled □ No
10	High Blood Pressure			→ □□□□ Not Occurred	lf y	Yes yes, disease/ Yes	□ No symptoms controlled □ No
11	Hypercholesterolemi	ia		ー レニール Not Occurred	 d If <u>}</u>	Yes yes, disease, Yes	No Symptoms controlled
12	Diabetes mellitus			UUUUI Not Occurred	lf y	Yes yes, disease/ Yes	No No No
13	Smoker			UUUUU	lf y	Yes es, disease/ Yes	No No No No
14				UUUUU Not Occurred	d If y	Yes yes, disease, Yes	No Symptoms controlled No
15				UUUUI Not Occurred	d If y	Yes yes, disease/ Yes	□ No Symptoms controlled □ No
16				UUUU Not Occurred	lf y	☐ Yes	□ No symptoms controlled □ No

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MEDICAL	OR SURGICA	L HISTORY MHX	
	t Medical/Surgical History otl liovascular risk factors.	her than the disease studied a	nd other thrombovascular
Medi	CAL / SURGICAL HISTORY	START DATE Month Year	Ongoing
1			☐ Yes ☐ No If yes, disease/symptoms controlled ☐ Yes ☐ No
2			☐ Yes ☐ No If yes, disease/symptoms controlled: ☐ Yes ☐ No
3			☐ Yes ☐ No If yes, disease/symptoms controlled ☐ Yes ☐ No
4			☐ Yes ☐ No If yes, disease/symptoms controlled: ☐ Yes ☐ No
5			☐ Yes ☐ No If yes, disease/symptoms controlled: ☐ Yes ☐ No
6			☐ Yes ☐ No If yes, disease/symptoms controlled ☐ Yes ☐ No
7			☐ Yes ☐ No If yes, disease/symptoms controlled ☐ Yes ☐ No
8			☐ Yes ☐ No If yes, disease/symptoms controlled ☐ Yes ☐ No

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MEDICATION BIPHOSPHONATES MED_02

None \square

Record all biphosphonates therapies that the subject has taken.

	DRUG / MEDICATION (Brand or Generic Name)	DOSAGE (TOTAL DAILY DOSE)	Dose Unit	R оυте*	Day	START DATE Month	Year	END DATE OR TICK IF ONGOING Day Month Year
1								Ongoing
2							JUU	Ongoing
3								Ongoing
4								Ongoing
5								Ongoing
6								Ongoing
7								Ongoing
8								Ongoing
9								Ongoing
10								Ongoing
*	R OUTE: 19 = Ir	ntravenous		23 =	= Oral			24 = Other

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ANALGESIC MEDICATION SHOULD BE COLLECTED DAILY FOR SEVEN CONSECUTIVE DAYS PRIOR TO THE FIRST STUDY DRUG ADMINISTRATION

* ROUTE: Cutaneous 19 Intravenous 27 Rectal 1 2 Buccal 23 Oral 28 Subcutaneous Sublingua Inhalation 6 24 Other 29 12 Intramuscular



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MEDICATION ANALGESIC MED_02

		/
	V	-)
\setminus		
1	_	

PLEASE RECORD ALL ANALGESIC MEDICATION EXCLUDING BIPHOSPHONATE.

None \Box

	DRUG / MEDICATION (Brand or Generic Name)	DOSAGE (TOTAL DAILY DOSE)	Dose Unit	ROUTE *	START DATE Day Month Yea	END DATE OR TICK IF ONGOING Day Month Year
1						Ongoing
2						Ongoing
3						Ongoing
4					UU UUU UUU	Ongoing
5					UU UUU UUUI	Ongoing
6						Ongoing
7						Ongoing
8						Ongoing
9						Ongoing
10					UU UUU UUU	Ongoing

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TO BE PERFORMED OVER 7 CONSECUTIVE DAYS PRIOR TO THE RANDOMIZATION, AND THE LAST DAILY EVALUATION SHOULD BE OBTAINED WITHIN 3 DAYS PRIOR TO RANDOMIZATION.



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PAIN EVALUATION

NOT DONE

	D	ATE OF ASSESSA	MENT	PRESENT PAIN INTENSITY
	Day	Month	Year	Score
1st Day				LJ
2nd Day				LJ
3rd Day				LJ
4th Day				LJ
5th Day				LJ
6th Day				LJ
7th Day				LJ

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S	CREENING V 00	,	<u> </u>
M	EDICATION PRIOR MED_02		
	PLEASE RECORD ALL MEDICATIONS C ANALGESIC AND BIPHOSPHONATE	OTHER THAN ANTI-CANCER DRUG T MEDICATION WITHIN 21 DAYS PRICE	
\	one 🔲		
	DRUG / MEDICATION (Brand or Generic Name)	START DATE Day Month Year	END DATE OR TICK IF ONGOING Day Month Year
1			Ongoing
2			
3			
4			Ongoing
5			Ongoing
6			Ongoing
7			
8			Ongoing
9			Ongoing
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SCRE	ENING	V 00				
_	_	IARKERS 7	TMARK_01			
	In o	CORD THE THREE LAST VAL CASE OF RISING PSA AT S PROTOCOL-DEFINED RISI	TUDY ENTRY, RECOR	D AS MANY VALU	JES AS NEEDED TO	EVIDENCE
Test		Date of Evaluation	VALUE	Unit	Norm	al range
	day	month year			Lower limit	Upper limit
1. PSA						
2. PSA		2 0				
3. PSA		2,0,				
		IISTRY LABI	B_1			
		TO BE PERFORM	MED WITHIN 21 DAY	S PRIOR TO RANI	DOMIZATION.	
_aborato Address:	ry Name:					
Date of	sampling	day month	2 0 1 9 1 1 1 1 1			
		Теѕт	VALUE (MD if not done	Unit	IF OTHE	·
	Testoste	erone		NG/D	L	
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STATUS AT STUDY ENTRY

• Extent at study entry. • Invertisation • Income the content of t	•	Extent at study entry:	Metastatic	☐ Loco regiona
--	---	------------------------	------------	----------------

- Criteria for progression: (tick all that apply)
 - ☐ Increase in measurable disease (RECIST)
 - Appearance of new lesions including those on bone scan
 - ☐ Rising PSA

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PHYSICAL EXAMINATION AND PRE-EXISTING SIGNS AND SYMPTOMS AT BASELINE



TO BE PERFORMED WITHIN 8 DAYS PRIOR TO RANDOMIZATION.

ANY EXISTING EVENT SHOULD BE REPORTED ON MEDICAL OR SURGICAL HISTORY PAGE, AND ANY EXISTING EVENT THAT BECAME SERIOUS SHOULD BE REPORTED ON AN ADDITIONAL AE PAGE AT VO.



TO BE PERFORMED WITHIN 8 DAYS PRIOR TO	O RANDOMIZATION.
Date performed: LLLLLL20LL day month year	
Height: cm	Weight: 니니니 . L kg
- Blood pressure: Systolic LILI mmHg / Diasto	olic LILLI mmHg
ECOG Performance Status 0 1 2 3 4	

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SKELETAL RELATED EVENT EVALUATION

• Occurence of SRE: Yes
No



In case of:

- pathological fractures and/or spinal cord compression, please fill in an AE/SAE Form at cycle 1.
- bone irradiation, including radioisotopes or bone surgery, please complete the radiation or surgery Form as appropriate.
- change of antineoplastic therapy (including introduction of biphosphonates in the face of increase in pain) to treat bone pain, please fill in either further anticancer therapy and / or Biphosphonate Medication Form.

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TO BE PERFORMED WITHIN 8 DAYS PRIOR TO RANDOMIZATION.
THEN DURING TREATMENT PERIOD, IF CLINICALLY INDICATED. IN THIS CASE,
PLEASE USE AN ADDITIONAL ECG FORM.

ELECTROCARDIOGRAM ECG_01

Date performed:	LJ LJ		20	
•	day	month	year	
■ Normal				
☐ Abnormal				
If abnormal	clinicall	v significan	t? D Yes	\square No



IF ABNORMAL, CLINICALLY SIGNIFICANT, RECORD ON THE MEDICAL HISTORY FORM .

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SCREENING	V 00			
HEMATOLOGY	LABH_1			
		WITHIN 8 DAYS P MORE THAN 8 DA		
Date of sampling: LLL day		year		
Test		V ALUE (MD if not done)	Unit	IF OTHER UNIT, SPECIFY
Hemoglobin			g/L	
Platelets count			10 ⁹ /L	
WBC			10°/L	
Neutrophils			10 ⁹ /L	
<u> </u>	FORMED ONLY	FOR PATIENT UN	DER VITAMIN K A	NTAGONIST.
Date of sampling:	month	year		
ddress:				
Test		VALUE (MD if not done)	Unit	IF OTHER UNIT, SPECIFY
INR			Ratio	
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TO BE PERFORMED WITHIN 8 DAYS PRIOR TO RANDOMIZATION. TO BE REPEATED IF MORE THAN 8 DAYS BEFORE FIRST INFUSION.

BIOCHEMISTRY LABB_1 Laboratory Name: Address: day month

Test	VALUE (MD if not done)	Unit	IF OTHER UNIT, SPECIFY
Sodium		mmol/L	
Calcium		mmol/L	
Potassium		mmol/L	
Phosphorus		mmol/L	
Blood Urea Nitrogen		mg/dL	
Urea**		mmol/L	
Magnesium		mg/dL	
Creatinine		μmol/L	
Calculated Creatinine clearance*		ml/min	
Glucose		mmol/L	
AST		IU/L	
ALT		IU/L	
Alkaline phosphatase		IU/L	
Total bilirubin		mg/dL	
Total protein		g/dL	
Albumin		g/dL	

^{*} If creatinine > ULN, please report the calculated creatinine clearance. ** If BUN is not evaluated, UREA value must be documented.

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CREENI	NG	V 00			
	_			R TO RANDOMIZAT	
IPSTIC	CK URIN	ALYSIS	S LABU_1		
ate of samp	ling: LLL L		_ 0		
WBC	☐ Absent	- +	-++	-+++	□ Not evaluabl
RBC	☐ Absent	<u> </u>	++	- +++	☐ Not evaluabl
	NG SPOT	T URIN	ALYSIS	LABU_2	
t Done 🗖 Laboratory n	ame:				
Done 🗖 Laboratory n					
Done 🗖 Laboratory n	name:		0		IF OTHER UNIT, SPECIFY
Done 🗖 Laboratory n	oling: UL L		O O O O O O O O O O		· I

l-HOU	R URINALY	7SIS LABU_	_2			
		RMED WITHIN 8 I ED IF MORE THA				
	ame:					
art date of o	collection: 니니 L	month year				ection: L.:L.:l.:l.:l.:L.:L.:L.:L.:L.:L.:L.:L.:L.:L.:L.:L.:L.
art date of o	collection: 니니 L day ollection: 니니 L	month year 2 0	JE		of collec	24-hour
art date of o	collection: LL L day ollection: LL L day	month year LILI 2 0 L month year VALU	JE	• End time	of collec	24-hour ction::24-hour c
art date of o	TEST	month year LILI 2 0 L month year VALU	JE	• End time	of collec	24-hour ction::24-hour c
urt date of o	TEST	month year LILI 2 0 L month year VALU	JE	• End time UNI	of collec	24-hour ction::24-hour c
uring	TEST Try Volume in inine	month year LILI 2 0 L month year VALU	JE st done)	End time UNI L g/L g/L	of collect	24-hour of the control of the contro
urina	TEST Try Volume in inine	month year LiLi 2 0 L month year VALU (MD if no	JE st done)	End time UNIT L g/L g/L N 24-HOUF	of collect	24-hour of the control of the contro

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* LOCATION:				
LOCA	4110N•			
03	Bone			
06	Brain/CNS			
11	Lymph Nodes			
18	Prostate			
24	Abdomen			
26	Pelvis			
29	Thorax			
	Abdomino Pelvic			
30	Other			

**METHOD OF TUMOR MEASUREMENT:

ı	1	CT Scan	8	X-ray
I	2	Spiral CT Scan	9	Endoscopy
ı	3	MRI	10	Physical Exam
ı	4	PET	11	Multi-Slice CT
I	5	Scintigraphy	12	DCE MRI
I	6	SPECT	99	Other
I	7	Ultrasound		

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TUMOR EVALUATION (AT BASELINE) TUEVA_01

	\-
V	_)
1	
_	

TO BE PERFORMED WITHIN 21 DAYS PRIOR TO RANDOMIZATION.

	METHOD OF TUMOR MEASUREMENT**		Date	Normal	IF ABNORMAL,
	LOCATION	TUMOR MEASUREMENT	day month year		SPECIFY:
1.	<u> </u>				Tumor related Other:
2.					Tumor related Other:
3.	LJLJ.LJLJ				Tumor related Other:
4.	L L				Tumor related Other:
5.					Tumor related Other:
6.					Tumor related Other:
7.	<u> </u>				Tumor related Other:
8.		99 - Other, specify:			Tumor related Other:
9.	<u> </u>	99 - Other, specify:			Tumor related Other:
10.	Ш. Ш	99 - Other, specify:			Tumor related Other:

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*LOCATION:

01	Skin	11.09	Supraclavicular
02	Muscle/Soft Tissue	12	Liver
03	Bone	13	Stomach
04	Bone Marrow	14	Pancreas
05	Peripheral Blood Stream	15	Kidneys
06	Brain/CNS	17	Bladder
07	Head/Neck	18	Prostate
08	Eosaphagus	20.10	Colon
10	Lungs	20.20	Rectum
11	Lymph Nodes	21	Adrenal
11.01	Regional Lymph Nodes	22	Mediastinum
11.02	Distant Lymph Nodes	24	Abdomen
11.03	Axillary	25	Gastrointestinal Tract
11.04	Cervical	26	Pelvis
11.05	Inguinal	27	Peritoneum
11.06	Intra Abdominal	28	Testis
11.07	Mediastinal	29	Thorax
11.08	Para Aortic	29.01	Pleura
		30	Other
		l	

**METHOD OF TUMOR MEASUREMENT:

1	CT Scan	8	X-ray
2	Spiral CT Scan	9	Endoscopy
3	MRI	10	Physical Exam
4	PET	11	Multi-Slice CT
5	Scintigraphy	12	DCE MRI
6	SPECT	99	Other
7	Ultrasound		



LESION NUMBER	Lesion Location*	LESION DESCRIPTION (subsite)	DATE OF ASSESSMENT day month year	METHOD OF TUMOR MEASUREMENT**	MEASUREMENT OF TARGET LESION: longest diameter	NON Target	TUMOR	SCREENING	
1					mm			Q Q	
2							MEASUREMENT		
3							ZE S	<	Codility
4								0	9 140.
5							TA)		
6					mm		BAS		-
7	<u></u>						BASELINE)		000000000000000000000000000000000000000
8	L.L.								-
9	<u></u>						TUMEA_01		
10					LJLJ mm		3		- 280

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Screening	V 00	Centre No.	Subject No.		ı aye	

FA	CT	P

Assessment not done
Specify the primary reason:
☐ Subject is unable due to toxicity/disease
☐ Administrative failure to distribute the questionnaire to the patient
☐ Patient refusal
☐ Death
☐ Patient did not wish to show up
☐ Translation not available
☐ Other, specify:

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SCREENING	v 00				

FACT P QUESTIONNAIRE

Below is a list of statements that other people with your illness have said are important By circling one (1) number per line, please indicate how true each statement has been for you during the past 7 days.

	PHYSICAL WELL-BEING	Not at all	A little bit	Some- what	Quite a bit	Very much
GP1	Lhave a leak of anargy	0	1	2	3	4
- Gi i	I have a lack of energy	0	1	2	3	4
GP2	I have nausea	0	1	2	3	4
GP3	Because of my physical condition, I have trouble meeting the needs of my family	0	1	2	3	4
GP4	I have pain	0	1	2	3	4
GP5	I am bothered by side effects of treatment	0	1	2	3	4
GP6	I feel ill	0	1	2	3	4
GP7	I am forced to spend time in bed	0	1	2	3	4

	SOCIAL/FAMILY WELL-BEING	Not at all	A little bit	Some- what	Quite a bit	Very much
GS1	I feel close to my friends	0	1	2	3	4
GS2	I get emotional support from my family	0	1	2	3	4
GS3	I get support from my friends	0	1	2	3	4
GS4	My family has accepted my illness	0	1	2	3	4
GS5	I am satisfied with family communication about my illness	0	1	2	3	4
GS6	I feel close to my partner (or the person who is my main support)	0	1	2	3	4
Q1	Regardless of your current level of sexual activity, please answer the following question. If you prefer not to answer it, please check this box and go to the next section.					
GS7	I am satisfied with my sex life	. 0	1	2	3	4

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SCREENING	V 00					

By circling one (1) number per line, please indicate how true each statement has been for you <u>during the past 7 days</u>.

	EMOTIONAL WELL-BEING		A little bit	Some- what	Quite a bit	Very much
GE1	I feel sad	0	1	2	3	4
GE2	I am satisfied with how I am coping with my illness	. 0	1	2	3	4
GE3	I am losing hope in the fight against my illness	0	1	2	3	4
GE4	I feel nervous	0	1	2	3	4
GE5	I worry about dying	0	1	2	3	4
GE6	I worry that my condition will get worse	0	1	2	3	4

	FUNCTIONAL WELL-BEING		A little bit	Some- what	Quite a bit	Very much
GF1	I am able to work (include work at home)	0	1	2	3	4
GF2	My work (include work at home) is fulfilling	0	1	2	3	4
GF3	I am able to enjoy life	. 0	1	2	3	4
GF4	I have accepted my illness	. 0	1	2	3	4
GF5	I am sleeping well	. 0	1	2	3	4
GF6	I am enjoying the things I usually do for fun	0	1	2	3	4
GF7	I am content with the quality of my life right now	. 0	1	2	3	4

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SCREENING	v 00				

By circling one (1) number per line, please indicate how true each statement has been for you during the past 7 days.

