EFC6193 STUDY

CASE REPORT FORM

SCREEN FAILURE

A RANDOMIZED, OPEN LABEL MULTI-CENTER STUDY OF XRP6258 AT 25 MG/M^2 IN COMBINATION WITH PREDNISONE EVERY 3 WEEKS COMPARED TO MITOXANTRONE IN COMBINATION WITH PREDNISONE FOR THE TREATMENT OF HORMONE REFRACTORY METASTATIC PROSTATE CANCER PREVIOUSLY TREATED WITH A TAXOTERE®-CONTAINING REGIMEN

COUNTRY NUMBER: ⌊__⌋⌊__⌋⌊__⌋ CENTRE NUMBER: ⌊__⌋⌊__⌋⌊__⌋

SUBJECT NUMBER: ⌊__⌋⌊__⌋⌊__⌋ SUBJECT INITIALS: ⌊__⌋⌊__⌋⌊__⌋

See Page 12

DEMOGRAPHY

DEMOG_1

- Date of consent: day month **20** year
- Date of birth: day month **19** year
- Sex: Male ☑
- Race:
  - Caucasian ❑
  - Black ❑
  - Asian, Oriental ❑
  - Other ❑ *If Other, specify:*_____

INCLUSION CRITERIA

CRIT_1

The Patient must have:	YES	NO
1. Diagnosis of histologically or cytologically proven prostate adenocarcinoma, that is refractory to hormone therapy and previously treated with a Taxotere®-containing regimen. Patient must have documented progression of disease during or within 6 months after prior hormone therapy and disease progression during or after Taxotere®-containing therapies	❑	❑
2. Patient must have either measurable or non-measurable disease	❑	❑

· Patient with measurable disease must have documented progression of disease by RECIST criteria demonstrating at least one visceral or soft tissue metastatic lesion (including new lesion). This lesion must measure at least 10 mm in the longest diameter (or two times the slice thickness) on spiral CT scan or MRI (chest, abdomen, pelvis) or 20 mm on conventional CT or Chest X-ray for biopsy proven, clearly defined lung lesion surrounded by aerated lung. (Previously irradiated lesions, primary prostate lesion, and bone lesions will be considered non-measurable disease).

· Patient with non-measurable disease must have documented rising PSA levels or appearance of new lesion. [Rising PSA is defined as at least two consecutive rises in PSA to be documented over a reference value (measure 1) taken at least one week apart. The first rising PSA (measure 2) should be taken at least 7 days after the reference value. A third confirmatory PSA measure is required (2nd beyond the reference level) to be greater than the second measure and it must be obtained at least 7 days after the 2nd measure. If this is not the case, a fourth PSA measure is required to be taken and be greater than the 2nd measure. The third (or the fourth) confirmatory PSA should be taken within 4 weeks prior to randomization]

3. Received prior castration by orchiectomy and/or Luteinizing Hormone-Releasing Hormone (LH-RH) agonist with or without antiandrogen, antiandrogen withdrawal, monotherapy with estramustine, or other hormonal agents. (A prior treatment by antiandrogen is not mandatory. However, if the patient has been treated with antiandrogens, **and** PSA is above 5 ng/mL at the last administration of antiandrogens, presence or absence of antiandrogen withdrawal syndrome* should be confirmed prior to the study entry). (LH-RH agonist treatment should continue during the study treatment period. Chlormadinone acetate or flutamide must have been stopped at least 4 weeks prior to, while bicalutamide must have been stopped at least 6 weeks prior to, the last PSA evaluation.) *(* The antiandrogen withdrawal syndrome is a decrease in PSA seen upon stopping an antiandrogen such as chlormadinone acetate, flutamide, or bicalutamide; this occurs because the antiandrogen has induced a mutation in the androgen receptor which is allowing the antiandrogen to stimulate prostate cancer growth rather than inhibit it)*	❑	❑
4. Life expectancy > 2 months	❑	❑
5. Eastern Cooperative Oncology Group (ECOG) performance status 0 - 2	❑	❑
6. Age ≥ 18 years	❑	❑

IF THE ANSWER TO ANY OF THE INCLUSION CRITERIA IS NO, THE SUBJECT IS NOT ELIGIBLE FOR THE STUDY.

See Page 41

EXCLUSION CRITERIA

CRIT_2

	YES	NO
1. Previous treatment with mitoxantrone	❑	❑
2. Prior radiotherapy to ≥ 40% of bone marrow.	❑	❑
3. Prior surgery, radiation, chemotherapy, or other anti-cancer therapy within 4 weeks prior to enrollment in the study	❑	❑
4. Active secondary cancer including prior malignancy from which the patient has been disease-free for ≤ 5 years (However, adequately treated superficial basal cell skin cancer before 4 weeks prior to entry can be eligible to the study)	❑	❑
5. Known brain or leptomeningeal involvement	❑	❑
6. History of severe hypersensitivity reaction (≥ grade 3) to polysorbate 80 containing drugs	❑	❑
7. History of severe hypersensitivity reaction (≥ grade 3) or intolerance to prednisone	❑	❑
8. Other concurrent serious illness or medical conditions	❑	❑
9. Inadequate organ function as evidenced by the following peripheral blood counts, and serum chemistries at enrollment: · Neutrophils ≤ 1.5 x 10^9/L · Hemoglobin ≤ 10 g/dL · Platelets ≤ 100 x 10^9/L · Total bilirubin ≥ Upper limit of normal (ULN) · AST (SGOT) ≥ 1.5 x ULN · ALT (SGPT) ≥ 1.5 x ULN · Creatinine ≥ 1.5 x ULN	❑	❑
10. Uncontrolled cardiac arrhythmias, angina pectoris, and/or hypertension. History of congestive heart failure, or myocardial infarction within last 6 months is also not allowed	❑	❑
11. Left ventricular ejection fraction (LVEF) 50% by multi-gated radionuclide angiography (MUGA) scan or echocardiogram.	❑	❑
12. Uncontrolled diabetes mellitus	❑	❑
13. Active uncontrolled Gastroesophageal Reflux Disease (GERD)	❑	❑
14. Active infection requiring systemic antibiotic or anti-fungal medication	❑	❑
15. Participation in another clinical trial with any investigational drug within 30 days prior to study enrollment	❑	❑
16. Concurrent or planned treatment with strong inhibitors of cytochrome P450 3A4/5 (A one-week washout period is necessary for patients who are already on these treatments).	❑	❑

IF THE ANSWER TO ANY OF THE EXCLUSION CRITERIA IS YES, THE SUBJECT IS NOT ELIGIBLE FOR THE STUDY.

END OF STUDY

O.ENDST_1

Date of end of study*: ☐☐ ☐☐☐ ☐☐☐☐
day month year

Main reason for stopping trial (tick one box only):

- ☐ Completed follow-up period
- ☐ Death**
- ☐ Poor compliance to protocol
- ☐ Subject request, *specify* : _____
- ☐ Subject lost to follow-up
- ☐ Other reason, *specify* : _____

_____

**** Date of last contact in case of patient lost to follow-up***

***** In case of Death, complete the Death form.***

"I, the undersigned, certify that I have carefully examined all entries on the CRF for this subject. To the best of my knowledge, all information is correct."

Investigator signature: _____ Date: ☐☐ ☐☐☐ ☐☐☐☐
day month year

See Page 62

ADVERSE EVENT FORM

O.1_AE_1

☐ NONE

1. ADVERSE EVENT DIAGNOSIS	AE form no: ␣␣-␣␣ AE ref. no: ␣␣-␣␣	AE form no: ␣␣-␣␣ AE ref. no: ␣␣-␣␣
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ☐ Date of start: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐	1 ☐ Date of start: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐
3. GRADE (1 - 4)	1 ☐ 2 ☐ 3 ☐ 4 ☐	1 ☐ 2 ☐ 3 ☐ 4 ☐
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ☐ No ☐	Yes ☐ No ☐
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
6. CORRECTIVE TREATMENT/THERAPY	Yes ☐ No ☐	Yes ☐ No ☐
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ☐ / 4 ☐ Date: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) 6 ☐	1 ☐ / 4 ☐ Date: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) 6 ☐
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ☐ No ☐ ➲ IF YES - Date event became serious: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐	Yes ☐ No ☐ ➲ IF YES - Date event became serious: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐
Investigator's name, date of report and signature:		Monitoring representative's name, date of receipt:

** Is there a reasonable possibility that the AE was caused by study treatment?*

See Page 62

ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: ␣␣-␣␣ AE ref. no: ␣␣-␣␣	AE form no: ␣␣-␣␣ AE ref. no: ␣␣-␣␣
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) 6 ❑	1 ❑ / 4 ❑ Date: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES - Date event became serious: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES - Date event became serious: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:		Monitoring representative's name, date of receipt:

** Is there a reasonable possibility that the AE was caused by study treatment?*

NOT SUBMITTED

SAE COMPLEMENTARY FORM 1/2 *O.SAEC_1*

AE FORM NO.: ⌊_⌋⌊_⌋-⌊_⌋⌊_⌋

1. DEMOGRAPHIC INFORMATION

Date of birth: ⌊_⌋⌊_⌋ (day) ⌊_⌋⌊_⌋⌊_⌋ (month) ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ (year)

or Age: ⌊_⌋⌊_⌋

Sex: male ☑ female ☐

Race:
Caucasian ☐ Black ☐
Asian, Oriental ☐ Other ☐
*If other, specify:*_____

Height: ⌊_⌋⌊_⌋⌊_⌋ cm Weight: ⌊_⌋⌊_⌋⌊_⌋ . ⌊_⌋ kg

2. DETAILED DESCRIPTION OF THE SERIOUS ADVERSE EVENT
(including complementary investigations)

3. DATE OF START OF EVENT: ⌊_⌋⌊_⌋ (day) ⌊_⌋⌊_⌋⌊_⌋ (month) ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ (year)

4. STUDY TREATMENT

First administration of study treatment: ⌊_⌋⌊_⌋ (day) ⌊_⌋⌊_⌋⌊_⌋ (month) ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ (year)

	Last Administration Before SAE (day / month / year)	Last dosage Before SAE	Action taken*	New Dosage (dose reduced)
XRP6258	⌊_⌋⌊_⌋ / ⌊_⌋⌊_⌋⌊_⌋ / ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mg/m²/cycle	⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mg/m²/cycle
Mitoxantrone	⌊_⌋⌊_⌋ / ⌊_⌋⌊_⌋⌊_⌋ / ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mg/m²/cycle	⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mg/m²/cycle
Prednisone	⌊_⌋⌊_⌋ / ⌊_⌋⌊_⌋⌊_⌋ / ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mg	⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mg

* 0 = None 1 = Permanently discontinued 2 = Delayed 3 = Dose reduced 4 = Delayed/reduced 5 = Interrupted

5. IN CASE OF HOSPITALIZATION hospital report to be sent

Date of admission: ⌊_⌋⌊_⌋ (day) ⌊_⌋⌊_⌋⌊_⌋ (month) ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ (year)

6. IN CASE OF DEATH Autopsy report: Yes ☐ *(copy to be sent)* No ☐

NOT SUBMITTED

SAE COMPLEMENTARY FORM 2/2 *O.SAEC_1.1*

7. CORRECTIVE TREATMENT/THERAPY

(Relevant CRF page can be faxed)

8. PREVIOUS AND CONCOMITANT MEDICATIONS:

(Relevant CRF page can be faxed)

9. RELEVANT MEDICAL HISTORY AND CONCOMITANT DISEASES:

(Relevant CRF page can be faxed)

10. STATUS OF THE DISEASE

Is this SAE related to progression of the cancer? Yes ❑ No ❑ Unknown ❑

If Yes: Local ❑ Lymph nodes ❑ Peritoneum ❑ Brain ❑

Liver ❑ Bone ❑ Lung ❑

Other ❑ _____

NOT SUBMITTED

SAE FOLLOW-UP FORM *O.SAEF_1*

PROVIDE THE SPONSOR BY FAX WITH ALL ADDITIONAL INFORMATION INCLUDING AE FORM IF UPDATED

AE FORM NO.: |_|_|-|_|_|

1. SERIOUS ADVERSE EVENT (diagnosis):

2. DATE OF THE EVALUATION: |_|_| |_|_|_| |_|_|_|_| (day / month / year)

3. NEW RELEVANT INFORMATION ADDED TO INITIAL REPORT(S):

Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:

EFC6193 STUDY

CASE REPORT FORM

A RANDOMIZED, OPEN LABEL MULTI-CENTER STUDY OF XRP6258 AT 25 MG/M^2 IN COMBINATION WITH PREDNISONE EVERY 3 WEEKS COMPARED TO MITOXANTRONE IN COMBINATION WITH PREDNISONE FOR THE TREATMENT OF HORMONE REFRACTORY METASTATIC PROSTATE CANCER PREVIOUSLY TREATED WITH A TAXOTERE®-CONTAINING REGIMEN

COUNTRY NUMBER: ⌊__⌋⌊__⌋⌊__⌋ CENTRE NUMBER: ⌊__⌋⌊__⌋⌊__⌋

SUBJECT NUMBER: ⌊__⌋⌊__⌋⌊__⌋ SUBJECT INITIALS: ⌊__⌋⌊__⌋⌊__⌋

Dataset=DM
Dataset=DS
Dataset=SC
Dataset=SV

DEMOGRAPHY

DEMOG_1

- Date of consent: <DSSTDTC> ☐☐ ☐☐☐ **20**☐☐ <SCDTC>
  day month year
- Date of birth: <BRTHDTC> ☐☐ ☐☐☐ **19**☐☐
  day month year
- Sex: <SEX>
  Male ☑
- Race: <RACE>
  Caucasian ❑
  Black ❑
  Asian, Oriental ❑
  Other ❑ *If Other, specify:* <SCORRES>_____

CANCER DIAGNOSIS

O.MALIGN_1

Date of initial diagnosis: ☐☐ ☐☐☐ ☐☐☐☐ <CDORRES WHERE CDTESTCD=DIAGDATE>
day month year

PRIMARY SITE (TICK ONLY ONE)

☑ 18 Prostate <CDCAT>

INITIAL PATHOLOGY CELL TYPE

☑ Adenocarcinoma <CDORRES WHERE CDTESTCD=HISTTYPE>

EXTENT AT STUDY ENTRY <CDORRES WHERE CDTESTCD=EXTENT>

❑ Metastatic ❑ Advanced/Loco regional recurrence

GRADE <CDORRES WHERE CDTESTCD=HISTGRAD>

❑ Unknown ❑ Poorly differentiated

❑ Moderately differentiated ❑ Well differentiated ❑ Other

STAGING AT DIAGNOSIS	STAGE AT DIAGNOSIS
<CDORRES WHERE CDTESTCD=T> T ☐☐	<CDORRES WHERE CDTESTCD=STAGE> ❑ Stage I ☐
<CDORRES WHERE CDTESTCD=N> N ☐☐	❑ Stage II ☐
<CDORRES WHERE CDTESTCD=M> M ☐☐	❑ Stage III ☐
	❑ Stage IV ☐