	ADDITIONAL CONCERNS	Not at all	A little bit	Some- what	Quite a bit	Very much
C2	I am losing weight	0	1	2	3	4
C6	I have a good appetite	0	1	2	3	4
P1	I have aches and pains that bother me	0	1	2	3	4
P2	I have certain parts of my body where I experience pain	0	1	2	3	4
Р3	My pain keeps me from doing things I want to do	0	1	2	3	4
P4	I am satisfied with my present comfort level	0	1	2	3	4
P5	I am able to feel like a man	0	1	2	3	4
P6	I have trouble moving my bowels	0	1	2	3	4
P7	I have difficulty urinating	0	1	2	3	4
BL2	I urinate more frequently than usual	0	1	2	3	4
P8	My problems with urinating limit my activities	0	1	2	3	4
BL5	I am able to have and maintain an erection	0	1	2	3	4

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ONLY SERIOUS ADVERSE EVENT OCCURING BETWEEN INFORMED CONSENT AND FIRST DOSE SHOULD BE REPORTED



AVE0005 EFC6546	Country No.	Centre No. Subject No. Page
SCREENING	V 00	
ADVERSE EVEN	NT FORI	VI AE_03
None 🔲		
1. Adverse Event (Diagnosis)		AE form no: LILI-LILI AE ref. no: LILI-LILI
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change		1 Date of start: LILI LILI Year 2 (do not complete the remaining items in the column) 3
3. GRADE (1 - 4)		1 2 3 4 4
4. RELATIONSHIP TO INVESTIGATIONAL PRODUCTS*		Yes □ No ☑
5. ACTION TAKEN WITH INVESTIGATIONAL PRODUCTS**		0 🗹 1 🗆 2 🗀 3 🗀 4 🗀 5 🗀
6. Corrective Treatment/Therapy		Yes No U
7. OUTCOME 1= Recovered 4= Recovered with sequelae		1 Date: LLL LLLL year 4 Specify sequelae:
2= Recovering		3 🗖
3= Not recovered		5 Date of death:
5= Fatal (complete the death report form)		
6= Unknown		6 🗖
8. SERIOUSNESS CRITERIA IF YES, COMPLETE THIS S AND THE < <safety complemen<="" th=""><th></th><th>Yes No</th></safety>		Yes No
9. IS IT AN EVENT SUCH AS:		
OVERDOSE OF THE IP?		Yes □ No ☑
Investigator's name, date, and signa	ature:	Monitoring representative's name, date of receipt:
* Is there a reasonable possibility at the two series of the series of the two serie		sed by Investigational Product? duced / 4= Delayed and reduced / 5= Interrupted
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SCREENING	v 00					

ELIGIBILITY FOR RANDOMIZATION	I	ELIG_01
Will the subject continue in the randomization phase of the study?	☐ Yes	☐ No
Does the subject satisfy all inclusion/exclusion criteria?	☐ Yes	☐ No
If No, please specify the main criteria not met:		
Inclusion criterion number: 📙 🗀 🗀	ЩЩЩ	<u> </u>
Exclusion criterion number: 🕒 🗀 🗀	E	E
Are there other reasons why the subject cannot continue?	☐ Yes	□ No
If Yes, (tick "✓" all that apply):		
- Serious Adverse event*		
- Lost to follow-up		
- Subject did not wish to continue		
- Other reason		
If other reason, specify:		

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^{*} In case of an adverse event complete the Adverse Event form.

AVE0005 EFC6546	Country No.	Centre No.	Subject No.	NO	28 Page	
CYCLE 1	v 01		Date of visit:	day r		year
				·		
VITAL SIGNS	O.VITAL_2					
☐ Not Applicable	if already do	one within 8	days prior to	randomiz	zation.	
• Date performed : LLL L		0 year				
• Weight:	l kg					
- Blood pressure: Systolic		mmHg / E	Diastolic LLL	⊥∟ mr	nHg	
ECOG Performance Status						
0 1 2	3 4					
	PHYSIC	AL EXAMI	NATION			
	A PHYSICAI	L EXAMINATION	SHOULD BE PERI	FORMED.		
IF THERE ARE	ANY CLINICALLY RI	SIGNIFICANT CHECORD AS AN A		HE PREVIOUS	S EXAMINATION	۸,
NO 28			AVE0005	FF	C6546	
20	1	1 4		` `		

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	AVE0005 EFC6546		Centre No.	Subject No.	29 Page
YCLE 1 V 01					
		:	-		
	AATOLOGY				
	MATOLOGY	LABH_1			
	Not Applicable	if already do	one within 8 days	s prior to randon	nization.
		. ?			
)ate c	of sampling: Lay	month 2	year		
	Test		Value	Unit	Is other mart
	l IESI		(MD if not done)	UNII	IF OTHER UNIT, SPECIFY
	Hemoglobin			g/L	
	Platelets count			10 ⁹ /L	
	WBC			10 ⁹ /L	
	Neutrophils			10 ⁹ /L	
	NATOLOGY Not Applicable if		e within 8 days p		
Date o	TO BE PERFO	already done	FOR PATIENT UND		
Date o	TO BE PERFO TO SE PERFO of sampling: Lay	already done ORMED ONLY	FOR PATIENT UND		
Date o	TO BE PERFO TO SE PERFO of sampling: Lay	already done ORMED ONLY	FOR PATIENT UND		
Date o	TO BE PERFO TO SE PERFO of sampling: Lay	already done ORMED ONLY	FOR PATIENT UND		
Date o	TO BE PERFO of sampling: Lay ory Name:	already done ORMED ONLY	FOR PATIENT UND	ER VITAMIN K AN	IF OTHER UNIT,
Date o	TO BE PERFO	already done ORMED ONLY	VALUE (MD if not done)	Unit Ratio	IF OTHER UNIT,

AVE0005 EFC6546	Country No.	Centre No.	Subject No.	NO	30 Page	
CYCLE 1	V 01					

BIOCHEMI	STRY	LABB_1					
☐ Not App	olicable if al	ready done v	within 8 d	ays prior	to randor	mization.	
Laboratory Name:							
Address:							
Date of sampling:	day mon						

Теѕт	VALUE (MD if not done)	Unit	IF OTHER UNIT, SPECIFY
Sodium		mmol/L	
Calcium		mmol/L	
Potassium		mmol/L	
Phosphorus		mmol/L	
Blood Urea Nitrogen		mg/dL	
Urea**		mmol/L	
Magnesium		mg/dL	
Creatinine		μmol/L	
Calculated Creatinine clearance*		ml/min	
Glucose		mmol/L	
AST		IU/L	
ALT		IU/L	
Alkaline phosphatase		IU/L	
Total bilirubin		mg/dL	
Total protein		g/dL	
Albumin		g/dL	

^{*} If creatinine > ULN, please report the calculated creatinine clearance. ** If BUN is not evaluated, UREA value must be documented.

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C65	05 46	Country No.	Centre No.	Subject No.	O 31 Page
YCL	E 1	V 01			
	Not Applicable of sampling:	if already do	one within 8 da	ys prior to ran	domization.
WB	C	+	++		☐ Not evaluab
RBC	☐ Absent	+			☐ Not evaluab
IOF	RNING SPO	T URIN	ALYSIS	LABU_2	
□ _abor	RNING SPO Not Applicable ratory name:				domization.
□ _abor Addre	Not Applicable	if already do	one within 8 da		domization.
□ .abor Addre	Not Applicable ratory name:ess:	if already do	one within 8 da		domization. If OTHER UNIT, SPECIFY
] .abor Addre	Not Applicable ratory name:ess:of sampling: Lay	if already do	one within 8 da	ys prior to ran	If OTHER UNIT,
] .abor Addre	Not Applicable ratory name:ess:of sampling: Light Light day	if already do	one within 8 da	ys prior to ran	If OTHER UNIT,

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CYCLE 1	V 01	ocinic No.	Gusjeet No.		1 age	



TO BE PERFORMED AT DAY 1 JUST BEFORE THE STUDY DRUG INFUSION.

TUMOR MARKERS TMARK_01

PSA

■ Not Done

•	Date of evaluation:			20
		day	month	year

	TEST	VALUE	Unit		AL RANGE
	1201	17.1202	J	LOWER LIMIT	UPPER LIMIT
1.	PSA				

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CYCLE 1	V 01					

INVESTIGATIONAL PRODUCT ADMINISTRATION IPA_05

AFLIBERCEPT/PLACEBO

SCHEDULED DAY	Treatment Number	TICK IF NOT ADMINISTERED/ TAKEN	Date / Time*	INTENDED DOSE mg/kg	ACTUAL DOSE mg
Day 1		۵	START day month year		
			24-hour clock END 24-hour clock		

IF DOSE INTERRUPTED AND READMINISTERED, PLEASE REPORT THE INFORMATION BELOW:

SCHEDULED DAY	Treatment Number	TICK IF NOT ADMINISTERED/ TAKEN	Date / Time*	INTENDED DOSE mg/kg	ACTUAL DOSE mg
Day LJ		۵	START day month year		
			END 24-hour clock 24-hour clock		

*Time to be given only for PK patients

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AVE0005 EFC6546	Country No.	Centre No.	Subject No.	NO	34 Page
CYCLE 1	V 01				

INVESTIGATIONAL PRODUCT ADMINISTRATION IPA_04 DOCETAXEL

SCHEDULED DAY	Batch Number	TICK IF NOT ADMINISTERED/ TAKEN	Dате	INTENDED DOSE mg/m ²	ACTUAL DOSE mg
Day 1			day month year		

IF DOSE INTERRUPTED AND READMINISTERED, PLEASE REPORT THE INFORMATION BELOW:

SCHEDULED DAY	Batch Number	TICK IF NOT ADMINISTERED/ TAKEN	Dате	INTENDED DOSE mg/m ²	ACTUAL DOSE mg
Day 📖			day month year		

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VE0005 FC6546		46 Country No. Centre No. Subject No.				NO	35 Page	
YC	CLE 1		V 01					_
N١	VESTIG	ATIO	NAL PRODU	JCT ADM	INISTRA	ATION	IPA_10	
R	EDNIS(ONE /	PREDNISO	LONE				
	SCHEDULED PERIOD	TICK IF NOT ADMINISTERED/ TAKEN		Date (s)		INTENDED DAILY DOSE mg	Dose Modified	NUMBER OF DAYS WITH NO INTAKE
	Cycle 1		START L L day				☐ YES	
			END LILI L day	month ye	 ar		□ No	
E	TTING	'						
(Outpatient (clinic 🗖		Inpatient	clinic 🗖			
	·		PRE/POST DO	CETAXEL		OSTERO	ID ME	D_03
	Record	if docet	axel corticosteroïd	premedication	n has been a	dministered	as per pr	otocol.
one	e 🗖			<u>'</u>			<u> </u>	
cor	d informatio	n for the t	following medication	is during the cyc	cle.			
		(Drug	DRUG / MEDICA Class / Brand or C			Taken	N	ot Taken
			Corticostero	id				
			ompared to protoc			modified, pl	ease repo	rt the

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EFC6546

sanofi aventis

NO

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CYCLE 1	V 01					

VITAL SIGNS

VITAL_01



TO BE PERFORMED PREFERABLY DURING WEEK 2 EG BETWEEN D8 AND D15.

• Date performed:			20				
·	day	month	year				
Blood pressure:	Systolic		⊢mmHg /	Diastolic		Ш	⊥ mmHs

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AVE0005 EFC6546	Country No.	Centre No.	Subject No.	XT	37 Page	01
CYCLE 1	V 01					
MEDICATIO				.		

MEDICATION BIPHOSPHONATES MED_02

None \square

Record all biphosphonates therapies that the subject has taken within the cycle, and record any changes.

	DRUG / MEDICATION (Brand or Generic Name)	DOSAGE (TOTAL DAILY DOSE)	Dose Unit	ROUTE*	START DATE Day Month Year	END DATE OR TICK IF ONGOING Day Month Year	
1					□□ □□□ □□□□□□□□□□ Previously Reported	Ongoing	
2					Previously Reported	Ongoing	
3					Previously Reported	Ongoing	
4					Previously Reported	Ongoing	
5					Previously Reported	Ongoing	
6					Previously Reported	Ongoing	
7					Previously Reported	Ongoing	
8					Previously Reported	Ongoing	
9					Previously Reported	Ongoing	
10					Previously Reported	Ongoing	
*	* R OUTE: 19 = Intravenous 23 = Oral 24 = Other						

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ANALGESIC MEDICATION SHOULD BE COLLECTED DAILY FOR SEVEN CONSECUTIVE DAYS PRIOR TO THE NEXT INFUSION



THE LAST RECORDS SHOULD BE OBTAINED WITHIN 3 DAYS PRIOR TO THE NEXT INFUSION

* ROUTE: 27 Rectal 1 Cutaneous 19 Intravenous 2 23 Subcutaneous Buccal Oral 28 Inhalation 29 6 24 Other Sublingua 12 Intramuscular



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CYCLE 1	V 01					

MEDICATION ANALGESIC MED_02

T	7
1	
<u> </u>	

PLEASE RECORD ALL ANALGESIC MEDICATION EXCLUDING BIPHOSPHONATE.

None \square

	DRUG / MEDICATION (Brand or Generic Name)	DOSAGE (TOTAL DAILY DOSE)	Dose Unit	ROUTE *	START DATE Day Month Year	END DATE OR TICK IF ONGOING Day Month Year
1					Previously Reported	Ongoing
2					Previously Reported	Ongoing
3					Previously Reported	Ongoing
4					Previously Reported	Ongoing
5					Previously Reported	Ongoing
6					Previously Reported	
7					Previously Reported	
8					Previously Reported	Ongoing
9					Previously Reported	Ongoing
10					Previously Reported	Ongoing

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- TO BE PERFORMED OVER 7 CONSECUTIVE DAYS PRIOR TO THE NEXT INFUSION.
- THE LAST RECORDS SHOULD BE OBTAINED WITHIN 3 DAYS PRIOR TO THE NEXT INFUSION.

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CYCLE 1	V 01					

PAIN EVALUATION

NOT DONE

	D	ATE OF ASSESSA	MENT	PRESENT PAIN INTENSITY
	Day	Month	Year	SCORE
1st Day				LJ
2nd Day				LJ
3rd Day				LJ
4th Day				LJ
5th Day				LJ
6th Day				LJ
7th Day				LJ

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CYCLE 1	V 01				

SKELETAL RELATED EVENT EVALUATION

• Occurence of SRE: Yes
No



In case of:

- pathological fractures and/or spinal cord compression, please fill in an AE/SAE Form as appropriate.
- bone irradiation, including radioisotopes or bone surgery, please complete the concomitant radiation or surgery Form as appropriate.
- change of antineoplastic therapy (including introduction of biphosphonates in the face of increase in pain) to treat bone pain, please fill in either further anticancer therapy and / or Biphosphonate Medication Form.

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CYCLE 1	V 01					

SURGERY CONCOMITANT SURG_01

NONE

Record relevant surgery information within the cycle.

	Surgery	Surgery Date Day Month Year
1		
2		
3		
4		
5		
6		

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*LOCATION:

al Lymph Nodes
Lymph Nodes
9

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CYCLE 1	V 01					

RADIATION THERAPY RADIX_01

CONCOMITANT TREATMENT RADIATION THERAPY

NONE

	SITE LOCATION*	START DATE day month year	STOP DATE day month year	TOTAL Dose	Units	INTENT
1					,	☐ Palliative☐ Curative
2	LJLJ.LJLJ					☐ Palliative☐ Curative
3					☐ Grays☐ Rads	☐ Palliative☐ Curative☐
4					☐ Grays☐ Rads	☐ Palliative☐ Curative☐
5	<u></u>				☐ Grays☐ Rads	☐ Palliative☐ Curative☐
6	<u></u>				☐ Grays☐ Rads	☐ Palliative☐ Curative☐
7					☐ Grays☐ Rads	☐ Palliative☐ Curative☐
8					☐ Grays☐ Rads	☐ Palliative☐ Curative☐
9	LJLJ.LJ				☐ Grays☐ Rads	☐ Palliative☐ Curative
10					☐ Grays☐ Rads	☐ Palliative☐ Curative

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CYCLE 1	V 01					

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Assessment not done	
Specify the primary reason:	
☐ Subject is unable due to toxicity/disease	
☐ Administrative failure to distribute the questionnaire to the patient	
☐ Patient refusal	
☐ Death	
☐ Patient did not wish to show up	
☐ Translation not available	
Other specify:	

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CYCLE 1	V 01					

FACT P QUESTIONNAIRE

Below is a list of statements that other people with your illness have said are important By circling one (1) number per line, please indicate how true each statement has been for you during the past 7 days.

	PHYSICAL WELL-BEING		A little bit	Some- what	Quite a bit	Very much
GP1	Lhave a leak of anargy	0	1	2	3	4
- Gi i	I have a lack of energy	0	1	2	3	4
GP2	I have nausea	0	1	2	3	4
GP3	Because of my physical condition, I have trouble meeting the needs of my family	0	1	2	3	4
GP4	I have pain	0	1	2	3	4
GP5	I am bothered by side effects of treatment	0	1	2	3	4
GP6	I feel ill	0	1	2	3	4
GP7	I am forced to spend time in bed	0	1	2	3	4

	SOCIAL/FAMILY WELL-BEING	Not at all	A little bit	Some- what	Quite a bit	Very much
GS1	I feel close to my friends	0	1	2	3	4
GS2	I get emotional support from my family	0	1	2	3	4
GS3	I get support from my friends	0	1	2	3	4
GS4	My family has accepted my illness	0	1	2	3	4
GS5	I am satisfied with family communication about my illness	0	1	2	3	4
GS6	I feel close to my partner (or the person who is my main support)	0	1	2	3	4
Q1	Regardless of your current level of sexual activity, please answer the following question. If you prefer not to answer it, please check this box and go to the next section.					
GS7	I am satisfied with my sex life	0	1	2	3	4

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CYCLE 1	V 01				

By circling one (1) number per line, please indicate how true each statement has been for you <u>during the past 7 days</u>.

	EMOTIONAL WELL-BEING		A little bit	Some- what	Quite a bit	Very much
GE1	I feel sad	0	1	2	3	4
GE2	I am satisfied with how I am coping with my illness	0	1	2	3	4
GE3	I am losing hope in the fight against my illness	0	1	2	3	4
GE4	I feel nervous	0	1	2	3	4
GE5	I worry about dying	0	1	2	3	4
GE6	I worry that my condition will get worse	0	1	2	3	4

	FUNCTIONAL WELL-BEING		A little bit	Some- what	Quite a bit	Very much
GF1	I am able to work (include work at home)	. 0	1	2	3	4
GF2	My work (include work at home) is fulfilling	. 0	1	2	3	4
GF3	I am able to enjoy life	. 0	1	2	3	4
GF4	I have accepted my illness	. 0	1	2	3	4
GF5	I am sleeping well	. 0	1	2	3	4
GF6	I am enjoying the things I usually do for fun	. 0	1	2	3	4
GF7	I am content with the quality of my life right now	. 0	1	2	3	4

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AVE0005 EFC6546	Country No.	Centre No.	Subject No.	NO	46 Page
CYCLE 1	V 01				

By circling one (1) number per line, please indicate how true each statement has been for you during the past 7 days.

	ADDITIONAL CONCERNS		A little bit	Some- what	Quite a bit	Very much
C2	I am losing weight	0	1	2	3	4
C6	I have a good appetite	0	1	2	3	4
P1	I have aches and pains that bother me	0	1	2	3	4
P2	I have certain parts of my body where I experience pain	0	1	2	3	4
Р3	My pain keeps me from doing things I want to do	0	1	2	3	4
P4	I am satisfied with my present comfort level	0	1	2	3	4
P5	I am able to feel like a man	0	1	2	3	4
P6	I have trouble moving my bowels	0	1	2	3	4
P7	I have difficulty urinating	0	1	2	3	4
BL2	I urinate more frequently than usual	0	1	2	3	4
P8	My problems with urinating limit my activities	0	1	2	3	4
BL5	I am able to have and maintain an erection	0	1	2	3	4

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*LOCATION:

01	Skin	11.09	Supraclavicular
02	Muscle/Soft Tissue	12	Liver
03	Bone	13	Stomach
04	Bone Marrow	14	Pancreas
05	Peripheral Blood Stream	15	Kidneys
06	Brain/CNS	17	Bladder
07	Head/Neck	18	Prostate
08	Eosaphagus	20.10	Colon
10	Lungs	20.20	Rectum
11	Lymph Nodes	21	Adrenal
11.01	Regional Lymph Nodes	22	Mediastinum
11.02	Distant Lymph Nodes	24	Abdomen
11.03	Axillary	25	Gastrointestinal Tract
11.04	Cervical	26	Pelvis
11.05	Inguinal	27	Peritoneum
11.06	Intra Abdominal	28	Testis
11.07	Mediastinal	29	Thorax
11.08	Para Aortic	29.01	Pleura
		30	Other

**METHOD OF TUMOR MEASUREMENT:

1	ı	CT Scan	8	X-ray
2	2	Spiral CT Scan	9	Endoscopy
3	3	MRI	10	Physical Exam
4	1	PET	11	Multi-Slice CT
5	5	Scintigraphy	12	DCE MRI
16	5	SPECT	99	Other
7	7	Ultrasound		



*** RESPONSE OF NON-TARGET LESIONS:

CR = Complete Response UNK = Unknown

IR/SD = Incomplete Response / Stable Disease NA = Not Applicable

PD = Progressive Disease NL = New Lesion

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CYCLE 1	V 01					

TUMOR MEASUREMENTS TUMEA_02

NONE

LESION NUMBER	LESION LOCATION*	DATE OF ASSESSMENT day month year	METHOD OF TUMOR MEASUREMENT**	MEASUREMENT OF TARGET LESION: longest diameter	RESPONSE OF NON-TARGET LESIONS***
1	L.L.	□ Not Done			
2	L.I.L.I.L.I	□ Not Done			
3	L_ L	□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□			
4		□ Not Done			
5	L.L.L.	□ Not Done			
6		□ Not Done			
7		□ Not Done			
8		□ Not Done			
9	L.L.	□ Not Done			
10		□ Not Done		L L mm	
11		□ Not Done			
12		□ Not Done			

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CYCLE 1	V 01				



SINCE LAST CYCLE, IF ANY OF THE FOLLOWING EVENTS OCCUR

OR IF THERE IS A WORSENING INTENSITY OF ONGOING LISTED BELOW EVENTS,

PLEASE TICK YES AND COMPLETE AN ADVERSE EVENT FORM.

CLINICAL EVENT "THROMBOVASCULAR" CLINE_01

■ None

	YES	No
Angina Pectoris / Unstable Angina / Myocardial Infarction		
Stroke / Transient Ischemic Attack		
Peripheral Arterial Thrombosis		
Deep Venous Thrombosis		
Pulmonary Embolism		
Intraabdominal Arterial Thrombosis		
Other Thrombovascular Event		
Specify:		

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AVE0005 EFC6546	Country No.	Centre No. Subject No. Page
CYCLE 1	V 01	
ADVERSE EV	ENT FORI	M AE_03
1. Adverse Ev (Diagnosi		AE form no: LL-LL AE ref. no: LLL-LL
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change		1 Date of start:
3. GRADE (1 - 4) 4. RELATIONSHIP TO INVESTIGATIONAL PRODUCT	'S*	1
5. ACTION TAKEN WITH INVESTIGATIONAL PRODUCTS*		0 1 2 3 4 5 5
7. OUTCOME 1 = Recovered 4 = Recovered with sequelae 2 = Recovering 3 = Not recovered 5 = Fatal (complete the death report form)		Yes No Date:
6= Unknown		6
8. SERIOUSNESS CRITERIA IF YES, COMPLETE T AND THE <safety compl<="" td=""><td>HIS SECTION</td><td>Yes No</td></safety>	HIS SECTION	Yes No
9. IS IT AN EVENT SUCH AS: OVERDOSE OF THE IP?		Yes No
Investigator's name, date, and	signature:	Monitoring representative's name, date of receipt:
** 0= None / 1= Permanently disconti	nued / 2= Delayed / 3= Dose re	sed by Investigational Product? duced / 4= Delayed and reduced / 5= Interrupted AVE0005 EFC6546
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	Centre No.	Subject No.	NO	49 Page	
V 02		Date of visit:	day r		year
					_
O.VITAL_2					
	0 year				
⊥ kg					
	mmHg / I	Diastolic LL	⊥LJ mi	mHg	
3 4					
PHYSIC	`AI FXAMI	NATION			
Titible		THE TOTAL			
A PHYSICAL	L EXAMINATION	SHOULD BE PERF	ORMED.		
			E PREVIOUS	S EXAMINATION	ON,
	Country No. V 02 O.WITAL_2 I 2 1 2 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	Country No. Centre No. V 0 2 O.VITAL_2	Country No. Centre No. Subject No. V 0 2 Date of visit: O.VITAL_2	O.WITAL_2 O.WITAL_2 Subject No. Subject No. O.WITAL_2 O.WITAL_2	O.VITAL_2 O.VITAL_2 PHYSICAL EXAMINATION A PHYSICAL EXAMINATION A PHYSICAL EXAMINATION A PHYSICAL EXAMINATION SHOULD BE PERFORMED. ANY CLINICALLY SIGNIFICANT CHANGES FROM THE PREVIOUS EXAMINATION

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FC6546	Country No.	Centre No.	Subject No.	50 Page
CLE 2	V 02			
IEMATOLOGY Pate of sampling:	LABH_1	0		
Теѕт		VALUE (MD if not done)	Unit	IF OTHER UNIT,
Hemoglobin			g/L	
Platelets count			10°/L	
WBC			10 ⁹ /L	
Neutrophils			10°/L	
Not Done TO BE PERFO	RMED ONLY	FOR PATIENT UND	ER VITAMIN K AN	TAGONIST.
Date of sampling: LLL L	month	year		
ddress:				
ddress:		VALUE (MD if not done)	Unit	IF OTHER UNIT, SPECIFY
			Unit Ratio	
Теѕт		(MD if not done)	Ratio	

AVE0005 EFC6546				NO	51	
	Country No.	Centre No.	Subject No.		Page	
CYCLE 2	V 02					

BIOCHEMISTRY	LABB_1
Laboratory Name:	
Address:	
• Date of sampling:	

Test	VALUE (MD if not done)	Unit	IF OTHER UNIT, SPECIFY
Sodium		mmol/L	
Calcium		mmol/L	
Potassium		mmol/L	
Phosphorus		mmol/L	
Blood Urea Nitrogen		mg/dL	
Urea**		mmol/L	
Magnesium		mg/dL	
Creatinine		μmol/L	
Calculated Creatinine clearance*		ml/min	
Glucose		mmol/L	
AST		IU/L	
ALT		IU/L	
Alkaline phosphatase		IU/L	
Total bilirubin		mg/dL	
Total protein		g/dL	
Albumin		g/dL	

^{*} If creatinine > ULN, please report the calculated creatinine clearance. ** If BUN is not evaluated, UREA value must be documented.

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FC6546	1	Country No.	Centre No.	Subject No.	52 Page
YCLE 2		V 02			
DIPSTIC	K URIN	ALYSI	S LABU_1		
Date of samplir	ıg: ШШ L day		0		
WBC	☐ Absent	+			☐ Not evaluab
WBC					
RBC	☐ Absent G SPOT	- +	++	□ +++ LABU_2	□ Not evaluab
RBC WORNIN Not Done:	G SPOT	T URIN			□ Not evaluab
RBC MORNIN Not Done: Laboratory nar Address:	G SPOT	T URIN	ALYSIS		□ Not evaluab
RBC WORNIN Not Done: Laboratory nar	G SPO 1	T URIN	ALYSIS		IF OTHER UNIT,
RBC WORNIN Not Done: Laboratory nar Address:	ng: UL L	T URIN	ALYSIS O O O O O O O O O O O O O O O O O O O	LABU_2	If OTHER UNIT,

If proteinuria is associated with hematuria then LDH, haptoglobin, schistocytes and orosomucoid will be measured in blood. Please complete page 655.

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CYCLE 2	V 02				



TO BE PERFORMED AT DAY 1 JUST BEFORE THE STUDY DRUG INFUSION.

TUMOR	MARKERS	TMARK_01
--------------	----------------	----------

PSA

■ Not don	e
-----------	---

•	Date of evaluation:			
		day	month	year

	TEST	VALUE	Unit	Norma	AL RANGE
	1231	7/1202	J	LOWER LIMIT	UPPER LIMIT
1.	PSA				

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CYCLE 2	V 02					

INVESTIGATIONAL PRODUCT ADMINISTRATION IPA_05

AFLIBERCEPT/PLACEBO

SCHEDULED DAY	Treatment Number	TICK IF NOT ADMINISTERED/ TAKEN	Date / Time*	INTENDED DOSE mg/kg	ACTUAL DOSE mg
Day 1		٥	START day month year		
			24-hour clock END 24-hour clock		

IF DOSE INTERRUPTED AND READMINISTERED, PLEASE REPORT THE INFORMATION BELOW:

SCHEDULED DAY	Treatment Number	TICK IF NOT ADMINISTERED/ TAKEN	Date / Time*	INTENDED DOSE mg/kg	ACTUAL DOSE mg
Day 🗀		۵	START day month year		
			24-hour clock		
			END LJL:LJL 24-hour clock		

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AVE0005 EFC6546	Country No.	Centre No.	Subject No.	NO	55 Page	
CYCLE 2	V 02					

INVESTIGATIONAL PRODUCT ADMINISTRATION IPA_04 DOCETAXEL

SCHEDULED DAY	BATCH Number	TICK IF NOT ADMINISTERED/ TAKEN	Date	INTENDED DOSE mg/m ²	ACTUAL DOSE mg
Day 1		٥	day month year		

IF DOSE INTERRUPTED AND READMINISTERED, PLEASE REPORT THE INFORMATION BELOW:

SCHEDULED DAY	Batch Number	TICK IF NOT ADMINISTERED/ TAKEN	D ате	INTENDED DOSE mg/m ²	ACTUAL DOSE mg
Day 📖			day month year		

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	0005 6546	Count	try No.	Centre No.	Subject No.	NO	56 Page	
CYC	CLE 2	V ()2					
IN۱	/ESTIG	ATIONAL PR	RODL	JCT ADMIN	ISTRAT	ION	IPA_10	
PR	EDNIS(ONE / PREDN	IISO	LONE				
	SCHEDULED PERIOD	Treatment name	TICK IF NOT ADMINISTERED/ TAKEN	Date (s	;)	INTENDED DAILY DOSE mg	Dose Modified	NUMBER OF DAYS WITH NO INTAKE
	Cycle 1	Prednisone/Prednisolone		START day month	year		YES	
				END day month	year		□ No	
SE	TTING							
	Outpatient	clinic 🗖 ON: PRE/POS	T DC	Inpatient clin		STERO!	ID ME	D_03
1	Record	I if docetaxel cortico	steroïd	premedication ha	ıs been adm	inistered		
lone ecor		on for the following med	dication	s during the cycle.				
	DRUG / MEDICATION TAKEN NOT TAKEN (Drug Class / Brand or Generic Name)						OT TAKEN	
1		Cortic	costeroi	d				
		change compared to ation on the Concon			or dose mo	dified, ple	ease repo	rt the

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AVE0005 EFC6546	Country No.	Centre No.	Subject No.	NO	57 Page	
CYCLE 2	V 02					

VITAL SIGNS

VITAL_01



TO BE PERFORMED PREFERABLY DURING WEEK 2 BETWEEN D8 AND D15.

• Date performed:			20						
·	day	month	year						
Blood pressure:	Systolic		I mmHg /	Diastolic	ı	П	11	ı	mmH

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CYCLE 2	V 02					
	·					

MEDICATION BIPHOSPHONATES MED_02

None \square

Record all biphosphonates therapies that the subject has taken within the cycle, and record any changes.

	Drug / Medication (Brand or Generic Name)	DOSAGE (TOTAL DAILY DOSE)	Dose Unit	R OUTE*	START DATE Day Month Year	END DATE OR TICK IF ONGOING Day Month Year
1					Previously Reported	Ongoing
2					Previously Reported	Ongoing
3					Previously Reported	Ongoing
4					Previously Reported	Ongoing
5					Previously Reported	Ongoing
6					Previously Reported	Ongoing
7					Previously Reported	Ongoing
8					Previously Reported	Ongoing
9					Previously Reported	Ongoing
10					Previously Reported	Ongoing
*	R OUTE: 19 = Ir	ntravenous		23 =	= Oral	24 = Other

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ANALGESIC MEDICATION SHOULD BE COLLECTED DAILY FOR SEVEN CONSECUTIVE DAYS PRIOR TO THE NEXT INFUSION



THE LAST RECORDS SHOULD BE OBTAINED WITHIN 3 DAYS PRIOR TO THE NEXT INFUSION

* ROUTE: 27 Cutaneous 19 Rectal Intravenous 1 2 Buccal 23 Oral 28 Subcutaneous 6 Inhalation 24 Other 29 Sublingua = 12 Intramuscular

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CYCLE 2	V 02					

MEDICATION ANALGESIC MED_02

		<u> </u>
r -	V.	- 1
l	1	- /
		_
1-	-	

PLEASE RECORD ALL ANALGESIC MEDICATION EXCLUDING BIPHOSPHONATE.

None \square

	Drug / Medication (Brand or Generic Name)	DOSAGE (TOTAL DAILY DOSE)	Dose Unit	ROUTE *	START DATE Day Month Year	END DATE OR TICK IF ONGOING Day Month Year
1					Previously Reported	Ongoing
2					Previously Reported	Ongoing
3					Previously Reported	Ongoing
4					Previously Reported	Ongoing
5					Previously Reported	Ongoing
6					Previously Reported	Ongoing
7					Previously Reported	Ongoing
8					Previously Reported	Ongoing
9					Previously Reported	Ongoing
10					□□ □□□ □□□□□ □ Previously Reported	

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- TO BE PERFORMED OVER 7 CONSECUTIVE DAYS PRIOR TO THE NEXT INFUSION.
- THE LAST RECORDS SHOULD BE OBTAINED WITHIN 3 DAYS PRIOR TO THE NEXT INFUSION.