PRIOR ANTI-CANCER SURGERIES EXCLUDING BIOPSY *O.SURGERY_1*

☐ NONE

	DATE Day Month Year	DESCRIBE PROCEDURE
<MHSPID>		
1	<MHSTDTC> ␣␣ ␣␣␣ ␣␣␣␣	<MHTERM>
2	␣␣ ␣␣␣ ␣␣␣␣	
3	␣␣ ␣␣␣ ␣␣␣␣	
4	␣␣ ␣␣␣ ␣␣␣␣	
5	␣␣ ␣␣␣ ␣␣␣␣	
6	␣␣ ␣␣␣ ␣␣␣␣	
7	␣␣ ␣␣␣ ␣␣␣␣	
8	␣␣ ␣␣␣ ␣␣␣␣	
9	␣␣ ␣␣␣ ␣␣␣␣	
10	␣␣ ␣␣␣ ␣␣␣␣	

1	**INTENT:** 1 - Neoadjuvant 2 - Adjuvant 3 - Advanced
2	**REASON FOR DISCONTINUATION:** 5 - Adverse Event 8 - Subject lost to follow-up 10 - Subject Request 12 - Disease Progression 14 - Completed Treatment 99 - Other
3	**BEST RESPONSE:** CR - Complete Response PR - Partial Response PD - Progressive Disease SD - Stable Disease UNK - Unknown NA - Not Applicable NE - Not Evaluable

Dataset=CM
Dataset=SUPPCM

PRIOR ANTI-CANCER THERAPY *O.MED_3*

☐ NONE

Intent:[1] ⌊__⌋ <CMINDC>

<SUPPCM.QNAM=CMRSON>

Reason for Discontinuation:[2] ⌊__⌋⌊__⌋

If other, *specify:* <SUPPCM.QNAM=CMENDRCM>

<SUPPCM.QNAM=CMPRGDTC>

Relapse / Progression Date: ⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋⌊__⌋
day month year

<SUPPCM.QNAM=CMRLTL>

Best Response:[3] ⌊__⌋⌊__⌋⌊__⌋

<CMDOSRGM>

<SUPPCM.QNAM=ENDTCOL>

REGIMEN NO.	DRUG PER REGIMEN <CMTRT>	CUMULATIVE DOSE <CMDOSE>	UNIT <CMDOSU>	START DATE DAY MONTH YEAR <CMSTDTC>	END DATE DAY MONTH YEAR <CMENDTC>
1.	1			⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋⌊__⌋	⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋⌊__⌋
	2			⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋⌊__⌋	⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋⌊__⌋
	3			⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋⌊__⌋	⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋⌊__⌋
	4			⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋⌊__⌋	⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋⌊__⌋
	5			⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋⌊__⌋	⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋⌊__⌋

PRIOR ANTI-CANCER THERAPY *O.MED_3*

Intent:[1] ⌊__⌋

Reason for Discontinuation:[2] ⌊__⌋⌊__⌋

If other, *specify:* _____

Relapse / Progression Date: ⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋⌊__⌋
day month year

Best Response:[3] ⌊__⌋⌊__⌋⌊__⌋

Regimen No.	Drug per Regimen	Cumulative Dose	Unit	Start Date DAY MONTH YEAR	End Date DAY MONTH YEAR
2.	1			⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋⌊__⌋	⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋⌊__⌋
	2			⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋⌊__⌋	⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋⌊__⌋
	3			⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋⌊__⌋	⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋⌊__⌋
	4			⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋⌊__⌋	⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋⌊__⌋
	5			⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋⌊__⌋	⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋⌊__⌋

See Page 16

PRIOR ANTI-CANCER THERAPY

O.MED_3

Intent:[1] ⌊__⌋

Reason for Discontinuation:[2] ⌊__⌋⌊__⌋

If other, *specify:* _____

Relapse / Progression Date: ⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋⌊__⌋
day month year

Best Response:[3] ⌊__⌋⌊__⌋⌊__⌋

Regimen No.	Drug per Regimen	Cumulative Dose	Unit	Start Date DAY MONTH YEAR	End Date DAY MONTH YEAR
3.	1			⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋⌊__⌋	⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋⌊__⌋
	2			⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋⌊__⌋	⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋⌊__⌋
	3			⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋⌊__⌋	⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋⌊__⌋
	4			⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋⌊__⌋	⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋⌊__⌋
	5			⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋⌊__⌋	⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋⌊__⌋

See Page 16

PRIOR ANTI-CANCER THERAPY

O.MED_3

Intent:[1] ⌊__⌋

Reason for Discontinuation:[2] ⌊__⌋⌊__⌋

If other, *specify:* _____

Relapse / Progression Date: ⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋⌊__⌋
day month year

Best Response:[3] ⌊__⌋⌊__⌋⌊__⌋

Regimen No.	Drug per Regimen	Cumulative Dose	Unit	Start Date DAY MONTH YEAR	End Date DAY MONTH YEAR
3.	1			⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋⌊__⌋	⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋⌊__⌋
	2			⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋⌊__⌋	⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋⌊__⌋
	3			⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋⌊__⌋	⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋⌊__⌋
	4			⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋⌊__⌋	⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋⌊__⌋
	5			⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋⌊__⌋	⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋⌊__⌋

PRIOR RADIATION THERAPY

O.RADTX_8

☐ NONE

<CMDOSE> <CMINDC>

	START DATE Day Month Year	STOP DATE Day Month Year	TOTAL DOSE	UNITS <CMDOSU>	LOCATION/ORGANS* <SUPPCM.QNAM = CMLOC>	TYPE OF THERAPY
1.	<CMSTDTC> ☐☐ ☐☐☐ ☐☐☐☐	<CMENDTC> ☐☐ ☐☐☐ ☐☐☐☐		☐ Grays ☐ Rads	☐☐.☐☐	☐ Palliative ☐ Curative
2.	☐☐ ☐☐☐ ☐☐☐☐	<SUPPCM.QNAM = ENDTCOL> ☐☐ ☐☐☐ ☐☐☐☐		☐ Grays ☐ Rads	☐☐.☐☐	☐ Palliative ☐ Curative
3.	☐☐ ☐☐☐ ☐☐☐☐	☐☐ ☐☐☐ ☐☐☐☐		☐ Grays ☐ Rads	☐☐.☐☐	☐ Palliative ☐ Curative
4.	☐☐ ☐☐☐ ☐☐☐☐	☐☐ ☐☐☐ ☐☐☐☐		☐ Grays ☐ Rads	☐☐.☐☐	☐ Palliative ☐ Curative
5.	☐☐ ☐☐☐ ☐☐☐☐	☐☐ ☐☐☐ ☐☐☐☐		☐ Grays ☐ Rads	☐☐.☐☐	☐ Palliative ☐ Curative
6.	☐☐ ☐☐☐ ☐☐☐☐	☐☐ ☐☐☐ ☐☐☐☐		☐ Grays ☐ Rads	☐☐.☐☐	☐ Palliative ☐ Curative

* Indicate location/organs of radiotherapy. Record numeric code (1 - 30 from below):

01 Skin	10 Lungs	18 Prostate	26 Pelvis
02 Muscle/Soft Tissue	11.01 Regional Lymph Nodes	19 Cervix	27 Peritoneum
03 Bone	11.02 Distant Lymph Nodes	20.10 Colon	28 Testis
04 Bone Marrow	12 Liver	20.20 Rectum	29 Thorax
05 Peripheral Blood Stream	13 Stomach	21 Adrenal	29.01 Pleura
06 Brain/CNS	14 Pancreas	22 Mediastinum	30 Other
07 Head/Neck	15 Kidneys	23 Uterus	
08 Esophagus	16 Ovaries	24 Abdomen	
09 Breast	17 Bladder	25 Gastrointestinal Tract	

Dataset=MH
Dataset=SUPPMH

PAST MEDICAL AND/OR SURGICAL HISTORY *MEDHIS_1*

- Please record relevant past medical or surgical history other than the disease studied. None ❑

	Date of diagnosis and/or intervention (month / year)	Past medical or surgical history	Persistence of symptoms (tick ✓) <SUPPMH.QNAM=MHPERSIS>			
<MHSPID>	<MHSTDTC>	<MHTERM>	Yes	No	Not applicable*	Disease Controlled
1	␣␣/␣␣␣␣		❑	❑	❑	❑
2	␣␣/␣␣␣␣		❑	❑	❑	❑
3	␣␣/␣␣␣␣		❑	❑	❑	❑
4	␣␣/␣␣␣␣		❑	❑	❑	❑
5	␣␣/␣␣␣␣		❑	❑	❑	❑
6	␣␣/␣␣␣␣		❑	❑	❑	❑
7	␣␣/␣␣␣␣		❑	❑	❑	❑
8	␣␣/␣␣␣␣		❑	❑	❑	❑
9	␣␣/␣␣␣␣		❑	❑	❑	❑
10	␣␣/␣␣␣␣		❑	❑	❑	❑
11	␣␣/␣␣␣␣		❑	❑	❑	❑
12	␣␣/␣␣␣␣		❑	❑	❑	❑
13	␣␣/␣␣␣␣		❑	❑	❑	❑
14	␣␣/␣␣␣␣		❑	❑	❑	❑
15	␣␣/␣␣␣␣		❑	❑	❑	❑

* In case of surgical history, the "Not Applicable" box for "Persistence of symptoms" must be ticked.

"yes" means: *symptoms persist, and disease is not controlled*
"no" means: *symptoms do not persist*
"not applicable": *use in case of surgical history*
"disease controlled" means: *condition still persists, but is controlled (by medication for example)*

See Page 21

PAST MEDICAL AND/OR SURGICAL HISTORY *MEDHIS_1*

- Please record relevant past medical or surgical history other than the disease studied. None ❑

	DATE OF DIAGNOSIS AND/OR INTERVENTION month year	PAST MEDICAL OR SURGICAL HISTORY	PERSISTENCE OF SYMPTOMS (tick ✓) YES	NO	NOT APPLICABLE*	DISEASE CONTROLLED
1	❑❑❑ ❑❑❑❑		❑	❑	❑	❑
2	❑❑❑ ❑❑❑❑		❑	❑	❑	❑
3	❑❑❑ ❑❑❑❑		❑	❑	❑	❑
4	❑❑❑ ❑❑❑❑		❑	❑	❑	❑
5	❑❑❑ ❑❑❑❑		❑	❑	❑	❑
6	❑❑❑ ❑❑❑❑		❑	❑	❑	❑
7	❑❑❑ ❑❑❑❑		❑	❑	❑	❑
8	❑❑❑ ❑❑❑❑		❑	❑	❑	❑
9	❑❑❑ ❑❑❑❑		❑	❑	❑	❑
10	❑❑❑ ❑❑❑❑		❑	❑	❑	❑
11	❑❑❑ ❑❑❑❑		❑	❑	❑	❑
12	❑❑❑ ❑❑❑❑		❑	❑	❑	❑
13	❑❑❑ ❑❑❑❑		❑	❑	❑	❑
14	❑❑❑ ❑❑❑❑		❑	❑	❑	❑
15	❑❑❑ ❑❑❑❑		❑	❑	❑	❑

* In case of surgical history, the "Not Applicable" box for "Persistence of symptoms" must be ticked.

"yes" means: *symptoms persist, and disease is not controlled*
"no" means: *symptoms do not persist*
"not applicable": *use in case of surgical history*
"disease controlled" means: *condition still persists, but is controlled (by medication for example)*

See Page 21

PAST MEDICAL AND/OR SURGICAL HISTORY *MEDHIS_1*

• Please record relevant past medical or surgical history other than the disease studied. None ❑

	DATE OF DIAGNOSIS AND/OR INTERVENTION month year	PAST MEDICAL OR SURGICAL HISTORY	PERSISTENCE OF SYMPTOMS (tick ✓) YES	NO	NOT APPLICABLE*	DISEASE CONTROLLED
1	❑❑❑ ❑❑❑❑		❑	❑	❑	❑
2	❑❑❑ ❑❑❑❑		❑	❑	❑	❑
3	❑❑❑ ❑❑❑❑		❑	❑	❑	❑
4	❑❑❑ ❑❑❑❑		❑	❑	❑	❑
5	❑❑❑ ❑❑❑❑		❑	❑	❑	❑
6	❑❑❑ ❑❑❑❑		❑	❑	❑	❑
7	❑❑❑ ❑❑❑❑		❑	❑	❑	❑
8	❑❑❑ ❑❑❑❑		❑	❑	❑	❑
9	❑❑❑ ❑❑❑❑		❑	❑	❑	❑
10	❑❑❑ ❑❑❑❑		❑	❑	❑	❑
11	❑❑❑ ❑❑❑❑		❑	❑	❑	❑
12	❑❑❑ ❑❑❑❑		❑	❑	❑	❑
13	❑❑❑ ❑❑❑❑		❑	❑	❑	❑
14	❑❑❑ ❑❑❑❑		❑	❑	❑	❑
15	❑❑❑ ❑❑❑❑		❑	❑	❑	❑

* In case of surgical history, the "Not Applicable" box for "Persistence of symptoms" must be ticked.

"yes" means: *symptoms persist, and disease is not controlled*
"no" means: *symptoms do not persist*
"not applicable": *use in case of surgical history*
"disease controlled" means: *condition still persists, but is controlled (by medication for example)*

HEMATOLOGY

LABH_1

To be performed within 28 days prior to randomization.

Date of sampling: <LBDTC> ☐☐ ☐☐☐ ☐☐☐☐
day month year

TEST <LBTEST>	VALUE (MD if not done) <LBORRES>	UNIT <LBORRESU>	IF OTHER UNIT, SPECIFY <LBORRESU>
WBC		10^9/L	
RBC		10^6/mm^3	
Neutrophils		10^9/L	
Eosinophils		10^9/L	
Basophils		10^9/L	
Monocytes		10^9/L	
Lymphocytes		10^9/L	
Platelets		10^9/L	
Hemoglobin		g/dL	

BIOCHEMISTRY

LABB_1

To be performed within 28 days prior to randomization.

Date of sampling: <LBDTC> ☐☐ ☐☐☐ ☐☐☐☐ (day / month / year)

TEST <LBTEST>	<LBORRES> VALUE (MD if not done)	UNIT <LBORRESU>	<LBORRESU> IF OTHER UNIT, SPECIFY
Sodium		mmol/L	
Potassium		mmol/L	
SGOT (AST)		U/L	
SGPT (ALT)		U/L	
Alkaline phosphatase		U/L	
Total bilirubin		mg/dL	
BUN		mg/dL	
Creatinine		mg/dL	
Glucose		mg/dL	
Chloride		mmol/L	
Bicarbonate		mmol/L	

TESTOSTERONE

LABB_1

To be performed within 28 days prior to randomization.

Date of sampling: <LBDTC> ☐☐ ☐☐☐ ☐☐☐☐ (day / month / year)

TEST <LBTEST>	<LBORRES> VALUE (MD if not done)	UNIT <LBORRESU>	<LBORRESU> IF OTHER UNIT, SPECIFY
Testosterone		ng/dL	

PSA - 1

LABH_1

DATE OF SAMPLING day month year <LBDTC>	TEST <LBTEST>	VALUE (MD if not done)	UNIT <LBORRESU>	IF OTHER UNIT, SPECIFY
⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	PSA	<LBORRES>	ng/mL	<LBORRESU>

PSA - 2

LABH_1

The first rising PSA should be taken at least 7 days after the reference value.