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CYCLE 2	V 02					

PAIN EVALUATION

NOT DONE

	D	ATE OF ASSESSA	MENT	PRESENT PAIN INTENSITY
	Day	Month	Year	Score
1st Day				<u> </u>
2nd Day				LJ
3rd Day				<u> </u>
4th Day				<u>[</u>]
5th Day				LJ
6th Day				LJ
7th Day	L			<u> </u>

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CYCLE 2	V 02	'	•		· ·	

SKELETAL RELATED EVENT EVALUATION

• Occurence of SRE: Yes
No



In case of:

- pathological fractures and/or spinal cord compression, please fill in an AE/SAE Form as appropriate.
- bone irradiation, including radioisotopes or bone surgery, please complete the concomitant radiation or surgery Form as appropriate.
- change of antineoplastic therapy (including introduction of biphosphonates in the face of increase in pain) to treat bone pain, please fill in either further anticancer therapy and / or Biphosphonate Medication Form.

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CYCLE 2	V 02					

SURGERY CONCOMITANT SURG_01

NONE

Record relevant surgery information within the cycle.

	Surgery	SURGERY DATE Day Month Year
1		
2		
3		
4		
5		
6		

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*LOCATION:

03	Bone
11.01	Regional Lymph Nodes
11.02	Distant Lymph Nodes
18	Prostate
99	Other



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CYCLE 2	V 02					

RADIATION THERAPY RADIX_01

CONCOMITANT TREATMENT RADIATION THERAPY

NONE

	SITE LOCATION*	START DATE day month year	STOP DATE day month year	TOTAL Dose	Units	INTENT
1					,	☐ Palliative☐ Curative
2	LJLJ.LJLJ					☐ Palliative☐ Curative
3					☐ Grays☐ Rads	☐ Palliative☐ Curative☐
4					☐ Grays☐ Rads	☐ Palliative☐ Curative☐
5	<u></u>				☐ Grays☐ Rads	☐ Palliative☐ Curative☐
6	<u> </u>				☐ Grays☐ Rads	☐ Palliative☐ Curative☐
7					☐ Grays☐ Rads	☐ Palliative☐ Curative☐
8					☐ Grays☐ Rads	☐ Palliative☐ Curative☐
9	LJLJ.LJ				☐ Grays☐ Rads	☐ Palliative☐ Curative
10					☐ Grays☐ Rads	☐ Palliative☐ Curative

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L1 000+0	Country No.	Centre No.	Subject No.		Page	
CYCLE 2	V 02					

_	

Assessment not done
Specify the primary reason:
☐ Subject is unable due to toxicity/disease
☐ Administrative failure to distribute the questionnaire to the patient
☐ Patient refusal
☐ Death
☐ Patient did not wish to show up
☐ Translation not available
☐ Other <i>specify</i> :

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CYCLE 2	V 02				

FACT P QUESTIONNAIRE

Below is a list of statements that other people with your illness have said are important By circling one (1) number per line, please indicate how true each statement has been for you during the past 7 days.

	PHYSICAL WELL-BEING		A little bit	Some- what	Quite a bit	Very much
GP1	Lhave a leak of anargy	0	1	2	3	4
- Gi i	I have a lack of energy	0	1	2	3	4
GP2	I have nausea	0	1	2	3	4
GP3	Because of my physical condition, I have trouble meeting the needs of my family	0	1	2	3	4
GP4	I have pain	0	1	2	3	4
GP5	I am bothered by side effects of treatment	0	1	2	3	4
GP6	I feel ill	0	1	2	3	4
GP7	I am forced to spend time in bed	0	1	2	3	4

	SOCIAL/FAMILY WELL-BEING	Not at all	A little bit	Some- what	Quite a bit	Very much
GS1	I feel close to my friends	0	1	2	3	4
GS2	I get emotional support from my family	0	1	2	3	4
GS3	I get support from my friends	0	1	2	3	4
GS4	My family has accepted my illness	0	1	2	3	4
GS5	I am satisfied with family communication about my illness	0	1	2	3	4
GS6	I feel close to my partner (or the person who is my main support)	0	1	2	3	4
Q1	Regardless of your current level of sexual activity, please answer the following question. If you prefer not to answer it, please check this box and go to the next section.					
GS7	I am satisfied with my sex life	0	1	2	3	4

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CYCLE 2	V 02				

By circling one (1) number per line, please indicate how true each statement has been for you <u>during the past 7 days</u>.

	EMOTIONAL WELL-BEING	Not at all	A little bit	Some- what	Quite a bit	Very much
GE1	I feel sad	0	1	2	3	4
GE2	I am satisfied with how I am coping with my illness	0	1	2	3	4
GE3	I am losing hope in the fight against my illness	0	1	2	3	4
GE4	I feel nervous	0	1	2	3	4
GE5	I worry about dying	. 0	1	2	3	4
GE6	I worry that my condition will get worse	0	1	2	3	4

	FUNCTIONAL WELL-BEING		A little bit	Some- what	Quite a bit	Very much
GF1	I am able to work (include work at home)	0	1	2	3	4
GF2	My work (include work at home) is fulfilling	. 0	1	2	3	4
GF3	I am able to enjoy life	. 0	1	2	3	4
GF4	I have accepted my illness	0	1	2	3	4
GF5	I am sleeping well	0	1	2	3	4
GF6	I am enjoying the things I usually do for fun	0	1	2	3	4
GF7	I am content with the quality of my life right now	0	1	2	3	4

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CYCLE 2	V 02				

By circling one (1) number per line, please indicate how true each statement has been for you during the past 7 days.

	ADDITIONAL CONCERNS		A little bit	Some- what	Quite a bit	Very much
C2	I am losing weight	0	1	2	3	4
C6	I have a good appetite	0	1	2	3	4
P1	I have aches and pains that bother me	0	1	2	3	4
P2	I have certain parts of my body where I experience pain	0	1	2	3	4
Р3	My pain keeps me from doing things I want to do	0	1	2	3	4
P4	I am satisfied with my present comfort level	0	1	2	3	4
P5	I am able to feel like a man	0	1	2	3	4
P6	I have trouble moving my bowels	0	1	2	3	4
P7	I have difficulty urinating	0	1	2	3	4
BL2	I urinate more frequently than usual	0	1	2	3	4
P8	My problems with urinating limit my activities	0	1	2	3	4
BL5	I am able to have and maintain an erection	0	1	2	3	4

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*LOCATION:

01	Skin	11.09	Supraclavicular
02	Muscle/Soft Tissue	12	Liver
03	Bone	13	Stomach
04	Bone Marrow	14	Pancreas
05	Peripheral Blood Stream	15	Kidneys
06	Brain/CNS	17	Bladder
07	Head/Neck	18	Prostate
08	Eosaphagus	20.10	Colon
10	Lungs	20.20	Rectum
11	Lymph Nodes	21	Adrenal
11.01	Regional Lymph Nodes	22	Mediastinum
11.02	Distant Lymph Nodes	24	Abdomen
11.03	Axillary	25	Gastrointestinal Tract
11.04	Cervical	26	Pelvis
11.05	Inguinal	27	Peritoneum
11.06	Intra Abdominal	28	Testis
11.07	Mediastinal	29	Thorax
11.08	Para Aortic	29.01	Pleura
		30	Other

**METHOD OF TUMOR MEASUREMENT:

1	CT Scan	8	X-ray
2	Spiral CT Scan	9	Endoscopy
3	MRI	10	Physical Exam
4	PET	11	Multi-Slice CT
5	Scintigraphy	12	DCE MRI
6	SPECT	99	Other
7	Ultrasound		

*** RESPONSE OF NON-TARGET LESIONS:

CR = Complete Response UNK = Unknown

IR/SD = Incomplete Response / Stable Disease NA = Not Applicable

PD = Progressive Disease NL = New Lesion

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CYCLE 2	V 02					

TUMOR MEASUREMENTS TUMEA_02

NONE

LESION NUMBER	LESION LOCATION*	D ATE OF ASSESSMENT day month year	METHOD OF TUMOR MEASUREMENT**	MEASUREMENT OF TARGET LESION: longest diameter	RESPONSE OF NON-TARGET LESIONS***
1		□ Not Done			
2		□ Not Done			
3		□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□			
4		□ Not Done			
5		□ Not Done			
6		□ Not Done			
7		□ Not Done			
8		□ Not Done			
9	L.L.	□ Not Done		L L mm	
10		□ Not Done			
11	L.I.L.I.L.I	□ Not Done	L!		
12	<u></u> Ш.Ш.	□ Not Done			

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CYCLE 2	V 02					



SINCE LAST CYCLE, IF ANY OF THE FOLLOWING EVENTS OCCUR

OR IF THERE IS A WORSENING INTENSITY OF ONGOING LISTED BELOW EVENTS,

PLEASE TICK YES AND COMPLETE AN ADVERSE EVENT FORM.

CLINICAL EVENT "THROMBOVASCULAR" CLINE_01

■ None

	YES	No
Angina Pectoris / Unstable Angina / Myocardial Infarction		
Stroke / Transient Ischemic Attack		
Peripheral Arterial Thrombosis		
Deep Venous Thrombosis		
Pulmonary Embolism		
Intraabdominal Arterial Thrombosis		
Other Thrombovascular Event		
Specify:	_	

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AVE0005 EFC6546	Country No.	Centre No. Subject No. AT 602 01		
CYCLE 2	V 02			
ADVERSE EV	ENT FOR	M AE_03		
1. Adverse Ev (Diagnosi		AE form no: LJL-LJL AE ref. no: LJL-LJL		
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change		1 Date of start: LL LLL year 2 (do not complete the remaining items in the column) 3 D		
3. GRADE (1 - 4) 4. RELATIONSHIP TO INVESTIGATIONAL PRODUCT	rs*	1		
5. ACTION TAKEN WITH INVESTIGATIONAL PRODUCTS* 6. CORRECTIVE TREATMENT/THERAP		0		
7. OUTCOME 1 = Recovered 4 = Recovered with sequelae 2 = Recovering 3 = Not recovered 5 = Fatal (complete the death report form)		Date:		
6= Unknown		6		
8. SERIOUSNESS CRITERIA IF YES, COMPLETE T AND THE <safety compl<="" td=""><td>HIS SECTION</td><td>- Date event became serious: - Date event became serious: - Life Hreatening - Requiring/prolonging hospitalization - Persistent/significant disability/incapacity - Congenital anomaly/birth defect - Other medically important event</td></safety>	HIS SECTION	- Date event became serious: - Date event became serious: - Life Hreatening - Requiring/prolonging hospitalization - Persistent/significant disability/incapacity - Congenital anomaly/birth defect - Other medically important event		
9. IS IT AN EVENT SUCH AS: OVERDOSE OF THE IP?		Yes No D		
Investigator's name, date, and	signature:	Monitoring representative's name, date of receipt:		
* Is there a reasonable possibility that the AE was caused by Investigational Product? ** 0= None / 1= Permanently discontinued / 2= Delayed / 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted XT 602 AVE0005 EFC6546				
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AVE0005 EFC6546	Country No.	Centre No. Subject No. Page
CYCLE 3	V 03	Date of visit: day / long / long year
		_
VITAL SIGNS	O.VITAL_2	
• Date performed : Lay		year
• Weight: LLL.L	⊥ kg	
- Blood pressure: Systolic ECOG Performance Status		mmHg / Diastolic LILILI mmHg
0 1 2	3 4	
	PHYSIC	CAL EXAMINATION
1	A PHYSICA	L EXAMINATION SHOULD BE PERFORMED.
IF THERE ARE A	ANY CLINICALLY	SIGNIFICANT CHANGES FROM THE PREVIOUS EXAMINATION, ECORD AS AN ADVERSE EVENT.

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	Country No.	Centre No.	Subject No.	71 Page
≣ 3	V 03			
IATOLOGY	LABH_1			
	. ?			
sampling: Lay	month	year		
Test		VALUE	Unit	If OTHER UNIT,
		(MD if not done)	J	SPECIFY
Hemoglobin			g/L	
Platelets count			10 ⁹ /L	
WBC			10 ⁹ /L	
Neutrophils			10 ⁹ /L	
Oone				
Done TO BE BERE	DRMED ONLY	EOD DATIENT LINID	ED VITAMINI V ANN	TACONIST
TO BE PERFO			ER VITAMIN K AN	TAGONIST.
			ER VITAMIN K AN	TAGONIST.
TO BE PERFO	2] _0	ER VITAMIN K AN	TAGONIST.
TO BE PERFO] _0	ER VITAMIN K AN	TAGONIST.
TO BE PERFO] _0	ER VITAMIN K AN	TAGONIST.
TO BE PERFO] _0	ER VITAMIN K AN	IF OTHER UNIT, SPECIFY
	sampling: Lay TEST Hemoglobin Platelets count WBC	sampling: La	sampling: Light Li	sampling: Light Li

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CYCLE 3	V 03				

BIOCHEMISTRY	LABB_1
Laboratory Name:	
Address:	
Date of sampling: LLL L	

TEST	VALUE (MD if not done)	Unit	IF OTHER UNIT, SPECIFY
Sodium		mmol/L	
Calcium		mmol/L	
Potassium		mmol/L	
Phosphorus		mmol/L	
Blood Urea Nitrogen		mg/dL	
Urea**		mmol/L	
Magnesium		mg/dL	
Creatinine		μmol/L	
Calculated Creatinine clearance*		ml/min	
Glucose		mmol/L	
AST		IU/L	
ALT		IU/L	
Alkaline phosphatase		IU/L	
Total bilirubin		mg/dL	
Total protein		g/dL	
Albumin		g/dL	

^{*} If creatinine > ULN, please report the calculated creatinine clearance. ** If BUN is not evaluated, UREA value must be documented.

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YCLE 3		V 03				
	•		_			•
IPSTI	CK URIN	IALYSI	S LABU_1			
ate ot samp	oling: LILI L day	month	year			
WBC	☐ Absent	+	++	-+++	■ Not eva	luable
DDC	Absent	 +	-++	-+++	- □ Not eva	luabl
RBC						
KRC						
———						
KBC						
	NG SPO	T URIN	IALYSIS	LABU_2		
ORNI			IALYSIS			
ORNI aboratory r						
IORNII aboratory r	name:		J O			
ORNII aboratory r	pling: LLL L][0][_] year			
ORNII aboratory r	name:		J O		IF OTHER UNIT	,
ORNII aboratory r	pling: LLL L		J O U U U Jear VALUE			,
aboratory raddress:	pling: LLL L		J O U U U Jear VALUE	Unit		, ,
aboratory raddress:	pling: LLL L day TEST		J O U U U Jear VALUE	Unit mg/dL		,
aboratory raddress: Prote	pling: LLL L day TEST ein tinine		J O U U U Jear VALUE	Unit mg/dL mg/dL	SPECIFY	,
aboratory raddress: Date of sam Prote Creat	pling: LLL L day TEST ein tinine CR is > 1 then 24 h ll as an urine prote	month our urine collectin electrophores	year VALUE (MD if not done) etion must be performatis. Please complete p	mg/dL mg/dL med to assess the upage 654.	SPECIFY	

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CYCLE 3	V 03					



TO BE PERFORMED AT DAY 1 JUST BEFORE THE STUDY DRUG INFUSION.

TUMOR MARKERS TMARK_01

PSA

Not done

• Date of evaluation :			
	day	month	vear

	TEST	VALUE	Unit	Normal range		
	1231	VALUE		LOWER LIMIT	UPPER LIMIT	
1.	PSA					

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CYCLE 3	V 03					

INVESTIGATIONAL PRODUCT ADMINISTRATION IPA_05

AFLIBERCEPT/PLACEBO

SCHEDULED DAY	Treatment Number	TICK IF NOT ADMINISTERED/ TAKEN	Date / Time*	INTENDED DOSE mg/kg	ACTUAL DOSE mg
Day 1			START day month year		
			24-hour clock		
			24-hour clock		

IF DOSE INTERRUPTED AND READMINISTERED, PLEASE REPORT THE INFORMATION BELOW:

SCHEDULED DAY	Treatment Number	TICK IF NOT ADMINISTERED/ TAKEN	Date / Time*	INTENDED DOSE mg/kg	ACTUAL DOSE mg
Day 🗀		۵	START day month year		
			L :L 24-hour clock		
			END 24-hour clock		

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AVE0005 EFC6546	Country No.	Centre No.	Subject No.	NO	76 Page	
CYCLE 3	V 03					

INVESTIGATIONAL PRODUCT ADMINISTRATION IPA_04 DOCETAXEL

SCHEDULED DAY	BATCH NUMBER	TICK IF NOT ADMINISTERED/ TAKEN	Dате	INTENDED DOSE mg/m ²	ACTUAL DOSE mg
Day 1			day month year		

IF DOSE INTERRUPTED AND READMINISTERED, PLEASE REPORT THE INFORMATION BELOW:

SCHEDULED DAY	Batch Number	TICK IF NOT ADMINISTERED/ TAKEN	D ате	INTENDED DOSE mg/m ²	ACTUAL DOSE mg
Day 🗀			day month year		

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Cyc	CLE 3	V)[3]				_	
		SATIONAL PR		ICT ADMINISTRA	TION	IPA_10		
FR	SCHEDULED PERIOD	TREATMENT NAME	TICK IF NOT ADMINISTERED/ TAKEN	DATE (s)	INTENDED DAILY DOSE mg	Dose Modified	NUMBER OF DAYS WITH NO INTAKE	
	Cycle 1	Prednisone/Prednisolone		START day month year END day month year		☐ YES		
	TTING Outpatient	clinic 🗖		Inpatient clinic 🗖				
ME				premedication has been adr			D_03	
None Recor	_	on for the following med	dication	s during the cycle.				
	Drug / Medication Taken (Drug Class / Brand or Generic Name)							
1		Cortic	osteroi	d				
		change compared to ation on the Concon		ol ie "Not taken" or dose mo 1edication Form.	odified, ple	ease repo	rt the	

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CYCLE 3	V 03					

VITAL SIGNS

VITAL_01



TO BE PERFORMED PREFERABLY DURING WEEK 2 BETWEEN D8 AND D15.