See PSA-1 for annotation

DATE OF SAMPLING day month year	TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	PSA		ng/mL	

PSA - 3

LABH_1

The third confirmatory PSA measure must be obtained at least 7 days after the second measure.

See PSA-1 for annotation

DATE OF SAMPLING day month year	TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	PSA		ng/mL	

PSA - 4

LABH_1

The fourth confirmatory PSA should be taken within 4 weeks prior to randomization.

See PSA-1 for annotation

DATE OF SAMPLING day month year	TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	PSA		ng/mL	

PHYSICAL EXAMINATION

PHYSEXAM_1

- Date performed: <PEDTC> ☐☐ ☐☐☐ ☐☐☐☐ * (day / month / year)

* If clinically relevant, please report on the Signs and Symptoms and/or Medical History forms.

Dataset=VS

VITAL SIGNS

VITAL_1

Please record below the assessment performed the closest to first administration of study drug.

Date performed: <VSDTC> ☐☐ ☐☐☐ ☐☐☐☐ (day / month / year)

<VSTEST> <VSORRES> <VSORRESU>
Height : ☐☐☐ cm

<VSTEST> <VSORRES> <VSORRESU>
Weight: ☐☐☐ . ☐ kg

<VSTEST> <VSORRES> <VSORRESU> <VSTEST> <VSORRES> <VSORRESU>
- Blood pressure: Systolic ☐☐☐ mmHg / Diastolic ☐☐☐ mmHg

- Heart rate: ☐☐☐ beats/min

<VSTEST> <VSORRES> <VSORRESU>
- Temperature: ☐☐ . ☐ °C

<VSMETHOD>
(tick appropriate box): Oral ❑ Rectal ❑ Auricular ❑

ECOG Performance Status <VSTEST>

<VSORRES>

0	1	2	3	4
❑	❑	❑	❑	❑

Dataset=EG
Dataset=SUPPEG

ECG

ECG_1

To be performed within 28 days prior to the first study drug administration.

- Date performed: <EGDTC> ␣␣/␣␣/␣␣␣␣ (day / month / year)

- **ECG:** Normal ❑ Abnormal* ❑ <EGORRES>

If abnormal, specify: _____

<SUPPEG.QNAM=EGORRES2>

* If clinically relevant, please report on the Signs and Symptoms and/or Medical History forms.

ECHOCARDIOGRAPHY *ECHOCARD_1*

To be performed within 28 days prior to the first study drug administration.

<CXSTAT>
NOT DONE ❑

<CXDTC>
- Date performed: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
  day month year

<CXMETHOD> <CXORRES WHERE CXTESTCD=CARDEX>
- **2D-Echocardiography:** Normal ❑ Abnormal* ❑

<CXORRES WHERE CXTESTCD=LVEF>
- Left ventricular ejection fraction (LVEF) ⌊_⌋⌊_⌋ . ⌊_⌋ %

<CXORNRLO>
- Lower Limit Normal of LVEF ⌊_⌋⌊_⌋ . ⌊_⌋ %<CXORRESU>

* If clinically relevant, please report on the Signs and Symptoms and/or Medical History forms.

RADIONUCLIDE VENTRICULOGRAPHY *MUGA_1*

To be performed within 28 days prior to the first study drug administration.

<CXSTAT>
NOT DONE ❑

<CXDTC>
- Date performed: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
  day month year

<CXMETHOD> <CXORRES WHERE CXTESTCD=CARDEX>
- **Radionuclide Ventriculography:** Normal ❑ Abnormal* ❑

<CXORRES WHERE CXTESTCD=LVEF>
- Left ventricular ejection fraction (LVEF) ⌊_⌋⌊_⌋ . ⌊_⌋ %

<CXORNRLO>
- Lower Limit Normal of LVEF ⌊_⌋⌊_⌋ . ⌊_⌋ %<CXORRESU>

* If clinically relevant, please report on the Signs and Symptoms and/or Medical History forms.

*	**METHOD CODES:**		
	1 - CT Scan	3 - MRI	5 - Scintigraphy
	2 - Spiral CT	4 - PET	7 - Ultrasound
	8 - X-Ray	10 - Physical Exam	99 - Other
**	**LOCATION:**		
	1 - Abdominal	3 - Head	5 - Abdomen/Pelvis
	2 - Chest	4 - Pelvis	99 - Other

Dataset=PE
Dataset=SUPPPE

BASELINE TUMOR EVALUATION METHOD OF ASSESSMENT

O.ASSESS_1

METHOD* <PEMETHOD>	LOCATION** (sites)	DATE Day Month Year	NORMAL <PEORRES>	IF ABNORMAL, SPECIFY:
	<PETEST>	<PEDTC>	❑	❑ Tumor related <SUPPPE.QNAM=ASTUTK> ❑ Other: ______ <SUPPPE.QNAM=ASOTHTK>
			❑	❑ Tumor related ❑ Other: ______ <SUPPPE.QNAM=ASOTHCM>
			❑	❑ Tumor related ❑ Other: ______
			❑	❑ Tumor related ❑ Other: ______
			❑	❑ Tumor related ❑ Other: ______
			❑	❑ Tumor related ❑ Other: ______
			❑	❑ Tumor related ❑ Other: ______
<SUPPPE.QNAM=ASMETCM> 99 - Other Specify: ______			❑	❑ Tumor related ❑ Other: ______
99 - Other Specify: ______			❑	❑ Tumor related ❑ Other: ______
99 - Other Specify: ______			❑	❑ Tumor related ❑ Other: ______

***LOCATION:**

01	Skin	12	Liver	22	Mediastinum
02	Muscle/Soft Tissue	13	Stomach	23	Uterus
03	Bone	14	Pancreas	24	Abdomen
04	Bone Marrow	15	Kidneys	25	Gastrointestinal Tract
05	Peripheral Blood Stream	16	Ovaries	26	Pelvis
06	Brain/CNS	16.01	Fallopian Tubes	27	Peritoneum
07	Head/Neck	17	Bladder	28	Testis
08	Esophagus	18	Prostate	29	Thorax
09	Breast	19	Cervix	29.01	Pleura
10	Lungs	20.10	Colon	30	Other
11.01	Regional Lymph Nodes	20.20	Rectum		
11.02	Distant Lymph Nodes	21	Adrenal		

**** METHOD OF MEASUREMENT CODES:**

1 - CT Scan	3 - MRI	5 - Scintigraphy
2 - Spiral CT	4 - PET	7 - Ultrasound
8 - X-Ray	10 - Physical Exam	99 - Other

Dataset=LS
Dataset=SUPPLS

BASELINE TUMOR MEASUREMENTS

O.ASSESS_2

LESION NUMBER	LOCATION (site) * <LSLOC>	LESION DESCRIPTION (subsite) <SUPPLS.QNAM= LSSLOC>	DATE OF ASSESSMENT Day Month Year <LSDTC>	METHOD OF MEASUREMENT** <LSMETHOD>	MEASUREMENT OF TARGET LESION: longest diameter <LSORRES>	NON TARGET <LSCAT>
1	␣␣.␣␣		␣␣ ␣␣␣ ␣␣␣␣	␣␣	␣␣␣ mm	☐
2	␣␣.␣␣		␣␣ ␣␣␣ ␣␣␣␣	␣␣	␣␣␣ mm	☐
3	␣␣.␣␣		␣␣ ␣␣␣ ␣␣␣␣	␣␣	␣␣␣ mm	☐
4	␣␣.␣␣		␣␣ ␣␣␣ ␣␣␣␣	␣␣	␣␣␣ mm	☐
5	␣␣.␣␣		␣␣ ␣␣␣ ␣␣␣␣	␣␣	␣␣␣ mm	☐
6	␣␣.␣␣		␣␣ ␣␣␣ ␣␣␣␣	␣␣	␣␣␣ mm	☐
7	␣␣.␣␣		␣␣ ␣␣␣ ␣␣␣␣	␣␣	␣␣␣ mm	☐
8	␣␣.␣␣		␣␣ ␣␣␣ ␣␣␣␣	␣␣	␣␣␣ mm	☐
9	␣␣.␣␣		␣␣ ␣␣␣ ␣␣␣␣	␣␣	␣␣␣ mm	☐
10	␣␣.␣␣		␣␣ ␣␣␣ ␣␣␣␣	␣␣	␣␣␣ mm	☐
11	␣␣.␣␣		␣␣ ␣␣␣ ␣␣␣␣	␣␣	␣␣␣ mm	☐
12	␣␣.␣␣		␣␣ ␣␣␣ ␣␣␣␣	␣␣	␣␣␣ mm	☐
13	␣␣.␣␣		␣␣ ␣␣␣ ␣␣␣␣	␣␣	␣␣␣ mm	☐
14	␣␣.␣␣		␣␣ ␣␣␣ ␣␣␣␣	␣␣	␣␣␣ mm	☐

Dataset=AE
Dataset=SUPPAE

SIGNS AND SYMPTOMS PRESENT AT BASELINE *O.SYMPTOM_1*

None ❑

	Signs and Symptoms	Date of Onset Day Month Year	Grade (1 - 4)
1	<AETERM>	<AESTDTC> __/__/____	<SUPPAE.QNAM= AECOLGRN>
2		__/__/____	
3		__/__/____	
4		__/__/____	
5		__/__/____	
6		__/__/____	
7		__/__/____	
8		__/__/____	
9		__/__/____	
10		__/__/____	

SIGNS AND SYMPTOMS PRESENT AT BASELINE *O.SYMPTOM_1*

	SIGNS AND SYMPTOMS	DATE OF ONSET Day Month Year	GRADE (1 - 4)
1		⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	
2		⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	
3		⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	
4		⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	
5		⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	
6		⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	
7		⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	
8		⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	
9		⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	
10		⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	

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SIGNS AND SYMPTOMS PRESENT AT BASELINE *O.SYMPTOM_1*

	SIGNS AND SYMPTOMS	DATE OF ONSET Day Month Year	GRADE (1 - 4)
1		|__|__| |__|__|__| |__|__|__|__|	
2		|__|__| |__|__|__| |__|__|__|__|	
3		|__|__| |__|__|__| |__|__|__|__|	
4		|__|__| |__|__|__| |__|__|__|__|	
5		|__|__| |__|__|__| |__|__|__|__|	
6		|__|__| |__|__|__| |__|__|__|__|	
7		|__|__| |__|__|__| |__|__|__|__|	
8		|__|__| |__|__|__| |__|__|__|__|	
9		|__|__| |__|__|__| |__|__|__|__|	
10		|__|__| |__|__|__| |__|__|__|__|	

Dataset=CM
Dataset=SUPPCM

EXCLUDING PRIOR ANTI-CANCER THERAPIES.

PRIOR MEDICATION

O.MED_8

☐ NONE

Record any medications taken within 30 days prior to study treatment. Tick the "None" box if no medication(s) has been taken within 30 days prior to the first treatment. Any medications recorded as "Ongoing" must also be recorded on the Concomitant Medication page.

<SUPPCM.QNAM=ENDTCOL>

	MEDICATION	START DATE Day Month Year	END DATE Day Month Year	ONGOING
1.	<CMTRT>	<CMSTDTC>	<CMENDTC>	<SUPPCM.QNAM=CMONGO> ☐
2.		☐☐ ☐☐☐ ☐☐☐☐	☐☐ ☐☐☐ ☐☐☐☐	☐
3.		☐☐ ☐☐☐ ☐☐☐☐	☐☐ ☐☐☐ ☐☐☐☐	☐
4.		☐☐ ☐☐☐ ☐☐☐☐	☐☐ ☐☐☐ ☐☐☐☐	☐
5.		☐☐ ☐☐☐ ☐☐☐☐	☐☐ ☐☐☐ ☐☐☐☐	☐
6.		☐☐ ☐☐☐ ☐☐☐☐	☐☐ ☐☐☐ ☐☐☐☐	☐
7.		☐☐ ☐☐☐ ☐☐☐☐	☐☐ ☐☐☐ ☐☐☐☐	☐
8.		☐☐ ☐☐☐ ☐☐☐☐	☐☐ ☐☐☐ ☐☐☐☐	☐
9.		☐☐ ☐☐☐ ☐☐☐☐	☐☐ ☐☐☐ ☐☐☐☐	☐

See Page 37

EXCLUDING PRIOR ANTI-CANCER THERAPIES.

PRIOR MEDICATION

O.MED_8

❑ NONE

Record any medications taken within 30 days prior to study treatment. Tick the "None" box if no medication(s) has been taken within 30 days prior to the first treatment. Any medications recorded as "Ongoing" must also be recorded on the Concomitant Medication page.

	MEDICATION	START DATE Day Month Year	END DATE Day Month Year	ONGOING
1.		⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	❑
2.		⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	❑
3.		⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	❑
4.		⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	❑
5.		⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	❑
6.		⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	❑
7.		⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	❑
8.		⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	❑
9.		⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	❑

<IETEST> <SUPPIE.QNAM=IETEST1>

INCLUSION CRITERIA

CRIT_1

The Patient must have: YES NO

<IETESTCD>

1. Diagnosis of histologically or cytologically proven prostate adenocarcinoma, that is refractory to hormone therapy and previously treated with a Taxotere®-containing regimen. Patient must have documented progression of disease during or within 6 months after prior hormone therapy and disease progression during or after Taxotere®-containing therapies . . . . . ❑ ❑
2. Patient must have either measurable or non-measurable disease . . . . . ❑ ❑

   · Patient with measurable disease must have documented progression of disease by RECIST criteria demonstrating at least one visceral or soft tissue metastatic lesion (including new lesion). This lesion must measure at least 10 mm in the longest diameter (or two times the slice thickness) on spiral CT scan or MRI (chest, abdomen, pelvis) or 20 mm on conventional CT or Chest X-ray for biopsy proven, clearly defined lung lesion surrounded by aerated lung. (Previously irradiated lesions, primary prostate lesion, and bone lesions will be considered non-measurable disease).

   · Patient with non-measurable disease must have documented rising PSA levels or appearance of new lesion. [Rising PSA is defined as at least two consecutive rises in PSA to be documented over a reference value (measure 1) taken at least one week apart. The first rising PSA (measure 2) should be taken at least 7 days after the reference value. A third confirmatory PSA measure is required (2nd beyond the reference level) to be greater than the second measure and it must be obtained at least 7 days after the 2nd measure. If this is not the case, a fourth PSA measure is required to be taken and be greater than the 2nd measure. The third (or the fourth) confirmatory PSA should be taken within 4 weeks prior to randomization]
3. Received prior castration by orchiectomy and/or Luteinizing Hormone-Releasing Hormone (LH-RH) agonist with or without antiandrogen, antiandrogen withdrawal, monotherapy with estramustine, or other hormonal agents. (A prior treatment by antiandrogen is not mandatory. However, if the patient has been treated with antiandrogens, **and** PSA is above 5 ng/mL at the last administration of antiandrogens, presence or absence of antiandrogen withdrawal syndrome* should be confirmed prior to the study entry). (LH-RH agonist treatment should continue during the study treatment period. Chlormadinone acetate or flutamide must have been stopped at least 4 weeks prior to, while bicalutamide must have been stopped at least 6 weeks prior to, the last PSA evaluation.) *(* The antiandrogen withdrawal syndrome is a decrease in PSA seen upon stopping an antiandrogen such as chlormadinone acetate, flutamide, or bicalutamide; this occurs because the antiandrogen has induced a mutation in the androgen receptor which is allowing the antiandrogen to stimulate prostate cancer growth rather than inhibit it)* . . . . . ❑ ❑
4. Life expectancy > 2 months . . . . . ❑ ❑
5. Eastern Cooperative Oncology Group (ECOG) performance status 0 - 2 . . . . . ❑ ❑
6. Age ≥ 18 years . . . . . ❑ ❑

IF THE ANSWER TO ANY OF THE INCLUSION CRITERIA IS NO, THE SUBJECT IS NOT ELIGIBLE FOR THE STUDY.

<IETEST> <SUPPIE.QNAM=IETEST1>

INCLUSION CRITERIA

CRIT_1

<IETESTCD> **The Patient must have:** | **YES** | **NO**

1a. Diagnosis of histologically or cytologically proven prostate adenocarcinoma, that is refractory to hormone therapy and previously treated with a Taxotere® (or docetaxel)-containing regimen. Patient must have documented progression of disease during or within 6 months after prior hormone therapy and disease progression during or after Taxotere® (or docetaxel)-containing regimen . . . . . ❑ ❑

2. Patient must have either measurable or non-measurable disease . . . . . ❑ ❑

· Patient with measurable disease must have documented progression of disease by RECIST criteria demonstrating at least one visceral or soft tissue metastatic lesion (including new lesion). This lesion must measure at least 10 mm in the longest diameter (or two times the slice thickness) on spiral CT scan or MRI (chest, abdomen, pelvis) or 20 mm on conventional CT or Chest X-ray for biopsy proven, clearly defined lung lesion surrounded by aerated lung. (Previously irradiated lesions, primary prostate lesion, and bone lesions will be considered non-measurable disease).

· Patient with non-measurable disease must have documented rising PSA levels or appearance of new lesion. [Rising PSA is defined as at least two consecutive rises in PSA to be documented over a reference value (measure 1) taken at least one week apart. The first rising PSA (measure 2) should be taken at least 7 days after the reference value. A third confirmatory PSA measure is required (2nd beyond the reference level) to be greater than the second measure and it must be obtained at least 7 days after the 2nd measure. If this is not the case, a fourth PSA measure is required to be taken and be greater than the 2nd measure. The third (or the fourth) confirmatory PSA should be taken within 4 weeks prior to randomization]

3. Received prior castration by orchiectomy and/or Luteinizing Hormone-Releasing Hormone (LH-RH) agonist with or without antiandrogen, antiandrogen withdrawal, monotherapy with estramustine, or other hormonal agents. (A prior treatment by antiandrogen is not mandatory. However, if the patient has been treated with antiandrogens, **and** PSA is above 5 ng/mL at the last administration of antiandrogens, presence or absence of antiandrogen withdrawal syndrome* should be confirmed prior to the study entry). (LH-RH agonist treatment should continue during the study treatment period. Chlormadinone acetate or flutamide must have been stopped at least 4 weeks prior to, while bicalutamide must have been stopped at least 6 weeks prior to, the last PSA evaluation.) *(* The antiandrogen withdrawal syndrome is a decrease in PSA seen upon stopping an antiandrogen such as chlormadinone acetate, flutamide, or bicalutamide; this occurs because the antiandrogen has induced a mutation in the androgen receptor which is allowing the antiandrogen to stimulate prostate cancer growth rather than inhibit it)* . . . . . ❑ ❑

4. Life expectancy > 2 months . . . . . ❑ ❑

5a. Eastern Cooperative Oncology Group (ECOG) performance status 0 - 2 (i.e., patients must be ambulatory, capable of all self-care, and up and about more than 50% of waking hours) . . . . ❑ ❑

6. Age ≥ 18 years . . . . . ❑ ❑

IF THE ANSWER TO ANY OF THE INCLUSION CRITERIA IS NO, THE SUBJECT IS NOT ELIGIBLE FOR THE STUDY.

<IETEST> <SUPPIE.QNAM=IETEST1>

EXCLUSION CRITERIA

CRIT_2

		YES	NO
<IETESTCD>	1. Previous treatment with mitoxantrone	❑	❑
	2. Prior radiotherapy to ≥ 40% of bone marrow.	❑	❑
	3. Prior surgery, radiation, chemotherapy, or other anti-cancer therapy within 4 weeks prior to enrollment in the study	❑	❑
	4. Active secondary cancer including prior malignancy from which the patient has been disease-free for ≤ 5 years (However, adequately treated superficial basal cell skin cancer before 4 weeks prior to entry can be eligible to the study)	❑	❑
	5. Known brain or leptomeningeal involvement	❑	❑
	6. History of severe hypersensitivity reaction (≥ grade 3) to polysorbate 80 containing drugs	❑	❑
	7. History of severe hypersensitivity reaction (≥ grade 3) or intolerance to prednisone	❑	❑
	8. Other concurrent serious illness or medical conditions	❑	❑
	9. Inadequate organ function as evidenced by the following peripheral blood counts, and serum chemistries at enrollment: · Neutrophils ≤ 1.5 x 10^9/L · Hemoglobin ≤ 10 g/dL · Platelets ≤ 100 x 10^9/L · Total bilirubin ≥ Upper limit of normal (ULN) · AST (SGOT) ≥ 1.5 x ULN · ALT (SGPT) ≥ 1.5 x ULN · Creatinine ≥ 1.5 x ULN	❑	❑
	10. Uncontrolled cardiac arrhythmias, angina pectoris, and/or hypertension. History of congestive heart failure, or myocardial infarction within last 6 months is also not allowed	❑	❑
	11. Left ventricular ejection fraction (LVEF) 50% by multi-gated radionuclide angiography (MUGA) scan or echocardiogram.	❑	❑
	12. Uncontrolled diabetes mellitus	❑	❑
	13. Active uncontrolled Gastroesophageal Reflux Disease (GERD)	❑	❑
	14. Active infection requiring systemic antibiotic or anti-fungal medication	❑	❑
	15. Participation in another clinical trial with any investigational drug within 30 days prior to study enrollment	❑	❑
	16. Concurrent or planned treatment with strong inhibitors of cytochrome P450 3A4/5 (A one-week washout period is necessary for patients who are already on these treatments).	❑	❑

IF THE ANSWER TO ANY OF THE EXCLUSION CRITERIA IS YES, THE SUBJECT IS NOT ELIGIBLE FOR THE STUDY.

<IETEST> <SUPPIE.QNAM=IETEST1>

EXCLUSION CRITERIA

CRIT_2

<IETESTCD>

		YES	NO
1a.	Previous treatment with mitoxantrone	❑	❑
2a.	Previous treatment with less than 3 cycles or <225 mg/m^2 cumulative dose of Taxotere® (or docetaxel)	❑	❑
3a.	Prior radiotherapy to ≥ 40% of bone marrow. Prior treatment with one dose of a bone-seeking radio-isotope (samarium-153, strontium-89, or P-32) is allowed, but 8 weeks must have elapsed after samarium-153 or P-32 and 12 weeks must have elapsed after strontium-89 prior to first study drug administration.	❑	❑
4a.	Prior surgery, radiation, chemotherapy, or other anti-cancer therapy within 4 weeks prior to enrollment in the study	❑	❑
5a.	Active grade ≥2 peripheral neuropathy.	❑	❑
6a.	Active grade ≥2 stomatitis.	❑	❑
7a.	Active secondary cancer including prior malignancy from which the patient has been disease-free for ≤ 5 years (However, adequately treated superficial basal cell skin cancer before 4 weeks prior to entry can be eligible to the study)	❑	❑
8a.	Known brain or leptomeningeal involvement	❑	❑
9a.	History of severe hypersensitivity reaction (≥ grade 3) to polysorbate 80 containing drugs	❑	❑
10a.	History of severe hypersensitivity reaction (≥ grade 3) or intolerance to prednisone	❑	❑
11a.	Other concurrent serious illness or medical conditions	❑	❑
12a.	Inadequate organ function as evidenced by the following peripheral blood counts, and serum chemistries at enrollment: · Neutrophils ≤ 1.5 x 10^9/L · Hemoglobin ≤ 10 g/dL · Platelets ≤ 100 x 10^9/L · Total bilirubin ≥ Upper limit of normal (ULN) · AST (SGOT) ≥ 1.5 x ULN · ALT (SGPT) ≥ 1.5 x ULN · Creatinine ≥ 1.5 x ULN	❑	❑
13a.	Uncontrolled cardiac arrhythmias, angina pectoris, and/or hypertension. History of congestive heart failure, or myocardial infarction within last 6 months is also not allowed	❑	❑
14a.	Left ventricular ejection fraction (LVEF) ≤50% by multi-gated radionuclide angiography (MUGA) scan or echocardiogram.	❑	❑
15a.	Uncontrolled diabetes mellitus	❑	❑
16a.	Active uncontrolled Gastroesophageal Reflux Disease (GERD)	❑	❑
17a.	Active infection requiring systemic antibiotic or anti-fungal medication	❑	❑
18a.	Participation in another clinical trial with any investigational drug within 30 days prior to study enrollment	❑	❑
19a.	Concurrent or planned treatment with strong inhibitors of cytochrome P450 3A4/5 (A one-week washout period is necessary for patients who are already on these treatments)	❑	❑
20a.	For patient enrolled in the United Kingdom, the following exclusion criterion must be applicable: Patient with reproductive potential not implementing accepted and effective method of contraception, described in Appendix I	❑	❑

IF THE ANSWER TO ANY OF THE EXCLUSION CRITERIA IS YES, THE SUBJECT IS NOT ELIGIBLE FOR THE STUDY.

PHYSICAL EXAMINATION

PHYSEXAM_2

NONE ❑ **NOT SUBMITTED**

To be done if the screening exam is more than 5 days from study drug administration

<PEDTC>

Date performed: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ (day / month / year)

<PEORRES>

- Were there any clinically significant changes from the previous evaluation? Yes* ❑ No ❑

**If yes, please complete the Signs and Symptoms form if performed prior the first dose. Otherwise, complete the Adverse Event form.*

See Page 27

VITAL SIGNS

VITAL_1

NOT DONE ❑

To be done if the screening exam is more than 5 days from study drug administration.

Weight: ⌊_⌋⌊_⌋⌊_⌋ . ⌊_⌋ kg

- Blood pressure: Systolic ⌊_⌋⌊_⌋⌊_⌋ mmHg / Diastolic ⌊_⌋⌊_⌋⌊_⌋ mmHg

- Heart rate: ⌊_⌋⌊_⌋⌊_⌋ beats/min

- Temperature: ⌊_⌋⌊_⌋ . ⌊_⌋ °C

(tick appropriate box): Oral ❑ Rectal ❑ Auricular ❑

ECOG Performance Status

0	1	2	3	4
❑	❑	❑	❑	❑

See Page 24

HEMATOLOGY

LABH_1

To be done if the screening exam is more than 5 days from study drug administration

Date of sampling: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
day month year

TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
WBC		10^9/L	
RBC		10^6/mm^3	
Neutrophils		10^9/L	
Eosinophils		10^9/L	
Basophils		10^9/L	
Monocytes		10^9/L	
Lymphocytes		10^9/L	
Platelets		10^9/L	
Hemoglobin		g/dL	

See Page 26

PSA

LABH_1

DATE OF SAMPLING (day month year)	TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	PSA		ng/mL	

See Page 25

BIOCHEMISTRY

LABB_1

To be done if the screening exam is more than 5 days from study drug administration

Date of sampling: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
day month year

TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
Sodium		mmol/L	
Potassium		mmol/L	
SGOT (AST)		U/L	
SGPT (ALT)		U/L	
Alkaline phosphatase		U/L	
Total bilirubin		mg/dL	
BUN		mg/dL	
Creatinine		mg/dL	
Glucose		mg/dL	
Chloride		mmol/L	
Bicarbonate		mmol/L	

See Page 24

HEMATOLOGY

LABH_1

Date of sampling: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
day month year

TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
WBC		10^9/L	
RBC		10^6/mm^3	
Neutrophils		10^9/L	
Eosinophils		10^9/L	
Basophils		10^9/L	
Monocytes		10^9/L	
Lymphocytes		10^9/L	
Platelets		10^9/L	
Hemoglobin		g/dL	

See Page 24

HEMATOLOGY

LABH_1

Date of sampling: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
day month year

TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
WBC		10^9/L	
RBC		10^6/mm^3	
Neutrophils		10^9/L	
Eosinophils		10^9/L	
Basophils		10^9/L	
Monocytes		10^9/L	
Lymphocytes		10^9/L	
Platelets		10^9/L	
Hemoglobin		g/dL	

SPECIFIC CONCOMITANT MEDICATION SPMED_1

None ❑

- Please record all premedication administered prior to study drug XRP6258 or Mitoxantrone infusion or tick "None".