• Date performed:			20						
·	day	month	year						
Blood pressure:	Systolic		I mmHg /	Diastolic	ı	П	11	ı	mmH

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CYCLE 3	V 03		
MEDICATIO	N BIPHOSI	PHONATES MED_02	
None \square			
Record all biphosphonat	es therapies that the sub	ject has taken within the cycle, and rec	ord any changes.

	DRUG / MEDICATION (Brand or Generic Name)	DOSAGE (TOTAL DAILY DOSE)	Dose Unit	R оυте*	START DATE Day Month Year	END DATE OR TICK IF ONGOING Day Month Year
1					Previously Reported	Ongoing
2					Previously Reported	Ongoing
3					Previously Reported	Ongoing
4					Previously Reported	Ongoing
5					Previously Reported	Ongoing
6					Previously Reported	Ongoing
7					Previously Reported	Ongoing
8					Previously Reported	Ongoing
9					Previously Reported	Ongoing
10					Previously Reported	Ongoing
*	R OUTE: 19 = Ir	ntravenous		23 =	= Oral	24 = Other

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ANALGESIC MEDICATION SHOULD BE COLLECTED DAILY FOR SEVEN CONSECUTIVE DAYS PRIOR TO THE NEXT INFUSION



THE LAST RECORDS SHOULD BE OBTAINED WITHIN 3 DAYS PRIOR TO THE NEXT INFUSION

* ROUTE: Rectal 1 Cutaneous 19 Intravenous 27 2 Subcutaneous 23 Buccal Oral 28 6 Inhalation 24 Other 29 Sublingua 12 Intramuscular

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CYCLE 3	V 03					

MEDICATION ANALGESIC MED_02

		<u> </u>
-	w.	- 1
	Ŧ	- /
10	_	

PLEASE RECORD ALL ANALGESIC MEDICATION EXCLUDING BIPHOSPHONATE.

None \square

	DRUG / MEDICATION (Brand or Generic Name)	DOSAGE (TOTAL DAILY DOSE)	Dose Unit	ROUTE *	START DATE Day Month Year	END DATE OR TICK IF ONGOING Day Month Year
1					Previously Reported	Ongoing
2					Previously Reported	Ongoing
3					Previously Reported	Ongoing
4					Previously Reported	Ongoing
5					Previously Reported	Ongoing
6					Previously Reported	
7					Previously Reported	
8					Previously Reported	Ongoing
9					Previously Reported	Ongoing
10					Previously Reported	Ongoing

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- TO BE PERFORMED OVER 7 CONSECUTIVE DAYS PRIOR TO THE NEXT INFUSION.
- THE LAST RECORDS SHOULD BE OBTAINED WITHIN 3 DAYS PRIOR TO THE NEXT INFUSION.



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CYCLE 3	V 03					

PAIN EVALUATION

NOT DONE

	D	ATE OF ASSESSA	MENT	PRESENT PAIN INTENSITY
	Day	Month	Year	Score
1st Day				LJ
2nd Day				LJ
3rd Day				LJ
4th Day				LJ
5th Day				LJ
6th Day				LJ
7th Day				LJ

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CYCLE 3	V 03				

SKELETAL RELATED EVENT EVALUATION

• Occurrence of SRE: Yes
No



In case of:

- pathological fractures and/or spinal cord compression, please fill in an AE/SAE Form as appropriate.
- bone irradiation, including radioisotopes or bone surgery, please complete the concomitant radiation or surgery Form as appropriate.
- change of antineoplastic therapy (including introduction of biphosphonates in the face of increase in pain) to treat bone pain, please fill in either further anticancer therapy and / or Biphosphonate Medication Form.

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CYCLE 3	V 03					

SURGERY CONCOMITANT SURG_01

NONE

Record relevant surgery information within the cycle.

	Surgery	Surgery Date Day Month Year
1		
2		
3		
4		
5		
6		

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*LOCATION:

Bone
Regional Lymph Nodes
Distant Lymph Nodes
Prostate
Other



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CYCLE 3	V 03					

RADIATION THERAPY RADIX_01

CONCOMITANT TREATMENT RADIATION THERAPY

NONE

	SITE LOCATION*	START DATE day month year	STOP DATE day month year	TOTAL DOSE	Units	Intent
1					,	Palliative Curative
2	L					☐ Palliative☐ Curative
3					☐ Grays☐ Rads	☐ Palliative☐ Curative☐
4					☐ Grays☐ Rads	☐ Palliative☐ Curative☐
5	<u></u>				☐ Grays☐ Rads	☐ Palliative☐ Curative
6	<u></u>				☐ Grays☐ Rads	☐ Palliative☐ Curative☐
7	L.L.				☐ Grays☐ Rads	☐ Palliative☐ Curative
8					☐ Grays☐ Rads	☐ Palliative☐ Curative☐
9	Ш				☐ Grays☐ Rads	☐ Palliative☐ Curative☐
10					☐ Grays☐ Rads	☐ Palliative☐ Curative

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CYCLE 3	V 03					

F	Δ	CI	Г	P
	_ /	_		

Assessment not done
Specify the primary reason:
☐ Subject is unable due to toxicity/disease
☐ Administrative failure to distribute the questionnaire to the patient
☐ Patient refusal
☐ Death
☐ Patient did not wish to show up
☐ Translation not available
☐ Other, specify:

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CYCLE 3	V 03				

FACT P QUESTIONNAIRE

Below is a list of statements that other people with your illness have said are important By circling one (1) number per line, please indicate how true each statement has been for you during the past 7 days.

	PHYSICAL WELL-BEING		A little bit	Some- what	Quite a bit	Very much
GP1	I have a lack of energy	0	1	2	3	4
GP2	I have nausea		1	2	3	4
GP3	Because of my physical condition, I have trouble					
	meeting the needs of my family	0	1	2	3	4
GP4	I have pain	0	1	2	3	4
GP5	I am bothered by side effects of treatment	0	1	2	3	4
GP6	I feel ill	0	1	2	3	4
GP7	I am forced to spend time in bed	0	1	2	3	4

	SOCIAL/FAMILY WELL-BEING		A little bit	Some- what	Quite a bit	Very much
GS1	I feel close to my friends	0	1	2	3	4
GS2	I get emotional support from my family	0	1	2	3	4
GS3	I get support from my friends		1	2	3	4
GS4	My family has accepted my illness		1	2	3	4
GS5	I am satisfied with family communication about my illness		1	2	3	4
GS6	I feel close to my partner (or the person who is my main support)		1	2	3	4
Q1	Regardless of your current level of sexual activity, please answer the following question. If you prefer not to answer it, please check this box and go to the next section.					
GS7	I am satisfied with my sex life	. 0	1	2	3	4

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CYCLE 3	V 03				

By circling one (1) number per line, please indicate how true each statement has been for you <u>during the past 7 days</u>.

	EMOTIONAL WELL-BEING		A little bit	Some- what	Quite a bit	Very much
GE1	I feel sad	0	1	2	3	4
GE2	I am satisfied with how I am coping with my illness	0	1	2	3	4
GE3	I am losing hope in the fight against my illness		1	2	3	4
GE4	I feel nervous	0	1	2	3	4
GE5	I worry about dying	. 0	1	2	3	4
GE6	I worry that my condition will get worse		1	2	3	4

	FUNCTIONAL WELL-BEING		A little bit	Some- what	Quite a bit	Very much
GFI	I am able to work (include work at home)	. 0	1	2	3	4
GF2	My work (include work at home) is fulfilling		1	2	3	4
GF3	I am able to enjoy life		1	2	3	4
GF4	I have accepted my illness		1	2	3	4
GF5	I am sleeping well		1	2	3	4
GF6	I am enjoying the things I usually do for fun		1	2	3	4
GF7	I am content with the quality of my life right now	. 0	1	2	3	4

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CYCLE 3	V 03				

By circling one (1) number per line, please indicate how true each statement has been for you during the past 7 days.

	ADDITIONAL CONCERNS		A little bit	Some- what	Quite a bit	Very much
C2	I am losing weight	0	1	2	3	4
C6	I have a good appetite	0	1	2	3	4
P1	I have aches and pains that bother me	0	1	2	3	4
P2	I have certain parts of my body where I experience pain	0	1	2	3	4
Р3	My pain keeps me from doing things I want to do		1	2	3	4
P4	I am satisfied with my present comfort level	0	1	2	3	4
P5	I am able to feel like a man	0	1	2	3	4
P6	I have trouble moving my bowels	0	1	2	3	4
P7	I have difficulty urinating	0	1	2	3	4
BL2	I urinate more frequently than usual	0	1	2	3	4
P8	My problems with urinating limit my activities	0	1	2	3	4
BL5	I am able to have and maintain an erection	0	1	2	3	4

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*LOCATION:

01	Skin	11.09	Supraclavicular
02	Muscle/Soft Tissue	12	Liver
03	Bone	13	Stomach
04	Bone Marrow	14	Pancreas
05	Peripheral Blood Stream	15	Kidneys
06	Brain/CNS	17	Bladder
07	Head/Neck	18	Prostate
08	Eosaphagus	20.10	Colon
10	Lungs	20.20	Rectum
11	Lymph Nodes	21	Adrenal
11.01	Regional Lymph Nodes	22	Mediastinum
11.02	Distant Lymph Nodes	24	Abdomen
11.03	Axillary	25	Gastrointestinal Tract
11.04	Cervical	26	Pelvis
11.05	Inguinal	27	Peritoneum
11.06	Intra Abdominal	28	Testis
11.07	Mediastinal	29	Thorax
11.08	Para Aortic	29.01	Pleura
		30	Other

**METHOD OF TUMOR MEASUREMENT:

1	CT Scan	8	X-ray
2	Spiral CT Scan	9	Endoscopy
3	MRI	10	Physical Exam
4	PET	11	Multi-Slice CT
5	Scintigraphy	12	DCE MRI
6	SPECT	99	Other
7	Ultrasound		



*** RESPONSE OF NON-TARGET LESIONS:

CR = Complete Response UNK = Unknown

IR/SD = Incomplete Response / Stable Disease NA = Not Applicable

PD = Progressive Disease NL = New Lesion

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CYCLE 3	V 03				

TUMOR MEASUREMENTS TUMEA_02

NONE

LESION NUMBER	LESION LOCATION*	day month year TUMOR TARG		MEASUREMENT OF TARGET LESION: longest diameter	RESPONSE OF NON-TARGET LESIONS***
1		□ Not Done			
2	L.I	□ Not Done			
3	L_1 L1 , L1 L1	□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□			
4		□ Not Done			
5		□ Not Done			
6		□ Not Done			
7		□ Not Done			
8		□ Not Done			
9	L.L.	□ Not Done			
10		□ Not Done			
11		□ Not Done			
12		□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□			

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CYCLE 3	V 03					



SINCE LAST CYCLE, IF ANY OF THE FOLLOWING EVENTS OCCUR

OR IF THERE IS A WORSENING INTENSITY OF ONGOING LISTED BELOW EVENTS,

PLEASE TICK YES AND COMPLETE AN ADVERSE EVENT FORM.

CLINICAL EVENT "THROMBOVASCULAR" CLINE_01

■ None

	YES	No
	1 E3	NO
Angina Pectoris / Unstable Angina / Myocardial Infarction		
Stroke / Transient Ischemic Attack		
Peripheral Arterial Thrombosis		
Deep Venous Thrombosis		
Pulmonary Embolism		
Intraabdominal Arterial Thrombosis		
Other Thrombovascular Event		
Specify:	_	

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CYCLE 3	V 03	
ADVERSE EVEN	IT FOR	M AE_03
1.		AE form no:
Adverse Event (Diagnosis)		AE ref. no:
2. STATUS OF AE 1= New		1 Date of start: LLLLLLLLLLLLLLLLLLLLLLLLLLLLLLLLLLLL
2= Ongoing from previous period without change 3= Ongoing with change		2 (do not complete the remaining items in the column) 3
3. GRADE (1 - 4)		
4. RELATIONSHIP TO INVESTIGATIONAL PRODUCTS*		Yes No No
5. ACTION TAKEN WITH INVESTIGATIONAL PRODUCTS**		0 1 2 3 4 5 5
6. CORRECTIVE TREATMENT/THERAPY		Yes 🗖 No 🗖
7. OUTCOME 1= Recovered 4= Recovered with sequelae		1 Date: LIL LILL year 4 Specify sequelae:
2= Recovering 3= Not recovered		3 ☐ 5 ☐ Date of death: ☐☐ ☐☐ ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐
5= Fatal (complete the death report form) 6= Unknown		6 🗖
8. SERIOUSNESS CRITERIA IF YES, COMPLETE THIS S AND THE <safety complemen<="" th=""><th></th><th>Yes □ No □ - Date event became serious: □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □</th></safety>		Yes □ No □ - Date event became serious: □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □
		day month year - Tick below all criteria that apply: Resulting in death
9. Is it an event such as:		
OVERDOSE OF THE IP?		Yes No D
Investigator's name, date, and signa		Monitoring representative's name, date of receipt:
,		educed / 4= Delayed and reduced / 5= Interrupted
XT 603		AVE0005 EFC6546

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VISIT 99	V 99					

END OF TREATMENT	EOT_02
Main reason for stopping treatment (tick " \checkmark " one box only):	
- Adverse event*	
- Disease progression	
- Poor compliance to protocol	
- Lost to follow-up	
- Other reason	
If other reason, specify:	

In case of code-breaking, complete the Code Breaking CRF page.

* In case of an adverse event complete the Adverse Event form.

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AVE0005 EFC6546	Country No.	Centre No.	Subject No.	NO	502 Page	
VISIT 99	V 99					

END OF TREATMENT

EOT_03

In case of early, permanent discontinuation of one of the Study Treatments, specify the reason:

- Adverse Event*	
- Other reason	
If other reason, specify:	

In case of code-breaking, complete the Code Breaking CRF page.

* In case of an adverse event complete the Adverse Event form.

NO 502 AVE0005 EFC6546

AVE0005 EFC6546	Country No.	Centre No.	Subject No.	NO	503 Page	
Visit 99	V 99					

CODE BREAKING	(ON	SITE)	CODEB_01
The code has been broken by:	☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐	Investigator Pharmacist Study nurse Other (site sta	ff)
Name:			
Performed by:		IVRS Code Breaking	
Date performed: LLL LLL day mont		year	Time performed: LLL: LLL 24-hour clock
Reason: AE			
Other If other, specify:			
Treatment number:			

The code must be broken only in exceptional circumstances when knowledge of the study medication is essential for treating the subject. If possible contact the Monitoring Team before breaking the code.

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AVE0005 EFC6546	Country No.	Centre No.	Subject No.	NO	801 Page	
V80 End of treatment visit	V 80		Date of visit:	day /	month /	year
						_
VITAL SIGNS	O.VITAL_2					
• Date performed : Lay		year				
● Weight: □□□.∟	⊔ kg					
- Blood pressure: Systoli	с ШШШ	mmHg /	Diastolic L L	⊥L m	ımHg	
ECOG Performance Status						
0 1 2	3 4					
	PHYSIC	CAL EXAM	INATION			
	A PHYSICA	L EXAMINATION	SHOULD BE PERF	ORMED.		



IF THERE ARE ANY CLINICALLY SIGNIFICANT CHANGES FROM THE PREVIOUS EXAMINATION, RECORD AS AN ADVERSE EVENT.

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	IATOLOGY LA	ABH_1			
٧c	ot done	_			
of	f sampling: ШШ ШШ day mon		0		
ſ					
	Test		VALUE (MD if not done)	Unit	IF OTHER UNIT, SPECIFY
				g/L	
ı	Platelets count			10 ⁹ /L	
П	WBC			10 ⁹ /L	
ı				10 ⁹ /L	
	Neutrophils IATOLOGY LA Done	ABH_1		.07=	
	IATOLOGY LA		OR PATIENT UND		NTAGONIST.
	IATOLOGY LA Done TO BE PERFORME	D ONLY FO			NTAGONIST.
[IATOLOGY <i>LA</i> Done	D ONLY FO			NTAGONIST.
of	Done TO BE PERFORMENT f sampling:	D ONLY FO	0		NTAGONIST.
of or	TO BE PERFORMED f sampling: Lay Lay day mon ry Name:	D ONLY FO	0		NTAGONIST.
of	TO BE PERFORMED f sampling: Lay Lay day mon ry Name:	D ONLY FO	O	ER VITAMIN K AI	NTAGONIST.
of	TO BE PERFORMED f sampling: Lay Lay day mon ry Name:	D ONLY FO	0		IF OTHER UNIT, SPECIFY

AVE0005 EFC6546	Country No.	Centre No.	Subject No.	NO	803 Page	
V80 END OF TREATMENT VISIT	V 80	Centre No.	Subject No.		raye	

BIOCHEMI	STRY LABB_1
■ Not done	
Laboratory Name: _	
Address:	
• Date of sampling:	day month year

Test	VALUE (MD if not done)	Unit	IF OTHER UNIT, SPECIFY
Sodium		mmol/L	
Calcium		mmol/L	
Potassium		mmol/L	
Phosphorus		mmol/L	
Blood Urea Nitrogen		mg/dL	
Urea**		mmol/L	
Magnesium		mg/dL	
Creatinine		μmol/L	
Calculated Creatinine clearance*		ml/min	
Glucose		mmol/L	
AST		IU/L	
ALT		IU/L	
Alkaline phosphatase		IU/L	
Total bilirubin		mg/dL	
Total protein		g/dL	
Albumin		g/dL	

^{*} If creatinine > ULN, please report the calculated creatinine clearance. ** If BUN is not evaluated, UREA value must be documented.

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C6546		Country No.	Centre No.	Subject No.) 804 Page
80 End REATMEN		V 80			
IPSTIC	CK URIN	IALYSI	S LABU_1		
Not done	e				
ate of samp	lling: LLL L		year		
WBC	☐ Absent	- +	-++	-+++	□ Not evaluable
RBC	☐ Absent	+			□ Not evaluabl
ORNII Not done	NG SPO	T URIN	IALYSIS	LABU_2	□ Not evaluabl
IORNII Not done aboratory r	NG SPO	T URIN	IALYSIS	LABU_2	□ Not evaluabl
IORNII Not done aboratory r	NG SPO	T URIN	IALYSIS	LABU_2	□ Not evaluabl
Not done aboratory r	NG SPOTE	T URIN	IALYSIS	LABU_2	IF OTHER UNIT, SPECIFY
Not done aboratory r	NG SPOTE name: pling: L L day	T URIN	IALYSIS O year Value	LABU_2	If OTHER UNIT,

as well as an urine protein electrophoresis. Please complete page 654.

If proteinuria is associated with hematuria then LDH, haptoglobin, schistocytes and orosomucoid will be measured in blood. Please complete page 655.

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AVE0005 EFC6546	Country No.	Centre No.	Subject No.	NO	805 Page	
V80 End of TREATMENT VISIT	V 80					,

PSA

	TEST	VALUE	Unit	Norma	AL RANGE
	11231	VALUE	ONII	LOWER LIMIT	UPPER LIMIT
1.	PSA				

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*LOCATION:

01	Skin	11.09	Supraclavicular
02	Muscle/Soft Tissue	12	Liver
03	Bone	13	Stomach
04	Bone Marrow	14	Pancreas
05	Peripheral Blood Stream	15	Kidneys
06	Brain/CNS	17	Bladder
07	Head/Neck	18	Prostate
08	Eosaphagus	20.10	Colon
10	Lungs	20.20	Rectum
11	Lymph Nodes	21	Adrenal
11.01	Regional Lymph Nodes	22	Mediastinum
11.02	Distant Lymph Nodes	24	Abdomen
11.03	Axillary	25	Gastrointestinal Tract
11.04	Cervical	26	Pelvis
11.05	Inguinal	27	Peritoneum
11.06	Intra Abdominal	28	Testis
11.07	Mediastinal	29	Thorax
11.08	Para Aortic	29.01	Pleura
		30	Other

**METHOD OF TUMOR MEASUREMENT:

1	CT Scan	8	X-ray
2	Spiral CT Scan	9	Endoscopy
3	MRI	10	Physical Exam
4	PET	11	Multi-Slice CT
5	Scintigraphy	12	DCE MRI
6	SPECT	99	Other
7	Ultrasound		
'	Citaboana		



*** RESPONSE OF NON-TARGET LESIONS:

CR = Complete Response UNK = Unknown

IR/SD = Incomplete Response / Stable Disease NA = Not Applicable

PD = Progressive Disease NL = New Lesion



AVE0005 EFC6546	Country No.	Centre No.	Subject No.	NO	806 Page	
V80 END OF TREATMENT VISIT	V 80				<u> </u>	

TUMOR MEASUREMENTS TUMEA_02

NONE

LESION NUMBER	LESION LOCATION*	D ATE OF ASSESSMENT day month year	METHOD OF TUMOR MEASUREMENT**	MEASUREMENT OF TARGET LESION: longest diameter	RESPONSE OF NON-TARGET LESIONS***
1		□ Not Done			
2	L.I	□ Not Done			
3	L_1 L1 , L1 L1	□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□			
4		□ Not Done			
5		□ Not Done			
6		□ Not Done			
7		□ Not Done			
8		□ Not Done			
9	L.L.	□ Not Done			
10		□ Not Done			
11		□ Not Done			
12		□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□			

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	Country No.	Centre No.	Subject No.		Page	
V80 END OF TREATMENT VISIT	V 80					

OVERALL OBJECTIVE RESPONSE RESP_01

BEST OVERALL OBJECTIVE RESPONSE

Date of Assessment:			
	day	month	year

Summary of Lesions						
Best Overall Objective Response*	CR	PR	SD	PD	UNK	NA

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^{*} Tick "✓" one box only

AVE0005 EFC6546	Country No.	Centre No.	Subject No.	NO	808 Page	
V80 END OF TREATMENT VISIT	V 80					

F	Δ	CI	Г	D
	_	\sim		

Assessment not done
Specify the primary reason:
☐ Subject is unable due to toxicity/disease
☐ Administrative failure to distribute the questionnaire to the patient
☐ Patient refusal
☐ Death
☐ Patient did not wish to show up
☐ Translation not available
☐ Other, specify:

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AVE0005 EFC6546				NO	809	
EFC0340	Country No.	Centre No.	Subject No.		Page	
V80 End of TREATMENT VISIT	V 80					

FACT P QUESTIONNAIRE

Below is a list of statements that other people with your illness have said are important By circling one (1) number per line, please indicate how true each statement has been for you during the past 7 days.

	PHYSICAL WELL-BEING	Not at all	A little bit	Some- what	Quite a bit	Very much
GP1	I have a lack of energy	0	1	2	3	4
GP2	I have nausea	0	1	2	3	4
GP3	Because of my physical condition, I have trouble					
	meeting the needs of my family	0	1	2	3	4
GP4	I have pain	0	1	2	3	4
GP5	I am bothered by side effects of treatment	0	1	2	3	4
GP6	I feel ill	0	1	2	3	4
GP7	I am forced to spend time in bed	0	1	2	3	4

	SOCIAL/FAMILY WELL-BEING	Not at all	A little bit	Some- what	Quite a bit	Very much
GS1	I feel close to my friends	0	1	2	3	4
GS2	I get emotional support from my family	0	1	2	3	4
GS3	I get support from my friends	0	1	2	3	4
GS4	My family has accepted my illness	0	1	2	3	4
GS5	I am satisfied with family communication about my illness	0	1	2	3	4
GS6	I feel close to my partner (or the person who is my main support)	0	1	2	3	4
Q1	Regardless of your current level of sexual activity, please answer the following question. If you prefer not to answer it, please check this box and go to the next section.					
GS7	I am satisfied with my sex life	0	1	2	3	4

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AVE0005 EFC6546	Country No.	Centre No.	Subject No.	NO	810 Page
V80 END OF TREATMENT VISIT	V 80	Centre No.	Subject No.		raye

By circling one (1) number per line, please indicate how true each statement has been for you <u>during the past 7 days</u>.

	EMOTIONAL WELL-BEING	Not at all	A little bit	Some- what	Quite a bit	Very much
GE1	I feel sad	0	1	2	3	4
GE2	I am satisfied with how I am coping with my illness	0	1	2	3	4
GE3	I am losing hope in the fight against my illness	0	1	2	3	4
GE4	I feel nervous	0	1	2	3	4
GE5	I worry about dying	. 0	1	2	3	4
GE6	I worry that my condition will get worse	0	1	2	3	4

	FUNCTIONAL WELL-BEING		A little bit	Some- what	Quite a bit	Very much
GF1	I am able to work (include work at home)	. 0	1	2	3	4
GF2	My work (include work at home) is fulfilling		1	2	3	4
GF3	I am able to enjoy life	. 0	1	2	3	4
GF4	I have accepted my illness		1	2	3	4
GF5	I am sleeping well		1	2	3	4
GF6	I am enjoying the things I usually do for fun	. 0	1	2	3	4
GF7	I am content with the quality of my life right now	0	1	2	3	4

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	Country No.	Centre No.	Subject No.		Page	
V80 END OF TREATMENT VISIT	V 80					

By circling one (1) number per line, please indicate how true each statement has been for you during the past 7 days.

	ADDITIONAL CONCERNS No		A little bit	Some- what	Quite a bit	Very much
C2	I am losing weight	0	1	2	3	4
C6	I have a good appetite	0	1	2	3	4
P1	I have aches and pains that bother me	0	1	2	3	4
P2	I have certain parts of my body where I experience pain		1	2	3	4
Р3	My pain keeps me from doing things I want to do		1	2	3	4
P4	I am satisfied with my present comfort level		1	2	3	4
P5	I am able to feel like a man		1	2	3	4
P6	I have trouble moving my bowels	0	1	2	3	4
P7	I have difficulty urinating	0	1	2	3	4
BL2	I urinate more frequently than usual	0	1	2	3	4
P8	My problems with urinating limit my activities		1	2	3	4
BL5	I am able to have and maintain an erection	0	1	2	3	4

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LI C0340	Country No.	Centre No.	Subject No.	I	Page
V81/ Follow-up	V 81		Date of visit:	ay/	month year

SUBJECT STATUS

SUBST_01

Date	of last contact: LLLLL LJLLL gay month year
Subje	ct condition at the time of the scheduled visit (tick one condition only):
	Alive Lost to follow-up Dead*
Metho	od of contact:
	Scheduled visit Phone Other, specify:

* If the subject died, please complete a Death report form.

If the subject died/has had a sudden non-treatment related death please complete an Adverse Event form.

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AVE0005 EFC6546	Country No.	Centre No.	Subject No.	NO	813 Page	
V81/ Follow-up	V 81				_	
VITAL SIGNS	O.VITAL_2					
• Date performed : Lag		year				
- Blood pressure: Systoli	с ШШШ	mmHg /	Diastolic LLL	⊥i∟i mi	mHg	
ECOG Performance Status						
0 1 2	3 4					

PHYSICAL EXAMINATION



A PHYSICAL EXAMINATION SHOULD BE PERFORMED.

IF THERE ARE ANY CLINICALLY SIGNIFICANT CHANGES FROM THE PREVIOUS EXAMINATION, RECORD AS AN ADVERSE EVENT.

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AVE0005 EFC6546	Country No.	Centre No.	Subject No.	NO	814 Page	
V81/ Follow-up	V 81					

TUMOR MARKERS	TMARK_01
PSA	
Not done	
• Date of evaluation : LILI LILI day month	year

	TEST VALUE		Unit	Normal range			
			J	LOWER LIMIT	UPPER LIMIT		
1.	PSA						

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	/E0005 FC6546	Cour	itry No.	Centre I	No. 1	Subject No.	815 Page	01
	81/ OLLOW-UP		81					
M	IEDICATION	ВІРН	IOSF	PHON	TAI	'ES MED_02		
No	one 🔲							
Rec	cord all biphosphonates th	nerapies that	the subje	ect has tak	en wit	hin the follow-up peri	od, and record any	y changes.
	DRUG / MEDICATION (Brand or Generic Name)	DOSAGE (TOTAL DAILY DOSE)	Dose Unit	R оυте*	Day	START DATE Month Year	END DATE TICK IF ONG Day Month	
1						Previously Reported	Ongo	
2						Previously Reported	Ongo	
3						Previously Reported	Ongo	
4						Previously Reported	Ongo	
5						Previously Reported	Ongo	
6						Previously Reported	Ongo	
7						ШШШ ШШШШ Previously Reported	Ongo	
8						Previously Reported	Ongo	
9						Previously Reported	Ongo	
10						Previously Reported	Ongo	
*	R OUTE: 19 = Ir	ntravenous		23 :	= Oral		24 = Other	
	XT 815	L			A	VE0005	EFC6546	_
	0 (1) (1) = 5:			~~~		COOC	avootic	

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ANALGESIC MEDICATION SHOULD BE COLLECTED DAILY FOR SEVEN CONSECUTIVE DAYS PRIOR TO THE NEXT FOLLOW-UP VISIT.



THE LAST RECORDS SHOULD BE OBTAINED WITHIN 3 DAYS PRIOR TO THE NEXT FOLLOW-UP VISIT.

* ROUTE: Cutaneous 19 Intravenous 27 Rectal 1 2 Buccal 23 Oral 28 Subcutaneous 6 Inhalation 24 Other 29 Sublingua 12 Intramuscular



AVE0005 EFC6546	Country No.	Centre No.	Subject No.	XT	816 Page	01
V81/ Follow-up	V 81					

MEDICATION ANALGESIC MED_02

	1	7
	•	
10	_	

PLEASE RECORD ALL ANALGESIC MEDICATION EXCLUDING BIPHOSPHONATE.

None \square

	DRUG / MEDICATION (Brand or Generic Name)	DOSAGE (TOTAL DAILY DOSE)	Dose Unit	ROUTE *	START DATE Day Month Year	END DATE OR TICK IF ONGOING Day Month Year
1					Previously Reported	Ongoing
2					Previously Reported	Ongoing
3					Previously Reported	Ongoing
4					Previously Reported	Ongoing
5					Previously Reported	Ongoing
6					Previously Reported	Ongoing
7					Previously Reported	Ongoing
8					Previously Reported	Ongoing
9					Previously Reported	Ongoing
10					Previously Reported	Ongoing

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- TO BE PERFORMED OVER 7 CONSECUTIVE DAYS PRIOR TO THE NEXT FOLLOW-UP VISIT.
- THE LAST RECORDS SHOULD BE OBTAINED WITHIN 3 DAYS PRIOR TO THE NEXT FOLLOW-UP VISIT.

AVE0005 EFC6546	Country No.	Centre No.	Subject No.	NO	817 Page	
V81/ Follow-up	V 81					

PAIN EVALUATION

NOT DONE

	D	ATE OF ASSESSA	MENT	PRESENT PAIN INTENSITY
	Day	Month	Year	Score
1st Day				LJ
2nd Day				LJ
3rd Day				LJ
4th Day				<u> </u>
5th Day				LJ
6th Day				LJ
7th Day				LJ

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AVE0005 EFC6546	Country No.	Centre No.	Subject No.	NO	818 Page
V81/ Follow-up	V 81	'			

SKELETAL RELATED EVENT EVALUATION

• Occurence of SRE: Yes
No



In case of:

- pathological fractures and/or spinal cord compression, please fill in an AE/SAE Form as appropriate.
- bone irradiation, including radioisotopes or bone surgery, please complete the post radiation or surgery Form as appropriate.
- change of antineoplastic therapy (including introduction of biphosphonates in the face of increase in pain) to treat bone pain, please fill in either further anticancer therapy and / or Biphosphonate Medication Form.

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V81/ Follow-up	V 81			1	- 195	

SURGERY: POST TREATMENT ANTI-CANCER SURG_01

NONE 🔲

	Surgery	Surgery Date Day Month Year
1		
2		
3		

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*LOCATION:

03	Bone
11.01	Regional Lymph Nodes
11.02	Distant Lymph Nodes
18	Prostate
99	Other

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V81/ Follow-up	V 81					

RADIATION THERAPY RADIX_01

POST TREATMENT

NONE

	SITE LOCATION	START DATE day month year	STOP DATE day month year	TOTAL UNITS DOSE	Intent
1	<u></u>			l '	☐ Palliative☐ Curative☐
2				☐ Grays☐ Rads	Palliative Curative
3	LJL.LJL				☐ Palliative☐ Curative
4				· · · · · ·	☐ Palliative☐ Curative☐
5	LJLJ.LJ			☐ Grays☐ Rads	Palliative Curative
6	<u></u>			☐ Grays☐ Rads	Palliative Curative
7				☐ Grays☐ Rads	☐ Palliative☐ Curative☐
8				☐ Grays☐ Rads	Palliative Curative

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AVE0005 EFC6546	Country No.	Centre No.	Subject No.	NO	822 Page	
V81/ Follow-up	V 81	550110.	Casjourno.	1	. 390	

FA	CT	P

Assessment not done	
Specify the primary reason:	
☐ Subject is unable due to toxicity/disease	
☐ Administrative failure to distribute the questionnaire to the patient	
☐ Patient refusal	
☐ Death	
☐ Patient did not wish to show up	
☐ Translation not available	
Other, specify:	

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000.0	Country No.	Centre No.	Subject No.	I	Page
V81/ Follow-up	V 81				

FACT P QUESTIONNAIRE

Below is a list of statements that other people with your illness have said are important By circling one (1) number per line, please indicate how true each statement has been for you during the past 7 days.

	PHYSICAL WELL-BEING	Not at all	A little bit	Some- what	Quite a bit	Very much
GP1	I have a lack of energy	0	1	2	3	4
GP2	I have nausea	0	1	2	3	4
GP3	Because of my physical condition, I have trouble					
	meeting the needs of my family	0	1	2	3	4
GP4	I have pain	0	1	2	3	4
GP5	I am bothered by side effects of treatment		1	2	3	4
GP6	I feel ill	0	1	2	3	4
GP7	I am forced to spend time in bed	0	1	2	3	4

	SOCIAL/FAMILY WELL-BEING	Not at all	A little bit	Some- what	Quite a bit	Very much
GS1	I feel close to my friends	0	1	2	3	4
GS2	I get emotional support from my family	0	1	2	3	4
GS3	I get support from my friends	0	1	2	3	4
GS4	My family has accepted my illness		1	2	3	4
GS5	I am satisfied with family communication about my illness		1	2	3	4
GS6	I feel close to my partner (or the person who is my main support)	0	1	2	3	4
Q1	Regardless of your current level of sexual activity, please answer the following question. If you prefer not to answer it, please check this box and go to the next section.					
GS7	I am satisfied with my sex life	. 0	1	2	3	4

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AVE0005 EFC6546	Country No.	Centre No.	Subject No.	NO	824 Page
V81/ Follow-up	V 81		<u>.</u>		

By circling one (1) number per line, please indicate how true each statement has been for you during the past 7 days.