	MEDICATION	DOSAGE Number of Units	DOSAGE Unit	START DATE day month year	END DATE day month year
1	<CMTRT>	<CMDOSE>	<CMDOSU>	<CMSTDTC>	<CMENDTC>
2					<SUPPCM.QNAM= ENDTCOL>
3					
4					
5					
6					
7					
8					
9					
10					

INVESTIGATIONAL PRODUCT ADMINISTRATION ADMIN_1

TREATMENT NAME <EXTRT>	DATE AND TIME OF DOSING day month year 24-hour clock	INTENDED DOSE (mg/m2)	ACTUAL DOSE GIVEN (mg)
❑ XRP6258 ❑ Mitoxantrone	Start <EXSTDTC> ⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋ : ⌊__⌋⌊__⌋ End <EXENDTC> ⌊__⌋⌊__⌋ : ⌊__⌋⌊__⌋ <SUPPEX.QNAM=ENDTCOL>	<SUPPEX.QNAM=EXPDOSE>	<EXDOSE>

IF DOSE DELAYED AND/OR REDUCED AND/OR INTERRUPTED, SPECIFY REASON:

<SUPPEX.QNAM=ENDSREA>
❑ AE: Specify on AE form
<SUPPEX.QNAM=ENDSRCM>
❑ Other: _____

Dose change: interruption only at Cycle 1(delay and/or reduction are not applicable).*

*IF DOSE INTERRUPTED:

TREATMENT NAME <EXTRT>	DATE AND TIME OF DOSING day month year 24-hour clock	INTENDED DOSE (mg/m2)	ACTUAL DOSE GIVEN (mg)
❑ XRP6258 ❑ Mitoxantrone	Start <EXSTDTC> ⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋ : ⌊__⌋⌊__⌋ End <EXENDTC> ⌊__⌋⌊__⌋ : ⌊__⌋⌊__⌋	<SUPPEX.QNAM=EXPDOSE> NA	<EXDOSE>

See Page 49

INVESTIGATIONAL PRODUCT ADMINISTRATION *ADMIN_1*

TREATMENT NAME	DATE OF DOSING (day month year)	INTENDED DOSE (mg)	ACTUAL DOSE GIVEN (mg)
❑ Prednisone ❑ Prednisolone	Start ⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋⌊__⌋ End ⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋⌊__⌋		

IF DOSE DELAYED AND/OR REDUCED AND/OR INTERRUPTED, SPECIFY REASON:

❑ AE: Specify on AE form

❑ Other: _____

Dose change: interruption only at Cycle 1(delay and/or reduction are not applicable).*

*IF DOSE INTERRUPTED:

TREATMENT NAME	DATE OF DOSING (day month year)	INTENDED DOSE (mg)	ACTUAL DOSE GIVEN (mg)
❑ Prednisone ❑ Prednisolone	Start ⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋⌊__⌋ End ⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋⌊__⌋	NA	

BATCH NUMBERS

O.BATCH_1

	DRUG NAME	BATCH NUMBER
1	<EXTRT>	<EXLOT>
2		
3		
4		
5		

See Page 29

ECHOCARDIOGRAPHY

ECHOCARD_1

NOT DONE ❑

- Date performed: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
  day month year

- **2D-Echocardiography:** Normal ❑ Abnormal* ❑

- Left ventricular ejection fraction (LVEF) ⌊_⌋⌊_⌋ . ⌊_⌋ %

- Lower Limit Normal of LVEF ⌊_⌋⌊_⌋ . ⌊_⌋ %

* ***If clinically relevant, please report on the Signs and Symptoms form if performed prior first dose. Otherwise complete the Adverse Event form.***

RADIONUCLIDE VENTRICULOGRAPHY

MUGA_1

NOT DONE ❑

- Date performed: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
  day month year

- **Radionuclide Ventriculographyy:** Normal ❑ Abnormal* ❑

- Left ventricular ejection fraction (LVEF) ⌊_⌋⌊_⌋ . ⌊_⌋ %

- Lower Limit Normal of LVEF ⌊_⌋⌊_⌋ . ⌊_⌋ %

* ***If clinically relevant, please report on the Signs and Symptoms form if performed prior first dose. Otherwise complete the Adverse Event form.***

PAIN INTENSITY ASSESSMENT

PAINVAS1

Date corresponds to current cycle (7 days prior to dosing Day 1)

Date (Day Month Year)	PPI	Analgesic Score
1. <PNDTC> ␣␣ ␣␣␣ ␣␣␣␣	<PNORRES> ␣	<PNORRES> ␣␣␣.␣␣
2. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣.␣␣
3. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣.␣␣
4. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣.␣␣
5. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣.␣␣
6. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣.␣␣
7. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣.␣␣

*** Location:**

01	Skin	12	Liver	22	Mediastinum
02	Muscle/Soft Tissue	13	Stomach	23	Uterus
03	Bone	14	Pancreas	24	Abdomen
04	Bone Marrow	15	Kidneys	25	Gastrointestinal Tract
05	Peripheral Blood Stream	16	Ovaries	26	Pelvis
06	Brain/CNS	16.01	Fallopian Tubes	27	Peritoneum
07	Head/Neck	17	Bladder	28	Testis
08	Esophagus	18	Prostate	29	Thorax
09	Breast	19	Cervix	29.01	Pleura
10	Lungs	20.10	Colon	30	Other
11.01	Regional Lymph Nodes	20.20	Rectum		
11.02	Distant Lymph Nodes	21	Adrenal		

**** Method of Measurement Codes:**

1 - CT Scan	3 - MRI	5 - Scintigraphy
2 - Spiral CT	4 - PET	7 - Ultrasound
8 - X-Ray	10 - Physical Exam	99 - Other

*****Response of Non-Target Codes:**

CR - Complete Response	IR/SD - Incomplete Response/Stable Disease	PD - Progressive Disease
NL - New Lesion	NE - Not Evaluable	

TUMOR MEASUREMENTS

O.ASSESS_3

☐ NOT DONE

LESION NUMBER	LOCATION SITE* <LSLOC>	DATE OF ASSESSMENT Day Month Year <LSDTC>	METHOD OF MEASUREMENT** <LSMETHOD>	MEASUREMENT OF TARGET LESION: longest diameter	RESPONSE OF NON-TARGET LESIONS***
1	__.__	__ __ __ __ __ __ __ __ ☐ Not Done <LSSTAT>	__ __	<LSORRES> ___ mm	<LSORRES> __ __
2	__.__	__ __ __ __ __ __ __ __ ☐ Not Done	__ __	___ mm	__ __
3	__.__	__ __ __ __ __ __ __ __ ☐ Not Done	__ __	___ mm	__ __
4	__.__	__ __ __ __ __ __ __ __ ☐ Not Done	__ __	___ mm	__ __
5	__.__	__ __ __ __ __ __ __ __ ☐ Not Done	__ __	___ mm	__ __
6	__.__	__ __ __ __ __ __ __ __ ☐ Not Done	__ __	___ mm	__ __
7	__.__	__ __ __ __ __ __ __ __ ☐ Not Done	__ __	___ mm	__ __
8	__.__	__ __ __ __ __ __ __ __ ☐ Not Done	__ __	___ mm	__ __
9	__.__	__ __ __ __ __ __ __ __ ☐ Not Done	__ __	___ mm	__ __
10	__.__	__ __ __ __ __ __ __ __ ☐ Not Done	__ __	___ mm	__ __
11	__.__	__ __ __ __ __ __ __ __ ☐ Not Done	__ __	___ mm	__ __
12	__.__	__ __ __ __ __ __ __ __ ☐ Not Done	__ __	___ mm	__ __
13	__.__	__ __ __ __ __ __ __ __ ☐ Not Done	__ __	___ mm	__ __
14	__.__	__ __ __ __ __ __ __ __ ☐ Not Done	__ __	___ mm	__ __

NOT SUBMITTED

PHARMACOKINETIC - BLOOD SAMPLING (SCHEDULE 1) *PK_1*

❑ NOT APPLICABLE

SAMPLE ID	THEORETICAL TIME	SAMPLE DATE day month year	SAMPLE TIME 24 hour clock
P00	Prior to Infusion of XRP6528	__ __ __ __ __ __ __ __	__ __ : __ __
P01	30 minutes before end of infusion	__ __ __ __ __ __ __ __	__ __ : __ __
P02	5 minutes post end of Infusion	__ __ __ __ __ __ __ __	__ __ : __ __
P03	1 hour post end of infusion	__ __ __ __ __ __ __ __	__ __ : __ __
P04	6-10 hours post end of infusion	__ __ __ __ __ __ __ __	__ __ : __ __
P05	24-72 hours post end of infusion	__ __ __ __ __ __ __ __	__ __ : __ __

PHARMACOKINETIC - BLOOD SAMPLING (SCHEDULE 2) *PK_1*

❑ NOT APPLICABLE

SAMPLE ID	THEORETICAL TIME	SAMPLE DATE day month year	SAMPLE TIME 24 hour clock
P00	Prior to Infusion of XRP6528	__ __ __ __ __ __ __ __	__ __ : __ __
P01	10 minutes before end of infusion	__ __ __ __ __ __ __ __	__ __ : __ __
P02	10 minutes post end of Infusion	__ __ __ __ __ __ __ __	__ __ : __ __
P03	2 hours post end of infusion	__ __ __ __ __ __ __ __	__ __ : __ __
P04	8-12 hours post end of infusion	__ __ __ __ __ __ __ __	__ __ : __ __
P05	72-168 hours post end of infusion	__ __ __ __ __ __ __ __	__ __ : __ __

NOT SUBMITTED

PHARMACOKINETIC - BLOOD SAMPLING (SCHEDULE 1) *PK_1*

☐ NOT APPLICABLE

SAMPLE ID	THEORETICAL TIME	SAMPLE DATE day month year	SAMPLE TIME 24 hour clock
P00	Prior to Infusion of XRP6528	__ __ __ __ __ __ __ __	__ __ : __ __
P01	30 minutes before end of infusion	__ __ __ __ __ __ __ __	__ __ : __ __
P02	5 minutes post end of Infusion	__ __ __ __ __ __ __ __	__ __ : __ __
P03	1 hour post end of infusion	__ __ __ __ __ __ __ __	__ __ : __ __
P04	6-10 hours post end of infusion	__ __ __ __ __ __ __ __	__ __ : __ __
P05	24-168 hours post end of infusion	__ __ __ __ __ __ __ __	__ __ : __ __

PHARMACOKINETIC - BLOOD SAMPLING (SCHEDULE 2) *PK_1*

☐ NOT APPLICABLE

SAMPLE ID	THEORETICAL TIME	SAMPLE DATE day month year	SAMPLE TIME 24 hour clock
P00	Prior to Infusion of XRP6528	__ __ __ __ __ __ __ __	__ __ : __ __
P01	10 minutes before end of infusion	__ __ __ __ __ __ __ __	__ __ : __ __
P02	10 minutes post end of Infusion	__ __ __ __ __ __ __ __	__ __ : __ __
P03	2 hours post end of infusion	__ __ __ __ __ __ __ __	__ __ : __ __
P04	8-12 hours post end of infusion	__ __ __ __ __ __ __ __	__ __ : __ __
P05	24-168 hours post end of infusion	__ __ __ __ __ __ __ __	__ __ : __ __

NOT SUBMITTED

PHARMACOKINETIC - BLOOD SAMPLING (SCHEDULE 3) *PK_1*

☐ NOT APPLICABLE

SAMPLE ID	THEORETICAL TIME	SAMPLE DATE day month year	SAMPLE TIME 24 hour clock
P00	Prior to Infusion of XRP6528	__ __ __ __ __ __ __ __	__ __ : __ __
P01	30 minutes before end of infusion	__ __ __ __ __ __ __ __	__ __ : __ __
P02	20 minutes post end of Infusion	__ __ __ __ __ __ __ __	__ __ : __ __
P03	3 hours post end of infusion	__ __ __ __ __ __ __ __	__ __ : __ __
P04	10-14 hours post end of infusion	__ __ __ __ __ __ __ __	__ __ : __ __
P05	24-72 hours post end of infusion	__ __ __ __ __ __ __ __	__ __ : __ __

PHARMACOKINETIC - BLOOD SAMPLING (SCHEDULE 4) *PK_1*

☐ NOT APPLICABLE

SAMPLE ID	THEORETICAL TIME	SAMPLE DATE day month year	SAMPLE TIME 24 hour clock
P00	Prior to Infusion of XRP6528	__ __ __ __ __ __ __ __	__ __ : __ __
P01	10 minutes before end of infusion	__ __ __ __ __ __ __ __	__ __ : __ __
P02	30 minutes post end of Infusion	__ __ __ __ __ __ __ __	__ __ : __ __
P03	4 hours post end of infusion	__ __ __ __ __ __ __ __	__ __ : __ __
P04	12-24 hours post end of infusion	__ __ __ __ __ __ __ __	__ __ : __ __
P05	72-168 hours post end of infusion	__ __ __ __ __ __ __ __	__ __ : __ __

NOT SUBMITTED

PHARMACOKINETIC - BLOOD SAMPLING (SCHEDULE 3) *PK_1*

☐ NOT APPLICABLE

SAMPLE ID	THEORETICAL TIME	SAMPLE DATE day month year	SAMPLE TIME 24 hour clock
P00	Prior to Infusion of XRP6528	__ __ __ __ __ __ __ __	__ __ : __ __
P01	30 minutes before end of infusion	__ __ __ __ __ __ __ __	__ __ : __ __
P02	20 minutes post end of Infusion	__ __ __ __ __ __ __ __	__ __ : __ __
P03	3 hours post end of infusion	__ __ __ __ __ __ __ __	__ __ : __ __
P04	10-20 hours post end of infusion	__ __ __ __ __ __ __ __	__ __ : __ __
P05	24-168 hours post end of infusion	__ __ __ __ __ __ __ __	__ __ : __ __

PHARMACOKINETIC - BLOOD SAMPLING (SCHEDULE 4) *PK_1*

☐ NOT APPLICABLE

SAMPLE ID	THEORETICAL TIME	SAMPLE DATE day month year	SAMPLE TIME 24 hour clock
P00	Prior to Infusion of XRP6528	__ __ __ __ __ __ __ __	__ __ : __ __
P01	10 minutes before end of infusion	__ __ __ __ __ __ __ __	__ __ : __ __
P02	30 minutes post end of Infusion	__ __ __ __ __ __ __ __	__ __ : __ __
P03	4 hours post end of infusion	__ __ __ __ __ __ __ __	__ __ : __ __
P04	10-22 hours post end of infusion	__ __ __ __ __ __ __ __	__ __ : __ __
P05	24-168 hours post end of infusion	__ __ __ __ __ __ __ __	__ __ : __ __

Dataset=CM
Dataset=SUPPCM

CONCOMITANT MEDICATION

O.MED_9

☐ NONE

Tick the box if no medication(s) has been taken concomitantly with study drug.

<SUPPCM.QNAM = ENDTCOL>

	MEDICATION	START DATE Day Month Year	END DATE Day Month Year
1.	<CMTRT>	<CMSTDTC> ☐ Ongoing <SUPPCM.QNAM = CMONGB>	<CMENDTC> ☐ Ongoing <SUPPCM.QNAM = CMONGO>
2.		☐ Ongoing	☐ Ongoing
3.		☐ Ongoing	☐ Ongoing
4.		☐ Ongoing	☐ Ongoing
5.		☐ Ongoing	☐ Ongoing
6.		☐ Ongoing	☐ Ongoing
7.		☐ Ongoing	☐ Ongoing
8.		☐ Ongoing	☐ Ongoing
9.		☐ Ongoing	☐ Ongoing
10.		☐ Ongoing	☐ Ongoing

See Page 60

CONCOMITANT MEDICATION

O.MED_9

	MEDICATION	START DATE Day Month Year	END DATE Day Month Year
1.		❑ Ongoing	❑ Ongoing
2.		❑ Ongoing	❑ Ongoing
3.		❑ Ongoing	❑ Ongoing
4.		❑ Ongoing	❑ Ongoing
5.		❑ Ongoing	❑ Ongoing
6.		❑ Ongoing	❑ Ongoing
7.		❑ Ongoing	❑ Ongoing
8.		❑ Ongoing	❑ Ongoing
9.		❑ Ongoing	❑ Ongoing
10.		❑ Ongoing	❑ Ongoing

Dataset=AE
Dataset=SUPPAE

XRP6258 EFC6193	Country No.	Centre No.	Subject No.	XT 601	Page 01
CYCLE 1	V 01				

ADVERSE EVENT FORM

O.1_AE_1

☐ NONE

1. **ADVERSE EVENT DIAGNOSIS** <AETERM>	AE form no: 01-01 AE ref. no: __-__ <AESTDTC>	AE form no: 01-02 AE ref. no: __-__
2. **STATUS OF AE** 1= New <AEPATT> 2= Ongoing from previous period without change 3= Ongoing with change	1 ☐ Date of start: __/__/__ (day/month/year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐	1 ☐ Date of start: __/__/__ (day/month/year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐
<SUPPAE.QNAM=AECOLGRN> **3.** **GRADE (1 - 4)**	1 ☐ 2 ☐ 3 ☐ 4 ☐	1 ☐ 2 ☐ 3 ☐ 4 ☐
<AEREL> **4. RELATIONSHIP TO STUDY TREATMENT***	Yes ☐ No ☐	Yes ☐ No ☐
<AEACN> **5.** **ACTION TAKEN WITH STUDY TREATMENT**	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
<AECONTRT> **6. CORRECTIVE TREATMENT/THERAPY**	Yes ☐ No ☐	Yes ☐ No ☐
<AEOUT> **7.** **OUTCOME** 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ☐ / 4 ☐ Date: __/__/__ (day/month/year) <AEENDTC> Specify sequelae: _____ <SUPPAE.QNAM=AESEQUCM> 2 ☐ 3 ☐ 5 ☐ Date of death: __/__/__ <SUPPAE.QNAM=AEDTHDTC> 6 ☐	1 ☐ / 4 ☐ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __/__/__ 6 ☐
<AESER> **8.** **SERIOUSNESS CRITERIA** **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ☐ No ☐ ➲ IF YES - Date event became serious: <AESERDTC> __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death <AESDTH> ☐ Life-threatening <AESLIFE> ☐ Requiring/prolonging hospitalization <AESHOSP> ☐ Persistent/significant disability/incapacity <AESDISAB> ☐ Congenital anomaly/birth defect <AESCONG> ☐ Other medically important event <AESMIE> ☐	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐
Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:	

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 01-03 AE ref. no: __-__	AE form no: 01-04 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: __/__/__ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: __/__/__ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/__ (day/month/year) 6 ❑	1 ❑ / 4 ❑ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/__ (day/month/year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES: - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES: - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:	

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 01-05 AE ref. no: __-__	AE form no: 01-06 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: __/__/__ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: __/__/__ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/__ (day/month/year) 6 ❑	1 ❑ / 4 ❑ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/__ (day/month/year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:	

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 01-07 AE ref. no: ___-___	AE form no: 01-08 AE ref. no: ___-___
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: ___ ___ ___ (day / month / year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: ___ ___ ___ (day / month / year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: ___ ___ ___ (day / month / year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: ___ ___ ___ (day / month / year) 6 ❑	1 ❑ / 4 ❑ Date: ___ ___ ___ (day / month / year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: ___ ___ ___ (day / month / year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES: - Date event became serious: ___ ___ ___ (day / month / year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES: - Date event became serious: ___ ___ ___ (day / month / year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:	

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 01-09 AE ref. no: __-__	AE form no: 01-10 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ☐ Date of start: __ __ day __ __ __ month __ __ __ __ year 2 ☐ *(do not complete the remaining items in the column)* 3 ☐	1 ☐ Date of start: __ __ day __ __ __ month __ __ __ __ year 2 ☐ *(do not complete the remaining items in the column)* 3 ☐
3. GRADE (1 - 4)	1 ☐ 2 ☐ 3 ☐ 4 ☐	1 ☐ 2 ☐ 3 ☐ 4 ☐
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ☐ No ☐	Yes ☐ No ☐
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
6. CORRECTIVE TREATMENT/THERAPY	Yes ☐ No ☐	Yes ☐ No ☐
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ☐ / 4 ☐ Date: __ __ day __ __ __ month __ __ __ __ year Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __ __ day __ __ __ month __ __ __ __ year 6 ☐	1 ☐ / 4 ☐ Date: __ __ day __ __ __ month __ __ __ __ year Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __ __ day __ __ __ month __ __ __ __ year 6 ☐
8. SERIOUSNESS CRITERIA IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __ __ day __ __ __ month __ __ __ __ year - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __ __ day __ __ __ month __ __ __ __ year - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐
Investigator's name, date of report and signature:		Monitoring representative's name, date of receipt:

** Is there a reasonable possibility that the AE was caused by study treatment?*

ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 01-11 AE ref. no: __-__	AE form no: 01-12 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ☐ Date of start: __/__/__ (day/month/year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐	1 ☐ Date of start: __/__/__ (day/month/year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐
3. GRADE (1 - 4)	1 ☐ 2 ☐ 3 ☐ 4 ☐	1 ☐ 2 ☐ 3 ☐ 4 ☐
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ☐ No ☐	Yes ☐ No ☐
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
6. CORRECTIVE TREATMENT/THERAPY	Yes ☐ No ☐	Yes ☐ No ☐
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ☐ / 4 ☐ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __/__/__ (day/month/year) 6 ☐	1 ☐ / 4 ☐ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __/__/__ (day/month/year) 6 ☐
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐
Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:	

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: ⌊_⌊_-⌊_⌊_ AE ref. no: ⌊_⌊_-⌊_⌊_	AE form no: ⌊_⌊_-⌊_⌊_ AE ref. no: ⌊_⌊_-⌊_⌊_
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: ⌊_⌊_ ⌊_⌊_⌊_ ⌊_⌊_⌊_⌊_ (day / month / year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: ⌊_⌊_ ⌊_⌊_⌊_ ⌊_⌊_⌊_⌊_ (day / month / year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: ⌊_⌊_ ⌊_⌊_⌊_ ⌊_⌊_⌊_⌊_ (day / month / year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: ⌊_⌊_ ⌊_⌊_⌊_ ⌊_⌊_⌊_⌊_ (day / month / year) 6 ❑	1 ❑ / 4 ❑ Date: ⌊_⌊_ ⌊_⌊_⌊_ ⌊_⌊_⌊_⌊_ (day / month / year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: ⌊_⌊_ ⌊_⌊_⌊_ ⌊_⌊_⌊_⌊_ (day / month / year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES - Date event became serious: ⌊_⌊_ ⌊_⌊_⌊_ ⌊_⌊_⌊_⌊_ (day / month / year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES - Date event became serious: ⌊_⌊_ ⌊_⌊_⌊_ ⌊_⌊_⌊_⌊_ (day / month / year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:		Monitoring representative's name, date of receipt:

** Is there a reasonable possibility that the AE was caused by study treatment?*

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PHYSICAL EXAMINATION *PHYSEXAM_2*

NONE ❑

Date performed: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
day month year

- Were there any clinically significant changes from the previous evaluation? Yes* ❑ No ❑

  * ***If yes, please complete Adverse Event form.***

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VITAL SIGNS *VITAL_1*

NOT DONE ❑

Weight: ⌊_⌋⌊_⌋⌊_⌋ . ⌊_⌋ kg

- Blood pressure: Systolic ⌊_⌋⌊_⌋⌊_⌋ mmHg / Diastolic ⌊_⌋⌊_⌋⌊_⌋ mmHg

- Heart rate: ⌊_⌋⌊_⌋⌊_⌋ beats/min

- Temperature: ⌊_⌋⌊_⌋ . ⌊_⌋ °C

(tick appropriate box): Oral ❑ Rectal ❑ Auricular ❑

ECOG Performance Status

0	1	2	3	4
❑	❑	❑	❑	❑

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HEMATOLOGY

LABH_1

Date of sampling: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
day month year

TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
WBC		10^9/L	
RBC		10^6/mm^3	
Neutrophils		10^9/L	
Eosinophils		10^9/L	
Basophils		10^9/L	
Monocytes		10^9/L	
Lymphocytes		10^9/L	
Platelets		10^9/L	
Hemoglobin		g/dL	

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PSA

LABH_1

DATE OF SAMPLING (day month year)	TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	PSA		ng/mL	

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BIOCHEMISTRY

LABB_1

Date of sampling: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
day month year

TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
Sodium		mmol/L	
Potassium		mmol/L	
SGOT (AST)		U/L	
SGPT (ALT)		U/L	
Alkaline phosphatase		U/L	
Total bilirubin		mg/dL	
BUN		mg/dL	
Creatinine		mg/dL	
Glucose		mg/dL	
Chloride		mmol/L	
Bicarbonate		mmol/L	

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HEMATOLOGY

LABH_1

Date of sampling: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
day month year

TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
WBC		10^9/L	
RBC		10^6/mm^3	
Neutrophils		10^9/L	
Eosinophils		10^9/L	
Basophils		10^9/L	
Monocytes		10^9/L	
Lymphocytes		10^9/L	
Platelets		10^9/L	
Hemoglobin		g/dL	

See Page 24

HEMATOLOGY

LABH_1

Date of sampling: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
day month year

TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
WBC		10^9/L	
RBC		10^6/mm^3	
Neutrophils		10^9/L	
Eosinophils		10^9/L	
Basophils		10^9/L	
Monocytes		10^9/L	
Lymphocytes		10^9/L	
Platelets		10^9/L	
Hemoglobin		g/dL	

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SPECIFIC CONCOMITANT MEDICATION *SPMED_1*

None ❑

- Please record all premedication administered prior to study drug XRP6258 or Mitoxantrone infusion or tick "None".

	MEDICATION	DOSAGE		START DATE	END DATE
		Number of Units	Unit	day month year	day month year
1				␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣
2				␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣
3				␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣
4				␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣
5				␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣
6				␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣
7				␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣
8				␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣
9				␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣
10				␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣

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INVESTIGATIONAL PRODUCT ADMINISTRATION *ADMIN_1*

TREATMENT NAME	DATE AND TIME OF DOSING day month year 24-hour clock	INTENDED DOSE (mg/m^2)	ACTUAL DOSE GIVEN (mg)
❑ XRP6258 ❑ Mitoxantrone	Start ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋ : ⌊_⌋⌊_⌋ End ⌊_⌋⌊_⌋ : ⌊_⌋⌊_⌋		
IF DOSE DELAYED AND/OR REDUCED AND/OR INTERRUPTED, SPECIFY REASON:			
❑ AE: Specify on AE form ❑ Other: _____			

IF DOSE INTERRUPTED, complete below:

TREATMENT NAME	DATE AND TIME OF DOSING day month year 24-hour clock	INTENDED DOSE (mg/m^2)	ACTUAL DOSE GIVEN (mg)
❑ XRP6258 ❑ Mitoxantrone	Start ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋ : ⌊_⌋⌊_⌋ End ⌊_⌋⌊_⌋ : ⌊_⌋⌊_⌋	NA	

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INVESTIGATIONAL PRODUCT ADMINISTRATION *ADMIN_1*

TREATMENT NAME	DATE OF DOSING (day month year)	INTENDED DOSE (mg)	ACTUAL DOSE GIVEN (mg)
❑ Prednisone ❑ Prednisolone	Start ⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋⌊__⌋ End ⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋⌊__⌋		

IF DOSE DELAYED AND/OR REDUCED AND/OR INTERRUPTED, SPECIFY REASON:

❑ AE: Specify on AE form

❑ Other: _____

IF DOSE INTERRUPTED, complete below:

TREATMENT NAME	DATE OF DOSING (day month year)	INTENDED DOSE (mg)	ACTUAL DOSE GIVEN (mg)
❑ Prednisone ❑ Prednisolone	Start ⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋⌊__⌋ End ⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋⌊__⌋	NA	

See Page 51

BATCH NUMBERS

O.BATCH_1

	DRUG NAME	BATCH NUMBER
1		
2		
3		
4		
5		

*** Location:**

01	Skin	12	Liver	22	Mediastinum
02	Muscle/Soft Tissue	13	Stomach	23	Uterus
03	Bone	14	Pancreas	24	Abdomen
04	Bone Marrow	15	Kidneys	25	Gastrointestinal Tract
05	Peripheral Blood Stream	16	Ovaries	26	Pelvis
06	Brain/CNS	16.01	Fallopian Tubes	27	Peritoneum
07	Head/Neck	17	Bladder	28	Testis
08	Esophagus	18	Prostate	29	Thorax
09	Breast	19	Cervix	29.01	Pleura
10	Lungs	20.10	Colon	30	Other
11.01	Regional Lymph Nodes	20.20	Rectum		
11.02	Distant Lymph Nodes	21	Adrenal		

**** Method of Measurement Codes:**

1 - CT Scan	3 - MRI	5 - Scintigraphy
2 - Spiral CT	4 - PET	7 - Ultrasound
8 - X-Ray	10 - Physical Exam	99 - Other

*****Response of Non-Target Codes:**

CR - Complete Response	IR/SD - Incomplete Response/Stable Disease	PD - Progressive Disease
NL - New Lesion	NE - Not Evaluable	

TUMOR MEASUREMENTS

O.ASSESS_3

☐ NOT DONE

LESION NUMBER	LOCATION SITE*	DATE OF ASSESSMENT Day Month Year	METHOD OF MEASUREMENT**	MEASUREMENT OF TARGET LESION: longest diameter	RESPONSE OF NON-TARGET LESIONS***
1	☐☐.☐☐	☐☐ ☐☐☐ ☐☐☐☐ ☐ Not Done	☐☐	☐☐☐ mm	☐☐
2	☐☐.☐☐	☐☐ ☐☐☐ ☐☐☐☐ ☐ Not Done	☐☐	☐☐☐ mm	☐☐
3	☐☐.☐☐	☐☐ ☐☐☐ ☐☐☐☐ ☐ Not Done	☐☐	☐☐☐ mm	☐☐
4	☐☐.☐☐	☐☐ ☐☐☐ ☐☐☐☐ ☐ Not Done	☐☐	☐☐☐ mm	☐☐
5	☐☐.☐☐	☐☐ ☐☐☐ ☐☐☐☐ ☐ Not Done	☐☐	☐☐☐ mm	☐☐
6	☐☐.☐☐	☐☐ ☐☐☐ ☐☐☐☐ ☐ Not Done	☐☐	☐☐☐ mm	☐☐
7	☐☐.☐☐	☐☐ ☐☐☐ ☐☐☐☐ ☐ Not Done	☐☐	☐☐☐ mm	☐☐
8	☐☐.☐☐	☐☐ ☐☐☐ ☐☐☐☐ ☐ Not Done	☐☐	☐☐☐ mm	☐☐
9	☐☐.☐☐	☐☐ ☐☐☐ ☐☐☐☐ ☐ Not Done	☐☐	☐☐☐ mm	☐☐
10	☐☐.☐☐	☐☐ ☐☐☐ ☐☐☐☐ ☐ Not Done	☐☐	☐☐☐ mm	☐☐
11	☐☐.☐☐	☐☐ ☐☐☐ ☐☐☐☐ ☐ Not Done	☐☐	☐☐☐ mm	☐☐
12	☐☐.☐☐	☐☐ ☐☐☐ ☐☐☐☐ ☐ Not Done	☐☐	☐☐☐ mm	☐☐
13	☐☐.☐☐	☐☐ ☐☐☐ ☐☐☐☐ ☐ Not Done	☐☐	☐☐☐ mm	☐☐
14	☐☐.☐☐	☐☐ ☐☐☐ ☐☐☐☐ ☐ Not Done	☐☐	☐☐☐ mm	☐☐

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PAIN INTENSITY ASSESSMENT *PAINVAS1*

Date corresponds to current cycle (7 days prior to dosing Day 1)

Date (Day Month Year)	PPI	Analgesic Score
1. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
2. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
3. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
4. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
5. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
6. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
7. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣

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ECHOCARDIOGRAPHY

ECHOCARD_1

NOT DONE ❑

- Date performed: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
  day month year

- **2D-Echocardiography:** Normal ❑ Abnormal* ❑

- Left ventricular ejection fraction (LVEF) ⌊_⌋⌊_⌋ . ⌊_⌋ %

- Lower Limit Normal of LVEF ⌊_⌋⌊_⌋ . ⌊_⌋ %

* ***If clinically relevant, please complete the Adverse Event form.***

RADIONUCLIDE VENTRICULOGRAPHY

MUGA_1

NOT DONE ❑

- Date performed: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
  day month year

- **Radionuclide Ventriculographyy:** Normal ❑ Abnormal* ❑

- Left ventricular ejection fraction (LVEF) ⌊_⌋⌊_⌋ . ⌊_⌋ %

- Lower Limit Normal of LVEF ⌊_⌋⌊_⌋ . ⌊_⌋ %

* ***If clinically relevant, please complete the Adverse Event form.***

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CONCOMITANT MEDICATION

O.MED_9

❑ NONE

Tick the box if no medication(s) has been taken concomitantly with study drug.