	EMOTIONAL WELL-BEING	Not at all	A little bit	Some- what	Quite a bit	Very much
GE1	I feel sad	0	1	2	3	4
GE2	I am satisfied with how I am coping with my illness	0	1	2	3	4
GE3	I am losing hope in the fight against my illness	0	1	2	3	4
GE4	I feel nervous		1	2	3	4
GE5	I worry about dying		1	2	3	4
GE6	I worry that my condition will get worse	. 0	1	2	3	4

	FUNCTIONAL WELL-BEING	Not at all	A little bit	Some- what	Quite a bit	Very much
GF1	I am able to work (include work at home)	. 0	1	2	3	4
GF2	My work (include work at home) is fulfilling	. 0	1	2	3	4
GF3	I am able to enjoy life	. 0	1	2	3	4
GF4	I have accepted my illness	0	1	2	3	4
GF5	I am sleeping well	0	1	2	3	4
GF6	I am enjoying the things I usually do for fun	. 0	1	2	3	4
GF7	I am content with the quality of my life right now	0	1	2	3	4

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V81/ Follow-up	V 81					

By circling one (1) number per line, please indicate how true each statement has been for you during the past 7 days.

	ADDITIONAL CONCERNS	Not at all	A little bit	Some- what	Quite a bit	Very much
C2	I am losing weight	0	1	2	3	4
C6	I have a good appetite	0	1	2	3	4
P1	I have aches and pains that bother me	0	1	2	3	4
P2	I have certain parts of my body where I experience pain	0	1	2	3	4
Р3	My pain keeps me from doing things I want to do	0	1	2	3	4
P4	I am satisfied with my present comfort level	0	1	2	3	4
P5	I am able to feel like a man	0	1	2	3	4
P6	I have trouble moving my bowels	0	1	2	3	4
P7	I have difficulty urinating	0	1	2	3	4
BL2	I urinate more frequently than usual		1	2	3	4
P8	My problems with urinating limit my activities		1	2	3	4
BL5	I am able to have and maintain an erection	0	1	2	3	4

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*LOCATION:

01	Skin	11.09	Supraclavicular
02	Muscle/Soft Tissue	12	Liver
03	Bone	13	Stomach
04	Bone Marrow	14	Pancreas
05	Peripheral Blood Stream	15	Kidneys
06	Brain/CNS	17	Bladder
07	Head/Neck	18	Prostate
08	Eosaphagus	20.10	Colon
10	Lungs	20.20	Rectum
11	Lymph Nodes	21	Adrenal
11.01	Regional Lymph Nodes	22	Mediastinum
11.02	Distant Lymph Nodes	24	Abdomen
11.03	Axillary	25	Gastrointestinal Tract
11.04	Cervical	26	Pelvis
11.05	Inguinal	27	Peritoneum
11.06	Intra Abdominal	28	Testis
11.07	Mediastinal	29	Thorax
11.08	Para Aortic	29.01	Pleura
		30	Other

**METHOD OF TUMOR MEASUREMENT:

1	CT Scan	8	X-ray
2	Spiral CT Scan	9	Endoscopy
3	MRI	10	Physical Exam
4	PET	11	Multi-Slice CT
5	Scintigraphy	12	DCE MRI
6	SPECT	99	Other
7	Ultrasound		

*** RESPONSE OF NON-TARGET LESIONS:

CR = Complete Response UNK = Unknown

IR/SD = Incomplete Response / Stable Disease NA = Not Applicable

PD = Progressive Disease NL = New Lesion

AVE0005 EFC6546	Country No.	Centre No.	Subject No.	NO	826 Page	
V81/ Follow-up	V 81					

TUMOR MEASUREMENTS TUMEA_02

NONE

LESION NUMBER	LESION LOCATION*	D ATE OF ASSESSMENT day month year	METHOD OF TUMOR MEASUREMENT**	MEASUREMENT OF TARGET LESION: longest diameter	RESPONSE OF NON-TARGET LESIONS***
1		□ Not Done			
2	L.I	□ Not Done			
3		□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□			
4		□ Not Done			
5		□ Not Done			
6		□ Not Done			
7		□ Not Done			
8		□ Not Done			
9	L.L.	□ Not Done			
10		□ Not Done			
11		□ Not Done			
12		□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□			

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AVE0005 EFC6546	Country No.	Centre No.	Subject No.	NO	827 Page
V81/ Follow-up	V 81		,		



SINCE LAST CYCLE, IF ANY OF THE FOLLOWING EVENTS OCCUR

OR IF THERE IS A WORSENING INTENSITY OF ONGOING LISTED BELOW EVENTS,

PLEASE TICK YES AND COMPLETE AN ADVERSE EVENT FORM.

CLINICAL EVENT "THROMBOVASCULAR" CLINE_01

■ None

	YES	No
Angina Pectoris / Unstable Angina / Myocardial Infarction		
Stroke / Transient Ischemic Attack		
Peripheral Arterial Thrombosis		
Deep Venous Thrombosis		
Pulmonary Embolism		
Intraabdominal Arterial Thrombosis		
Other Thrombovascular Event		
Specify:		

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AVE0005 EFC6546 Country No.	Centre No. Subject No. Subject No. Page
V81/ FOLLOW-UP	
ADVERSE EVENT FOR	M AE_03
None 🔲	
1. Adverse Event (Diagnosis)	AE form no: LLL-LLL AE ref. no: LLL-LLL
2. STATUS OF AE 1= New 2= Ongoing from previous period without change	1 Date of start: Date
3= Ongoing with change	3 🗖
3. GRADE (1 - 4)	1 2 3 4 4
4. Relationship to Investigational Products*	Yes No No
5. ACTION TAKEN WITH INVESTIGATIONAL PRODUCTS**	0
6. Corrective Treatment/Therapy	Yes No 🗆
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering	1 Date: LLL LLLL year 4 Specify sequelae: 2 3 0
3= Not recovered	5
5= Fatal (complete the death report form)	day month year
6= Unknown	6 🗆
8. Seriousness Criteria If yes, complete this section AND THE < <safety complementary="" form="">></safety>	Yes
9. IS IT AN EVENT SUCH AS: OVERDOSE OF THE IP?	Yes No 🗆
Investigator's name, date, and signature:	Monitoring representative's name, date of receipt:
* Is there a reasonable possibility that the AE was cau. ** 0= None / 1= Permanently discontinued / 2= Delayed / 3= Dose r XT 681	educed / 4= Delayed and reduced / 5= Interrupted AVE0005 EFC6546

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AVE0005 EFC6546	Country No	Centre No.	Subject No.	NO	828
V82/ Follow-up	V 82	Centre No.	Date of visit:	day /	Page month year

SUBJECT STA	SUBST_01	
Date of last contact:	day month year	

Subject condition at the time of the scheduled visit (tick one condition only):

Alive

Lost to follow-up

☐ Dead*

Method of contact:

☐ Scheduled visit

Other, specify:

Phone

* If the subject died, please complete a Death report form.

If the subject died/has had a sudden non-treatment related death please complete an Adverse Event form.

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AVE0005 EFC6546	Country No.	Centre No.	Subject No.	NO	829 Page	
V82/ Follow-up	V 82				Ţ,	_
VITAL SIGNS	O.VITAL_2					
• Date performed : Lay		year				
- Blood pressure: Systol	ic ШШШ	mmHg /	Diastolic 📖	m	ımHg	
ECOG Performance Status 0 1 2	3 4					
ů i i						
	PHYSIC	CAL EXAM	NATION			



A PHYSICAL EXAMINATION SHOULD BE PERFORMED.

IF THERE ARE ANY CLINICALLY SIGNIFICANT CHANGES FROM THE PREVIOUS EXAMINATION, RECORD AS AN ADVERSE EVENT.

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AVE0005 EFC6546	Country No.	Centre No.	Subject No.	NO	830 Page	
V82/ Follow-up	V 82					

TUMOR MARKERS TMAKE	RK_C	01
I UMOR MARKERS TMAK	?K_(<i>91</i>

PSA

Not done \square			
• Date of evaluation :	L L day	month	year

	TEST VALUE		Unit	Normal range		
		VALGE	J	LOWER LIMIT	UPPER LIMIT	
1.	PSA					

NO 830 AVE0005 EFC6546

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	E0005 C6546	Cour	atry No.	Centre i	No.	Subject No.	XT	831 Page	01	
	82/ DLLOW-UP	-	8 1							
No	MEDICATION BIPHOSPHONATES MED_02 None □ Record all biphosphonates therapies that the subject has taken within the follow-up period, and record any changes.									
	DRUG / MEDICATION (Brand or Generic Name)	DOSAGE (TOTAL DAILY DOSE)	Dose Unit	R оυте*	Day	START DATE Month	Year	TICK IF	DATE OR ONGOING Onth Year	
1						ШШШ Ш Previously Rep			Ongoing	
2						Previously Rep			Ongoing	
3						Previously Rep			Ongoing	
4						⊔⊔⊔ ⊔∟ Previously Rep			Ongoing	
5						⊔⊔⊔ ⊔∟ Previously Rep			Ongoing	
6						ШШШ ШL Previously Rep			Ongoing	
7						⊔⊔⊔ ⊔∟ Previously Rep		_	Ongoing	
8						レロロ ロレ Previously Rep			Ongoing	
9						⊔⊔⊔ Ш∟ Previously Rep			Ongoing	
10						ШШШ ШС Previously Rep			Ongoing	
*	R OUTE: 19 = Ir	ntravenous		23 =	= Oral			24 = Oth	er	

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ANALGESIC MEDICATION SHOULD BE COLLECTED DAILY FOR SEVEN CONSECUTIVE DAYS PRIOR TO THE NEXT FOLLOW-UP VISIT.



THE LAST RECORDS SHOULD BE OBTAINED WITHIN 3 DAYS PRIOR TO THE NEXT FOLLOW-UP VISIT.

* ROUTE: 1 Cutaneous 19 Intravenous 27 Rectal 2 Buccal 23 28 Subcutaneous = Oral = 6 Inhalation 24 Other 29 Sublingua 12 Intramuscular

AVE0005 EFC6546	Country No.	Centre No.	Subject No.	XT	832 Page	01
V82/ 6 Months Follow-up	V 82	Centre No.	Oubject No.		T age	

MEDICATION ANALGESIC MED_02

	1	7	
	1		
1	÷		

PLEASE RECORD ALL ANALGESIC MEDICATION EXCLUDING BIPHOSPHONATE.

None \square

	DRUG / MEDICATION (Brand or Generic Name)	DOSAGE (TOTAL DAILY DOSE)	Dose Unit	ROUTE *	START DATE Day Month Year	END DATE OR TICK IF ONGOING Day Month Year
1					Previously Reported	Ongoing
2					Previously Reported	Ongoing
3					Previously Reported	Ongoing
4					Previously Reported	Ongoing
5					Previously Reported	Ongoing
6					Previously Reported	Ongoing
7					Previously Reported	Ongoing
8					Previously Reported	Ongoing
9					Previously Reported	Ongoing
10					Previously Reported	Ongoing

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- TO BE PERFORMED OVER 7 CONSECUTIVE DAYS PRIOR TO THE NEXT FOLLOW-UP VISIT.
- THE LAST RECORDS SHOULD BE OBTAINED WITHIN 3 DAYS PRIOR TO THE NEXT FOLLOW-UP VISIT.

AVE0005 EFC6546	Country No.	Centre No.	Subject No.	NO	833 Page	
V82/ Follow-up	V 82					

PAIN EVALUATION

NOT DONE

	D	ATE OF ASSESSA	MENT	PRESENT PAIN INTENSITY
	Day	Month	Year	Score
1st Day				LJ
2nd Day				LJ
3rd Day				LJ
4th Day			الالالا	<u> </u>
5th Day				Ll
6th Day				LJ
7th Day				LJ

NO 833 AVE0005 EFC6546

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AVE0005 EFC6546	Country No.	Centre No.	Subject No.	NO	834 Page	
V82/ Follow-up	V 82					

SKELETAL RELATED EVENT EVALUATION

•	Occurence of SRE:	Yes 🗌	No	
---	-------------------	-------	----	--



In case of:

- pathological fractures and/or spinal cord compression, please fill in an AE/SAE Form as appropriate.
- bone irradiation, including radioisotopes or bone surgery, please complete the post radiation or surgery Form as appropriate.
- change of antineoplastic therapy (including introduction of biphosphonates in the face of increase in pain) to treat bone pain, please fill in either further anticancer therapy and / or Biphosphonate Medication Form.

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AVE0005 EFC6546	Country No.	Centre No.	Subject No.	NO	835 Page	
V82/ Follow-up	V 82					

SURGERY: POST TREATMENT ANTI-CANCER SURG_01

NONE 🔲

	Surgery	Surgery Date or None Day Month Year
1		
2		
3		

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*LOCATION:

03	Bone
11.01	Regional Lymph Nodes
11.02	Distant Lymph Nodes
18	Prostate
99	Other

AVE0005 EFC6546				XT	836	01
LI 00340	Country No.	Centre No.	Subject No.	I	Page	
V82/ Follow-up	V 82					

RADIATION THERAPY RADTX_01

POST TREATMENT RADIATION THERAPY

NONE

	SITE LOCATION	START DATE day month ye	ear day	STOP DATE	year	TOTAL Dose	Units	Intent
1	LJL.LL						☐ Grays☐ Rads	☐ Palliative☐ Curative
2							☐ Grays☐ Rads	☐ Palliative☐ Curative
3	LJL.LJL							☐ Palliative☐ Curative☐
4							· .	☐ Palliative☐ Curative
5							☐ Grays ☐ Rads	☐ Palliative☐ Curative☐
6	<u></u>						☐ Grays☐ Rads	☐ Palliative☐ Curative☐
7							☐ Grays☐ Rads	☐ Palliative☐ Curative
8	<u></u>						☐ Grays☐ Rads	☐ Palliative☐ Curative☐

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AVE0005 EFC6546	Country No.	Centre No.	Subject No.	NO	838 Page	
V82/ Follow-up	V 82	Centre No.	Gubject No.		i age	

	$\overline{}$	_
FΔ		
\mathbf{r}		

Assessment not done
Specify the primary reason:
☐ Subject is unable due to toxicity/disease
☐ Administrative failure to distribute the questionnaire to the patient
☐ Patient refusal
☐ Death
☐ Patient did not wish to show up
☐ Translation not available
☐ Other, specify:

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AVE0005 EFC6546				NO	839
21 000 10	Country No.	Centre No.	Subject No.	1	Page
V82/ Follow-up	V 82				

FACT P QUESTIONNAIRE

Below is a list of statements that other people with your illness have said are important By circling one (1) number per line, please indicate how true each statement has been for you during the past 7 days.

	PHYSICAL WELL-BEING	Not at all	A little bit	Some- what	Quite a bit	Very much
GP1	Lhave a leak of anargy	0	1	2	3	4
- Gi i	I have a lack of energy	0	1	2	3	4
GP2	I have nausea	0	1	2	3	4
GP3	Because of my physical condition, I have trouble meeting the needs of my family	0	1	2	3	4
GP4	I have pain	0	1	2	3	4
GP5	I am bothered by side effects of treatment	0	1	2	3	4
GP6	I feel ill	0	1	2	3	4
GP7	I am forced to spend time in bed	0	1	2	3	4

	SOCIAL/FAMILY WELL-BEING	Not at all	A little bit	Some- what	Quite a bit	Very much
GS1	I feel close to my friends	0	1	2	3	4
GS2	I get emotional support from my family	0	1	2	3	4
GS3	I get support from my friends	0	1	2	3	4
GS4	My family has accepted my illness	0	1	2	3	4
GS5	I am satisfied with family communication about my illness	0	1	2	3	4
GS6	I feel close to my partner (or the person who is my main support)	0	1	2	3	4
Q1	Regardless of your current level of sexual activity, please answer the following question. If you prefer not to answer it, please check this box and go to the next section.					
GS7	I am satisfied with my sex life	. 0	1	2	3	4

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AVE0005 EFC6546	Country No.	Centre No.	Subject No.	NO	840 Page
V82/ Follow-up	V 82				

By circling one (1) number per line, please indicate how true each statement has been for you <u>during the past 7 days</u>.

	EMOTIONAL WELL-BEING		A little bit	Some- what	Quite a bit	Very much
GE1	I feel sad	0	1	2	3	4
GE2	I am satisfied with how I am coping with my illness	0	1	2	3	4
GE3	I am losing hope in the fight against my illness	0	1	2	3	4
GE4	I feel nervous	. 0	1	2	3	4
GE5	I worry about dying	. 0	1	2	3	4
GE6	I worry that my condition will get worse	. 0	1	2	3	4

	FUNCTIONAL WELL-BEING		A little bit	Some- what	Quite a bit	Very much
П						
GF1	I am able to work (include work at home)	. 0	1	2	3	4
GF2	My work (include work at home) is fulfilling	0	1	2	3	4
GF3	I am able to enjoy life	. 0	1	2	3	4
GF4	I have accepted my illness	. 0	1	2	3	4
GF5	I am sleeping well	. 0	1	2	3	4
GF6	I am enjoying the things I usually do for fun	0	1	2	3	4
GF7	I am content with the quality of my life right now	. 0	1	2	3	4

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AVE0005 EFC6546	Country No.	Centre No.	Subject No.	NO	841 Page
V82/ Follow-up	V 82				

By circling one (1) number per line, please indicate how true each statement has been for you during the past 7 days.

	ADDITIONAL CONCERNS	Not at all	A little bit	Some- what	Quite a bit	Very much
C2	I am losing weight	0	1	2	3	4
C6	I have a good appetite	0	1	2	3	4
P1	I have aches and pains that bother me	0	1	2	3	4
P2	I have certain parts of my body where I experience pain	0	1	2	3	4
Р3	My pain keeps me from doing things I want to do	0	1	2	3	4
P4	I am satisfied with my present comfort level	0	1	2	3	4
P5	I am able to feel like a man	0	1	2	3	4
P6	I have trouble moving my bowels	0	1	2	3	4
P7	I have difficulty urinating	0	1	2	3	4
BL2	I urinate more frequently than usual	0	1	2	3	4
P8	My problems with urinating limit my activities	0	1	2	3	4
BL5	I am able to have and maintain an erection	0	1	2	3	4

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*LOCATION:

01	Skin	11.09	Supraclavicular
02	Muscle/Soft Tissue	12	Liver
03	Bone	13	Stomach
04	Bone Marrow	14	Pancreas
05	Peripheral Blood Stream	15	Kidneys
06	Brain/CNS	17	Bladder
07	Head/Neck	18	Prostate
08	Eosaphagus	20.10	Colon
10	Lungs	20.20	Rectum
11	Lymph Nodes	21	Adrenal
11.01	Regional Lymph Nodes	22	Mediastinum
11.02	Distant Lymph Nodes	24	Abdomen
11.03	Axillary	25	Gastrointestinal Tract
11.04	Cervical	26	Pelvis
11.05	Inguinal	27	Peritoneum
11.06	Intra Abdominal	28	Testis
11.07	Mediastinal	29	Thorax
11.08	Para Aortic	29.01	Pleura
		30	Other
		l	

**METHOD OF TUMOR MEASUREMENT:

1	CT Scan	8	X-ray
2	Spiral CT Scan	9	Endoscopy
3	MRI	10	Physical Exam
4	PET	11	Multi-Slice CT
5	Scintigraphy	12	DCE MRI
6	SPECT	99	Other
7	Ultrasound		

*** RESPONSE OF NON-TARGET LESIONS:

CR = Complete Response UNK = Unknown

IR/SD = Incomplete Response / Stable Disease NA = Not Applicable

PD = Progressive Disease NL = New Lesion

AVE0005 EFC6546	Country No.	Centre No.	Subject No.	NO	842 Page
V82/ Follow-up	V 82				

TUMOR MEASUREMENTS TUMEA_02

NONE

LESION NUMBER	LESION LOCATION*	D ATE OF ASSESSMENT day month year	METHOD OF TUMOR MEASUREMENT**	MEASUREMENT OF TARGET LESION: longest diameter	RESPONSE OF NON-TARGET LESIONS***
1		□ Not Done			
2	LJLJ.LJ	□ Not Done			
3		□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□			
4		□ Not Done			
5		□ Not Done			
6		□ Not Done			
7		□ Not Done			
8		□ Not Done			
9	L.L.	□ Not Done			
10		□ Not Done			
11		□ Not Done			
12		□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□			

NO	842		AVE0005	EFC6546

AVE0005 EFC6546	Country No.	Centre No.	Subject No.	NO	843 Page
V82/ Follow-up	V 82	·			



SINCE LAST CYCLE, IF ANY OF THE FOLLOWING EVENTS OCCUR

OR IF THERE IS A WORSENING INTENSITY OF ONGOING LISTED BELOW EVENTS,

PLEASE TICK YES AND COMPLETE AN ADVERSE EVENT FORM.

CLINICAL EVENT "THROMBOVASCULAR" CLINE_01

■ None

	YES	No
Angina Pectoris / Unstable Angina / Myocardial Infarction		
Stroke / Transient Ischemic Attack		
Peripheral Arterial Thrombosis		
Deep Venous Thrombosis		
Pulmonary Embolism		
Intraabdominal Arterial Thrombosis		
Other Thrombovascular Event		
Specify:		

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AVE0005 EFC6546 Country No.	Centre No. Subject No. Page
V82/	33,551.00
FOLLOW-UP V 82	
ADVERSE EVENT FORM	AE_03
None 🔲	
1. Adverse Event (Diagnosis)	AE form no: LL-LL AE ref. no: LL-LL
2. STATUS OF AE 1= New	1 Date of start:
2= Ongoing from previous period without change	2 (do not complete the remaining items in the column)
3= Ongoing with change	3 🗖
3. GRADE (1 - 4)	1 🗆 2 🗔 3 🗔 4 🗔
4. RELATIONSHIP TO INVESTIGATIONAL PRODUCTS*	Yes No No
5. ACTION TAKEN WITH INVESTIGATIONAL PRODUCTS**	0 0 1 0 2 0 3 0 4 0 5 0
6. Corrective Treatment/Therapy	Yes No D
7. OUTCOME 1= Recovered 4= Recovered with sequelae	1 Date: LLL LLLL year 4 Specify sequelae:
2= Recovering	3 🗖
3= Not recovered	5 Date of death: U U U U U U Gay month year
5= Fatal (complete the death report form) 6= Unknown	6 🗖
8. SERIOUSNESS CRITERIA	Yes No 🗆
IF YES, COMPLETE THIS SECTION AND THE < <safety complementary="" form="">></safety>	- Date event became serious: - Date event became serious: - Tick below all criteria that apply: Resulting in death
9. Is it an event such as:	
Overdose of the IP?	Yes U No U
Investigator's name, date, and signature:	Monitoring representative's name, date of receipt:
* Is there a reasonable possibility that the AE was cause ** 0= None / 1= Permanently discontinued / 2= Delayed / 3= Dose redu XT 682	AVE0005 EFC6546
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AVE0005 EFC6546	Country No.	Centre No.	Subject No.	XT	551 Page	01
V ISIT 99	V 99					

MEDICATION MED_01

None

Record all concomitant medications other than analgesic and biphosphonates that the subject has taken during the study period as defined in the protocol.

DRUG / MEDICATION (Brand or Generic Name)	START DATE Day Month Year	END DATE OR TICK IF ONGOING Day Month Year
	D. Dennisonale Denominal	
	☐ Previously Reported	Ongoing UU UUU UUUU
	Previously Reported	Ongoing UUUUUUU
	Previously Reported	Ongoing UUUUUUUU
	Previously Reported	
	Previously Reported	Ongoing
	Previously Reported	Ongoing
	☐ Previously Reported	Ongoing
	☐ Previously Reported	Ongoing
	☐ Previously Reported	Ongoing UU UUU UUUU
	Previously Reported	☐ Ongoing

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AVE0005 EFC6546	Country No.	Centre No.	Subject No.	XT	551 Page	02
V ISIT 99	V 99					

MEDICATION MED_01



Record all concomitant medications other than analgesic and biphosphonates that the subject has taken during the study period as defined in the protocol.

DRUG / MEDICATION (Brand or Generic Name)	START DATE Day Month Year	END DATE OR TICK IF ONGOING Day Month Year
	□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□	Ongoing
	Previously Reported	□ Ongoing □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □
	Previously Reported	Ongoing
	Previously Reported	Ongoing
	Previously Reported	Ongoing UUUUU
	Previously Reported	Ongoing
	☐ Previously Reported	Ongoing

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	r 99	V 99			
)	ITIONAL H	EMATO	LOGY LAI	BH_1	
		.	0		
1	f sampling: Lay	month	year		
	Test		VALUE (MD if not done)	Unit	IF OTHER UNIT
l				g/L	
ı	Platelets count			10 ⁹ /L	
I	WBC			10 ⁹ /L	
ı	Neutrophils			10°/L	
/					
	Done				
	Done	DRMED ONLY	FOR PATIENT UND	ER VITAMIN K AN	NTAGONIST.
	TO BE PERFO	2	J. O	ER VITAMIN K AN	NTAGONIST.
[TO BE PERFO			ER VITAMIN K AN	NTAGONIST.
	TO BE PERFO f sampling: Lay day ry Name:	2	J. O	ER VITAMIN K AN	NTAGONIST.
101	TO BE PERFO f sampling: Lay day ry Name:	2	J. O	ER VITAMIN K AN	NTAGONIST.
> 1	TO BE PERFO f sampling: Lay day ry Name:	2	J. O	ER VITAMIN K AN	IF OTHER UNIT
1	TO BE PERFO f sampling: Lay ry Name:	2	year VALUE		If other unit

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Test	VALUE (MD if not done)	Unit	IF OTHER UNIT, SPECIFY
Sodium		mmol/L	
Calcium		mmol/L	
Potassium		mmol/L	
Phosphorus		mmol/L	
Blood Urea Nitrogen		mg/dL	
Urea**		mmol/L	
Magnesium		mg/dL	
Creatinine		μmol/L	
Calculated Creatinine clearance*		ml/min	
Glucose		mmol/L	
AST		IU/L	
ALT		IU/L	
Alkaline phosphatase		IU/L	
Total bilirubin		mg/dL	
Total protein		g/dL	
Albumin		g/dL	

^{*} If creatinine > ULN, please report the calculated creatinine clearance.

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^{**} If BUN is not evaluated, UREA value must be documented.

AVE00 EFC65	146	Country No.	Centre N	0.	Subject No.	XT	654 Page	01
Visi	i	99		'			J	_
		TC) BE COMP	LETED I	F UPCR >	1.		
24-F	IOUR URINAI	LYSIS	LABU_	2				
Labora	atory name:							
Addre	ess:							
• Start da	ate of collection: ШШ				• Start tin	ne of coll	ection: LL	:
	day	month	year		e Lu	6 11		-hour clock
• End da	te of collection: Lay	month	year		• End tim	e of colle		hour clock
	TEST		VAL (MD if no		U	NIT	IF OTHER UI	NIT,
	Urinary Volume					L		
	Protein				g	/L		
	Creatinine				g	/L		
		ELE	CTROP	HORE	ESIS			
	TEST		VAL (MD if no		Unit		IF OTHER UI SPECIFY	NIT,
	Albumin				g	/L		
	α1 Globulin				g	/L		
	α2 Globulin				g	/L		
	β Globulin				g	/L		
	γ Globulin				g	/L		
	IS THERE A	NY HEMO	GLOBIN C	OR RBC I	IN 24-HOL	JR URIN S	SAMPLE.	
	Hemoglobin			Negat	tive		Positive	
	RBC			Negat	tive		Positive	
_ '	XT 654			AVE	E0005	, El	FC6546	
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Visit 9		V 99	Centre No	o. S	ubject No.	l	Page	
			_					
!	Т	O BE COMPLETED	IF PROTEINU	JRIA IS ASS	OCIATED V	VITH HEM	ATURIA.	
HEMA	TOLOGY	LABH_1						
Date of s	ampling: LLL day	month	year	J				
		NEGATIVE (MD if not d				Positive done)		
	Schisto	ecytes					-	
BIOC I Laboratory	HEMISTE	RY LABB_1						
Address:								
Date of s	ampling: LJL day	J L L L L L L L L L L L L L L L L L L L	year	1				
	Test		VAL (MD if no		Un	NIT	IF OTHER SPECIF	
	LDH				IU	/L		
-	Haptoglobin				g/	Ľ		

TEST	VALUE (MD if not done)	Unit	IF OTHER UNIT, SPECIFY
LDH		IU/L	
Haptoglobin		g/L	
Orosomucoïd		g/L	

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	Γ		TESTS	DATE OF SAMPLING	VALUE	Unit	NORMA Lower	L RANGES Upper	Address:	UNSCHE!	VISIT	AVE0005 EFC6546
င္ပ	×			day month year			limit	limit	y: (- C) 005 546
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ı Final versi	_	2		UU UUU UUUU							_ <	+
on ■ 25-J		3								LABO	9	Country No.
lul-2007		4								LABORATORY		Cent
	A	5								ORY		Centre No.
SQI	AVE0005	6								TESTS		Subject No.
sanofi	_	7								STS		×
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Sitt	16	9										O1
		10									I	0 1

	/E0005 FC6546	Cou	untry No.	Centre No.	Subje	ect No.	XT	751 Page	01
V	і з іт 99	V	99						
	THER PROCI	EDU	RES	ОТ	HPR_03				
	Only additional procedures not planned in the protocol								procedures
	Procedure Descript	ION	1	PROCEDURE DA (day/month/yea			(Оитсоме	
1						□ No	onormal		significant?
	* Specify:		1			!			
2						□ No	onormal		significant?
	* Specify:		1						
3						□ N	ot Application ormal onormal abnormal Yes*		significant?
	* Specify:								
4				_ _		□ No	ot Application onormal abnormal □ Yes*		significant?
	* Specify:					-			
	XT 751	ı			AVE00	05	, Ef	-C6546	

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V іsіт 99	V 99					

ELECTROCARDIOGRAM ECG_01



IF ABNORMAL, CLINICALLY SIGNIFICANT, RECORD ON THE ADVERSE EVENT FORM.

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SYMPTOMATIC DETERIORATION SYMDE_01

Date: day month year

If symptomatic deterioration occurs during the study period as defined in the protocol, record on the Adverse Event form.

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V ISIT 99	V 99					

	TL	DEATH	01
v	\ TH	DEATH	υı

Date of death:							
	day	month	year				
Reason for death (tick "✓" one box only):							
☐ Disease pro	ogression						

Ц	Adverse event		
	Other	Specify: _	

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ADDITIONAL VITAL SIGNS 0.VITAL_2

• Date performed: UUUUUUUuday month year

- Blood pressure: Systolic | | | mmHg / Diastolic | mmHg

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	V 🔲	Subject initials					
		Cubject linears					
ADVERSE EVE	NT FOR	M AE_03					
None 🔲							
1.		AE form no: LJLJ-LJLJ					
Adverse Event (Diagnosis)	•	AE ref. no:					
2. STATUS OF AE 1= New		1 Date of start: LLLLLLLLLLLLLLLLLLLLLLLLLLLLLLLLLLLL					
2= Ongoing from previous period without change		2 (do not complete the remaining items in the column)					
3= Ongoing with change		3 🗖					
3. GRADE (1 - 4)		1					
4. Relationship to Investigational Products*		Yes No No					
5. ACTION TAKEN WITH INVESTIGATIONAL PRODUCTS**		0 1 2 3 4 5 5					
6. Corrective Treatment/Therapy		Yes No 🗆					
7. Оитсоме		1 Date: LL LLL LLLL year					
1= Recovered 4= Recovered with sequelae		4 🗖 🕽 Specify sequelae:					
2= Recovering		3 🗖					
3= Not recovered		5 Date of death: UU UUU UUU year					
5= Fatal (complete the death report form) 6= Unknown		6 🗖					
8. SERIOUSNESS CRITERIA		Yes No D					
IF YES, COMPLETE THIS AND THE <safety compleme<="" th=""><th></th><th>→ IF YES - Date event became serious:</th></safety>		→ IF YES - Date event became serious:					
		- Tick below all criteria that apply:					
		Resulting in death					
9. Is it an event such as:							
OVERDOSE OF THE IP?		Yes No					
Investigator's name, date, and sign	nature:	Monitoring representative's name, date of receipt:					
* Is there a reasonable possibility							
** 0= None / 1= Permanently discontinued XT	/ 2= Delayed / 3= Dose	reduced / 4= Delayed and reduced / 5= Interrupted AVE0005 EFC6546					

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	V 🔲					

		NUMBER: LL.L	Y FORI	VI SAEC_03			
1. DEMOGRAPHIC INFORMATION Date of birth:			Race: Caucasia Asian, O	riental	☐ Blacl ☐ Othe	Black Other	
Sex:	☐ male	☐ female	Height: 📖 l	cm W	Veight: LL	L kg	
	ESCRIPTION OF 1	THE ADVERSE EVENT tigations)					
3. DATE OF STA	ART OF EVENT (i	nitial date of onset of the cor	nsidered event);		month year	L L ar	
4. Investigation		s ion of study treatment:	L]L] L]L day mon				
Current T	reatment number	:	uay mon	,	rrent Cycle n° l		
Date of the I	LAST administrati	on before SAE:		Last dosage before SAE	Actio	on Taken*	
Aflibercept/Place	ebo:	day month year	J	ШШШ mg/Kg			
Docetaxel:		day month 20 year	_	□□□ mg/m²	!		
Prednisone/Pred	nisolone:	LILI LILI 20 LIL day month year	_	ШШШ mg/day	/		
* 0 = None; 1 = Pe	rmanently discontinu	ued; 2 = Delayed; 3 = Dose Redu		and reduced; 5 = Inte	errupted.		
5. IN CASE OF H	HOSPITALIZATION	N (hospital report to be sent)	Date of ad	mission:	month	20	
6. In Case of I	DEATH	Autopsy report:	Yes (c	copy to be sent)		No	
7. Corrective	TREATMENT/THI	ERAPY			(Relevant CRF pa	nge can be faxed)	
8. PREVIOUS AN	ND CONCOMITAI	NT MEDICATIONS:			(Relevant CRF pa	age can be faxed)	
9. RELEVANT MI	EDICAL HISTORY	AND CONCOMITANT DIS	EASES:		(Relevant CPE	aga can ha fayadi	
XT			ΔVEΩΩ)O5 !	FFC6546	nge can be faxed)	

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	0005				XT		
EFC	C6546	Country No.	Centre No.	Subject No.	1	Page	
		V 🔲					
			1				
SA	FETY FOLL	OW-UP F	FORM	SAEF_01			
	Provide THE			ALL ADDITION IF UPDATED	IAL INFOR	MATION	
				IF OPDATED			
AE /	SPECIFIC EVENT FORM	NUMBER:					
1.	ADVERSE EVENT (dia	ngnosis):					
2.	DATE OF THE EVALU	JATION: 📖					
		d	lay month	year			
3.	NEW RELEVANT INF	ORMATION A	DDED TO IN	IITIAL REPOR	T(S):		

Investigator's name, date and signature:

Monitoring representative's name, date of receipt:

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