	MEDICATION	START DATE Day Month Year	END DATE Day Month Year
1.		❑ Ongoing	❑ Ongoing
2.		❑ Ongoing	❑ Ongoing
3.		❑ Ongoing	❑ Ongoing
4.		❑ Ongoing	❑ Ongoing
5.		❑ Ongoing	❑ Ongoing
6.		❑ Ongoing	❑ Ongoing
7.		❑ Ongoing	❑ Ongoing
8.		❑ Ongoing	❑ Ongoing
9.		❑ Ongoing	❑ Ongoing
10.		❑ Ongoing	❑ Ongoing

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CONCOMITANT MEDICATION

O.MED_9

	MEDICATION	START DATE Day Month Year	END DATE Day Month Year
1.		❑ Ongoing	❑ Ongoing
2.		❑ Ongoing	❑ Ongoing
3.		❑ Ongoing	❑ Ongoing
4.		❑ Ongoing	❑ Ongoing
5.		❑ Ongoing	❑ Ongoing
6.		❑ Ongoing	❑ Ongoing
7.		❑ Ongoing	❑ Ongoing
8.		❑ Ongoing	❑ Ongoing
9.		❑ Ongoing	❑ Ongoing
10.		❑ Ongoing	❑ Ongoing

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ADVERSE EVENT FORM

O.1_AE_1

☐ NONE

1. ADVERSE EVENT DIAGNOSIS	AE form no: 02-01 AE ref. no: __-__	AE form no: 02-02 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ☐ Date of start: __/__/____ (day/month/year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐	1 ☐ Date of start: __/__/____ (day/month/year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐
3. GRADE (1 - 4)	1 ☐ 2 ☐ 3 ☐ 4 ☐	1 ☐ 2 ☐ 3 ☐ 4 ☐
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ☐ No ☐	Yes ☐ No ☐
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
6. CORRECTIVE TREATMENT/THERAPY	Yes ☐ No ☐	Yes ☐ No ☐
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ☐ / 4 ☐ Date: __/__/____ (day/month/year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __/__/____ (day/month/year) 6 ☐	1 ☐ / 4 ☐ Date: __/__/____ (day/month/year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __/__/____ (day/month/year) 6 ☐
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __/__/____ (day/month/year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __/__/____ (day/month/year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐
Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:	

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 02-03 AE ref. no: __-__	AE form no: 02-04 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: __/__/__ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: __/__/__ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/__ (day/month/year) 6 ❑	1 ❑ / 4 ❑ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/__ (day/month/year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:	

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 02-05 AE ref. no: __-__	AE form no: 02-06 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ☐ Date of start: __/__/__ (day/month/year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐	1 ☐ Date of start: __/__/__ (day/month/year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐
3. GRADE (1 - 4)	1 ☐ 2 ☐ 3 ☐ 4 ☐	1 ☐ 2 ☐ 3 ☐ 4 ☐
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ☐ No ☐	Yes ☐ No ☐
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
6. CORRECTIVE TREATMENT/THERAPY	Yes ☐ No ☐	Yes ☐ No ☐
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ☐ / 4 ☐ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __/__/__ (day/month/year) 6 ☐	1 ☐ / 4 ☐ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __/__/__ (day/month/year) 6 ☐
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ☐ No ☐ ➲ IF YES: - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐	Yes ☐ No ☐ ➲ IF YES: - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐
Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:	

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 02-07 AE ref. no: __-__	AE form no: 02-08 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: __/__/__ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: __/__/__ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/__ (day/month/year) 6 ❑	1 ❑ / 4 ❑ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/__ (day/month/year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:	

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 02-09 AE ref. no: __-__	AE form no: 02-10 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: __/__/____ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: __/__/____ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: __/__/____ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/____ (day/month/year) 6 ❑	1 ❑ / 4 ❑ Date: __/__/____ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/____ (day/month/year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __/__/____ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __/__/____ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:	

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 02-11 AE ref. no: __-__	AE form no: 02-12 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: __/__/__ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: __/__/__ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/__ (day/month/year) 6 ❑	1 ❑ / 4 ❑ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/__ (day/month/year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:	

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: ␣␣-␣␣ AE ref. no: ␣␣-␣␣	AE form no: ␣␣-␣␣ AE ref. no: ␣␣-␣␣
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) 6 ❑	1 ❑ / 4 ❑ Date: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES - Date event became serious: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES - Date event became serious: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:		Monitoring representative's name, date of receipt:

** Is there a reasonable possibility that the AE was caused by study treatment?*

See Page 43

PHYSICAL EXAMINATION

PHYSEXAM_2

NONE ❑

Date performed: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
day month year

- Were there any clinically significant changes from the previous evaluation? Yes* ❑ No ❑

  * ***If yes, please complete Adverse Event form.***

See Page 27

VITAL SIGNS

VITAL_1

NOT DONE ❑

Weight: ⌊_⌋⌊_⌋⌊_⌋ . ⌊_⌋ kg

- Blood pressure: Systolic ⌊_⌋⌊_⌋⌊_⌋ mmHg / Diastolic ⌊_⌋⌊_⌋⌊_⌋ mmHg

- Heart rate: ⌊_⌋⌊_⌋⌊_⌋ beats/min

- Temperature: ⌊_⌋⌊_⌋ . ⌊_⌋ °C

(tick appropriate box): Oral ❑ Rectal ❑ Auricular ❑

ECOG Performance Status

0	1	2	3	4
❑	❑	❑	❑	❑

See Page 24

HEMATOLOGY

LABH_1

Date of sampling: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
day month year

TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
WBC		10^9/L	
RBC		10^6/mm^3	
Neutrophils		10^9/L	
Eosinophils		10^9/L	
Basophils		10^9/L	
Monocytes		10^9/L	
Lymphocytes		10^9/L	
Platelets		10^9/L	
Hemoglobin		g/dL	

See Page 26

PSA

LABH_1

DATE OF SAMPLING (day month year)	TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	PSA		ng/mL	

See Page 25

BIOCHEMISTRY

LABB_1

Date of sampling: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
day month year

TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
Sodium		mmol/L	
Potassium		mmol/L	
SGOT (AST)		U/L	
SGPT (ALT)		U/L	
Alkaline phosphatase		U/L	
Total bilirubin		mg/dL	
BUN		mg/dL	
Creatinine		mg/dL	
Glucose		mg/dL	
Chloride		mmol/L	
Bicarbonate		mmol/L	

See Page 24

HEMATOLOGY

LABH_1

Date of sampling: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
day month year

TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
WBC		10^9/L	
RBC		10^6/mm^3	
Neutrophils		10^9/L	
Eosinophils		10^9/L	
Basophils		10^9/L	
Monocytes		10^9/L	
Lymphocytes		10^9/L	
Platelets		10^9/L	
Hemoglobin		g/dL	

See Page 24

HEMATOLOGY

LABH_1

Date of sampling: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
day month year

TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
WBC		10^9/L	
RBC		10^6/mm^3	
Neutrophils		10^9/L	
Eosinophils		10^9/L	
Basophils		10^9/L	
Monocytes		10^9/L	
Lymphocytes		10^9/L	
Platelets		10^9/L	
Hemoglobin		g/dL	

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SPECIFIC CONCOMITANT MEDICATION *SPMED_1*

None ❑

- Please record all premedication administered prior to study drug XRP6258 or Mitoxantrone infusion or tick "None".

	MEDICATION	DOSAGE		START DATE	END DATE
		Number of Units	Unit	day month year	day month year
1				␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣
2				␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣
3				␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣
4				␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣
5				␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣
6				␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣
7				␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣
8				␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣
9				␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣
10				␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣

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INVESTIGATIONAL PRODUCT ADMINISTRATION *ADMIN_1*

TREATMENT NAME	DATE AND TIME OF DOSING (day month year 24-hour clock)	INTENDED DOSE (mg/m^2)	ACTUAL DOSE GIVEN (mg)
❑ XRP6258 ❑ Mitoxantrone	Start ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋ : ⌊_⌋⌊_⌋ End ⌊_⌋⌊_⌋ : ⌊_⌋⌊_⌋		

IF DOSE DELAYED AND/OR REDUCED AND/OR INTERRUPTED, SPECIFY REASON:

❑ AE: Specify on AE form

❑ Other: _____

IF DOSE INTERRUPTED, complete below:

TREATMENT NAME	DATE AND TIME OF DOSING (day month year 24-hour clock)	INTENDED DOSE (mg/m^2)	ACTUAL DOSE GIVEN (mg)
❑ XRP6258 ❑ Mitoxantrone	Start ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋ : ⌊_⌋⌊_⌋ End ⌊_⌋⌊_⌋ : ⌊_⌋⌊_⌋	NA	

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INVESTIGATIONAL PRODUCT ADMINISTRATION *ADMIN_1*

TREATMENT NAME	DATE OF DOSING (day month year)	INTENDED DOSE (mg)	ACTUAL DOSE GIVEN (mg)
❑ Prednisone ❑ Prednisolone	Start ⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋⌊__⌋ End ⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋⌊__⌋		

IF DOSE DELAYED AND/OR REDUCED AND/OR INTERRUPTED, SPECIFY REASON:

❑ AE: Specify on AE form

❑ Other: _____

IF DOSE INTERRUPTED, complete below:

TREATMENT NAME	DATE OF DOSING (day month year)	INTENDED DOSE (mg)	ACTUAL DOSE GIVEN (mg)
❑ Prednisone ❑ Prednisolone	Start ⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋⌊__⌋ End ⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋ ⌊__⌋⌊__⌋⌊__⌋⌊__⌋	NA	

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BATCH NUMBERS

O.BATCH_1

	DRUG NAME	BATCH NUMBER
1		
2		
3		
4		
5		

*** Location:**

01	Skin	12	Liver	22	Mediastinum
02	Muscle/Soft Tissue	13	Stomach	23	Uterus
03	Bone	14	Pancreas	24	Abdomen
04	Bone Marrow	15	Kidneys	25	Gastrointestinal Tract
05	Peripheral Blood Stream	16	Ovaries	26	Pelvis
06	Brain/CNS	16.01	Fallopian Tubes	27	Peritoneum
07	Head/Neck	17	Bladder	28	Testis
08	Esophagus	18	Prostate	29	Thorax
09	Breast	19	Cervix	29.01	Pleura
10	Lungs	20.10	Colon	30	Other
11.01	Regional Lymph Nodes	20.20	Rectum		
11.02	Distant Lymph Nodes	21	Adrenal		

**** Method of Measurement Codes:**

1 - CT Scan	3 - MRI	5 - Scintigraphy
2 - Spiral CT	4 - PET	7 - Ultrasound
8 - X-Ray	10 - Physical Exam	99 - Other

*****Response of Non-Target Codes:**

CR - Complete Response	IR/SD - Incomplete Response/Stable Disease	PD - Progressive Disease
NL - New Lesion	NE - Not Evaluable	

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TUMOR MEASUREMENTS

O.ASSESS_3

❑ NOT DONE

LESION NUMBER	LOCATION SITE*	DATE OF ASSESSMENT Day Month Year	METHOD OF MEASUREMENT**	MEASUREMENT OF TARGET LESION: longest diameter	RESPONSE OF NON-TARGET LESIONS***
1	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
2	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
3	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
4	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
5	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
6	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
7	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
8	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
9	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
10	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
11	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
12	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
13	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
14	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣

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PAIN INTENSITY ASSESSMENT *PAINVAS1*

Date corresponds to current cycle (7 days prior to dosing Day 1)

Date (Day Month Year)	PPI	Analgesic Score
1. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
2. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
3. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
4. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
5. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
6. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
7. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣

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ECHOCARDIOGRAPHY *ECHOCARD_1*

NOT DONE ❑

- Date performed: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
  day month year

- **2D-Echocardiography:** Normal ❑ Abnormal* ❑

- Left ventricular ejection fraction (LVEF) ⌊_⌋⌊_⌋ . ⌊_⌋ %

- Lower Limit Normal of LVEF ⌊_⌋⌊_⌋ . ⌊_⌋ %

* ***If clinically relevant, please complete the Adverse Event form.***

RADIONUCLIDE VENTRICULOGRAPHY *MUGA_1*

NOT DONE ❑

- Date performed: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
  day month year

- **Radionuclide Ventriculographyy:** Normal ❑ Abnormal* ❑

- Left ventricular ejection fraction (LVEF) ⌊_⌋⌊_⌋ . ⌊_⌋ %

- Lower Limit Normal of LVEF ⌊_⌋⌊_⌋ . ⌊_⌋ %

* ***If clinically relevant, please complete the Adverse Event form.***

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CONCOMITANT MEDICATION

O.MED_9

❑ NONE

Tick the box if no medication(s) has been taken concomitantly with study drug.

	MEDICATION	START DATE Day Month Year	END DATE Day Month Year
1.		❑ Ongoing	❑ Ongoing
2.		❑ Ongoing	❑ Ongoing
3.		❑ Ongoing	❑ Ongoing
4.		❑ Ongoing	❑ Ongoing
5.		❑ Ongoing	❑ Ongoing
6.		❑ Ongoing	❑ Ongoing
7.		❑ Ongoing	❑ Ongoing
8.		❑ Ongoing	❑ Ongoing
9.		❑ Ongoing	❑ Ongoing
10.		❑ Ongoing	❑ Ongoing

See Page 60

CONCOMITANT MEDICATION

O.MED_9

	MEDICATION	START DATE Day Month Year	END DATE Day Month Year
1.		❑ Ongoing	❑ Ongoing
2.		❑ Ongoing	❑ Ongoing
3.		❑ Ongoing	❑ Ongoing
4.		❑ Ongoing	❑ Ongoing
5.		❑ Ongoing	❑ Ongoing
6.		❑ Ongoing	❑ Ongoing
7.		❑ Ongoing	❑ Ongoing
8.		❑ Ongoing	❑ Ongoing
9.		❑ Ongoing	❑ Ongoing
10.		❑ Ongoing	❑ Ongoing

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ADVERSE EVENT FORM

O.1_AE_1

❑ NONE

1. ADVERSE EVENT DIAGNOSIS	AE form no: 03-01 AE ref. no: __-__	AE form no: 03-02 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: __/__/____ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: __/__/____ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: __/__/____ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/____ (day/month/year) 6 ❑	1 ❑ / 4 ❑ Date: __/__/____ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/____ (day/month/year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __/__/____ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __/__/____ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑

Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 03-03 AE ref. no: __-__	AE form no: 03-04 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: __/__/__ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: __/__/__ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/__ (day/month/year) 6 ❑	1 ❑ / 4 ❑ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/__ (day/month/year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES: - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES: - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:	

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 03-05 AE ref. no: __-__	AE form no: 03-06 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ☐ Date of start: __/__/____ (day / month / year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐	1 ☐ Date of start: __/__/____ (day / month / year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐
3. GRADE (1 - 4)	1 ☐ 2 ☐ 3 ☐ 4 ☐	1 ☐ 2 ☐ 3 ☐ 4 ☐
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ☐ No ☐	Yes ☐ No ☐
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
6. CORRECTIVE TREATMENT/THERAPY	Yes ☐ No ☐	Yes ☐ No ☐
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ☐ / 4 ☐ Date: __/__/____ (day / month / year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __/__/____ (day / month / year) 6 ☐	1 ☐ / 4 ☐ Date: __/__/____ (day / month / year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __/__/____ (day / month / year) 6 ☐
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ☐ No ☐ ➲ IF YES: - Date event became serious: __/__/____ (day / month / year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐	Yes ☐ No ☐ ➲ IF YES: - Date event became serious: __/__/____ (day / month / year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐
Investigator's name, date of report and signature:		Monitoring representative's name, date of receipt:

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 03-07 AE ref. no: __-__	AE form no: 03-08 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: __/__/__ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: __/__/__ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/__ (day/month/year) 6 ❑	1 ❑ / 4 ❑ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/__ (day/month/year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES: - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES: - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:		Monitoring representative's name, date of receipt:

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 03-09 AE ref. no: __-__	AE form no: 03-10 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: __/__/____ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: __/__/____ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: __/__/____ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/____ (day/month/year) 6 ❑	1 ❑ / 4 ❑ Date: __/__/____ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/____ (day/month/year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __/__/____ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __/__/____ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:	

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 03-11 AE ref. no: __-__	AE form no: 03-12 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: __/__/____ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: __/__/____ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: __/__/____ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/____ (day/month/year) 6 ❑	1 ❑ / 4 ❑ Date: __/__/____ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/____ (day/month/year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __/__/____ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __/__/____ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:	

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: ␣␣-␣␣ AE ref. no: ␣␣-␣␣	AE form no: ␣␣-␣␣ AE ref. no: ␣␣-␣␣
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) 6 ❑	1 ❑ / 4 ❑ Date: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES - Date event became serious: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES - Date event became serious: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:		Monitoring representative's name, date of receipt:

** Is there a reasonable possibility that the AE was caused by study treatment?*

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PHYSICAL EXAMINATION

PHYSEXAM_2

NONE ❑

Date performed: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
day month year

- Were there any clinically significant changes from the previous evaluation? Yes* ❑ No ❑

**If yes, please complete Adverse Event form.*

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VITAL SIGNS

VITAL_1

NOT DONE ❑

Weight: ⌊_⌋⌊_⌋⌊_⌋ . ⌊_⌋ kg

- Blood pressure: Systolic ⌊_⌋⌊_⌋⌊_⌋ mmHg / Diastolic ⌊_⌋⌊_⌋⌊_⌋ mmHg

- Heart rate: ⌊_⌋⌊_⌋⌊_⌋ beats/min

- Temperature: ⌊_⌋⌊_⌋ . ⌊_⌋ °C

(tick appropriate box): Oral ❑ Rectal ❑ Auricular ❑

ECOG Performance Status

0	1	2	3	4
❑	❑	❑	❑	❑

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HEMATOLOGY

LABH_1

Date of sampling: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
day month year

TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
WBC		10^9/L	
RBC		10^6/mm^3	
Neutrophils		10^9/L	
Eosinophils		10^9/L	
Basophils		10^9/L	
Monocytes		10^9/L	
Lymphocytes		10^9/L	
Platelets		10^9/L	
Hemoglobin		g/dL	

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PSA

LABH_1

DATE OF SAMPLING (day month year)	TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	PSA		ng/mL	

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BIOCHEMISTRY

LABB_1

Date of sampling: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
day month year

TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
Sodium		mmol/L	
Potassium		mmol/L	
SGOT (AST)		U/L	
SGPT (ALT)		U/L	
Alkaline phosphatase		U/L	
Total bilirubin		mg/dL	
BUN		mg/dL	
Creatinine		mg/dL	
Glucose		mg/dL	
Chloride		mmol/L	
Bicarbonate		mmol/L	

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HEMATOLOGY

LABH_1

Date of sampling: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
day month year

TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
WBC		10^9/L	
RBC		10^6/mm^3	
Neutrophils		10^9/L	
Eosinophils		10^9/L	
Basophils		10^9/L	
Monocytes		10^9/L	
Lymphocytes		10^9/L	
Platelets		10^9/L	
Hemoglobin		g/dL	

See Page 24

HEMATOLOGY

LABH_1

Date of sampling: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
day month year

TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
WBC		10^9/L	
RBC		10^6/mm^3	
Neutrophils		10^9/L	
Eosinophils		10^9/L	
Basophils		10^9/L	
Monocytes		10^9/L	
Lymphocytes		10^9/L	
Platelets		10^9/L	
Hemoglobin		g/dL	

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SPECIFIC CONCOMITANT MEDICATION *SPMED_1*

None ❑

- Please record all premedication administered prior to study drug XRP6258 or Mitoxantrone infusion or tick "None".

	MEDICATION	DOSAGE		START DATE	END DATE
		Number of Units	Unit	day month year	day month year
1				␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣
2				␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣
3				␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣
4				␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣
5				␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣
6				␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣
7				␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣
8				␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣
9				␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣
10				␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣

INVESTIGATIONAL PRODUCT ADMINISTRATION *ADMIN_1*

TREATMENT NAME	DATE AND TIME OF DOSING day month year 24-hour clock	INTENDED DOSE (mg/m^2)	ACTUAL DOSE GIVEN (mg)
❑ XRP6258 ❑ Mitoxantrone	Start ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋ : ⌊_⌋⌊_⌋ End ⌊_⌋⌊_⌋ : ⌊_⌋⌊_⌋		
IF DOSE DELAYED AND/OR REDUCED AND/OR INTERRUPTED, SPECIFY REASON:			
❑ AE: Specify on AE form ❑ Other: _____			

IF DOSE INTERRUPTED, complete below:

TREATMENT NAME	DATE AND TIME OF DOSING day month year 24-hour clock	INTENDED DOSE (mg/m^2)	ACTUAL DOSE GIVEN (mg)
❑ XRP6258 ❑ Mitoxantrone	Start ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋ : ⌊_⌋⌊_⌋ End ⌊_⌋⌊_⌋ : ⌊_⌋⌊_⌋	NA	

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INVESTIGATIONAL PRODUCT ADMINISTRATION *ADMIN_1*

TREATMENT NAME	DATE OF DOSING (day month year)	INTENDED DOSE (mg)	ACTUAL DOSE GIVEN (mg)
❑ Prednisone ❑ Prednisolone	Start ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ End ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋		

IF DOSE DELAYED AND/OR REDUCED AND/OR INTERRUPTED, SPECIFY REASON:

❑ AE: Specify on AE form

❑ Other: _____

IF DOSE INTERRUPTED, complete below:

TREATMENT NAME	DATE OF DOSING (day month year)	INTENDED DOSE (mg)	ACTUAL DOSE GIVEN (mg)
❑ Prednisone ❑ Prednisolone	Start ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ End ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	NA	

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BATCH NUMBERS

O.BATCH_1

	DRUG NAME	BATCH NUMBER
1		
2		
3		
4		
5		

*** Location:**

01	Skin	12	Liver	22	Mediastinum
02	Muscle/Soft Tissue	13	Stomach	23	Uterus
03	Bone	14	Pancreas	24	Abdomen
04	Bone Marrow	15	Kidneys	25	Gastrointestinal Tract
05	Peripheral Blood Stream	16	Ovaries	26	Pelvis
06	Brain/CNS	16.01	Fallopian Tubes	27	Peritoneum
07	Head/Neck	17	Bladder	28	Testis
08	Esophagus	18	Prostate	29	Thorax
09	Breast	19	Cervix	29.01	Pleura
10	Lungs	20.10	Colon	30	Other
11.01	Regional Lymph Nodes	20.20	Rectum		
11.02	Distant Lymph Nodes	21	Adrenal		

**** Method of Measurement Codes:**

1 - CT Scan	3 - MRI	5 - Scintigraphy
2 - Spiral CT	4 - PET	7 - Ultrasound
8 - X-Ray	10 - Physical Exam	99 - Other

*****Response of Non-Target Codes:**

CR - Complete Response	IR/SD - Incomplete Response/Stable Disease	PD - Progressive Disease
NL - New Lesion	NE - Not Evaluable	

TUMOR MEASUREMENTS

O.ASSESS_3

☐ NOT DONE

LESION NUMBER	LOCATION SITE*	DATE OF ASSESSMENT Day Month Year	METHOD OF MEASUREMENT**	MEASUREMENT OF TARGET LESION: longest diameter	RESPONSE OF NON-TARGET LESIONS***
1	☐☐.☐☐	☐☐ ☐☐☐ ☐☐☐☐ ☐ Not Done	☐☐	☐☐☐ mm	☐☐
2	☐☐.☐☐	☐☐ ☐☐☐ ☐☐☐☐ ☐ Not Done	☐☐	☐☐☐ mm	☐☐
3	☐☐.☐☐	☐☐ ☐☐☐ ☐☐☐☐ ☐ Not Done	☐☐	☐☐☐ mm	☐☐
4	☐☐.☐☐	☐☐ ☐☐☐ ☐☐☐☐ ☐ Not Done	☐☐	☐☐☐ mm	☐☐
5	☐☐.☐☐	☐☐ ☐☐☐ ☐☐☐☐ ☐ Not Done	☐☐	☐☐☐ mm	☐☐
6	☐☐.☐☐	☐☐ ☐☐☐ ☐☐☐☐ ☐ Not Done	☐☐	☐☐☐ mm	☐☐
7	☐☐.☐☐	☐☐ ☐☐☐ ☐☐☐☐ ☐ Not Done	☐☐	☐☐☐ mm	☐☐
8	☐☐.☐☐	☐☐ ☐☐☐ ☐☐☐☐ ☐ Not Done	☐☐	☐☐☐ mm	☐☐
9	☐☐.☐☐	☐☐ ☐☐☐ ☐☐☐☐ ☐ Not Done	☐☐	☐☐☐ mm	☐☐
10	☐☐.☐☐	☐☐ ☐☐☐ ☐☐☐☐ ☐ Not Done	☐☐	☐☐☐ mm	☐☐
11	☐☐.☐☐	☐☐ ☐☐☐ ☐☐☐☐ ☐ Not Done	☐☐	☐☐☐ mm	☐☐
12	☐☐.☐☐	☐☐ ☐☐☐ ☐☐☐☐ ☐ Not Done	☐☐	☐☐☐ mm	☐☐
13	☐☐.☐☐	☐☐ ☐☐☐ ☐☐☐☐ ☐ Not Done	☐☐	☐☐☐ mm	☐☐
14	☐☐.☐☐	☐☐ ☐☐☐ ☐☐☐☐ ☐ Not Done	☐☐	☐☐☐ mm	☐☐

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PAIN INTENSITY ASSESSMENT

PAINVAS1

Date corresponds to current cycle (7 days prior to dosing Day 1)

Date (Day Month Year)	PPI	Analgesic Score
1. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
2. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
3. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
4. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
5. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
6. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
7. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣

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ECHOCARDIOGRAPHY

ECHOCARD_1

NOT DONE ❑

- Date performed: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
  day month year

- **2D-Echocardiography:** Normal ❑ Abnormal* ❑

- Left ventricular ejection fraction (LVEF) ⌊_⌋⌊_⌋ . ⌊_⌋ %

- Lower Limit Normal of LVEF ⌊_⌋⌊_⌋ . ⌊_⌋ %

* ***If clinically relevant, please complete the Adverse Event form.***

RADIONUCLIDE VENTRICULOGRAPHY

MUGA_1

NOT DONE ❑

- Date performed: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
  day month year

- **Radionuclide Ventriculographyy:** Normal ❑ Abnormal* ❑

- Left ventricular ejection fraction (LVEF) ⌊_⌋⌊_⌋ . ⌊_⌋ %

- Lower Limit Normal of LVEF ⌊_⌋⌊_⌋ . ⌊_⌋ %

* ***If clinically relevant, please complete the Adverse Event form.***

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CONCOMITANT MEDICATION

O.MED_9

❑ NONE

Tick the box if no medication(s) has been taken concomitantly with study drug.

	MEDICATION	START DATE Day Month Year	END DATE Day Month Year
1.		❑ Ongoing	❑ Ongoing
2.		❑ Ongoing	❑ Ongoing
3.		❑ Ongoing	❑ Ongoing
4.		❑ Ongoing	❑ Ongoing
5.		❑ Ongoing	❑ Ongoing
6.		❑ Ongoing	❑ Ongoing
7.		❑ Ongoing	❑ Ongoing
8.		❑ Ongoing	❑ Ongoing
9.		❑ Ongoing	❑ Ongoing
10.		❑ Ongoing	❑ Ongoing

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CONCOMITANT MEDICATION

O.MED_9

	MEDICATION	START DATE Day Month Year	END DATE Day Month Year
1.		❑ Ongoing	❑ Ongoing
2.		❑ Ongoing	❑ Ongoing
3.		❑ Ongoing	❑ Ongoing
4.		❑ Ongoing	❑ Ongoing
5.		❑ Ongoing	❑ Ongoing
6.		❑ Ongoing	❑ Ongoing
7.		❑ Ongoing	❑ Ongoing
8.		❑ Ongoing	❑ Ongoing
9.		❑ Ongoing	❑ Ongoing
10.		❑ Ongoing	❑ Ongoing

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ADVERSE EVENT FORM

O.1_AE_1

❑ NONE

1. ADVERSE EVENT DIAGNOSIS	AE form no: 04-01 AE ref. no: __-__	AE form no: 04-02 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: __/__/____ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: __/__/____ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: __/__/____ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/____ (day/month/year) 6 ❑	1 ❑ / 4 ❑ Date: __/__/____ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/____ (day/month/year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __/__/____ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __/__/____ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:	

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 04-03 AE ref. no: __-__	AE form no: 04-04 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: __/__/__ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: __/__/__ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/__ (day/month/year) 6 ❑	1 ❑ / 4 ❑ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/__ (day/month/year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES: - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES: - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:	

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 04-05 AE ref. no: __-__	AE form no: 04-06 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ☐ Date of start: __/__/____ (day / month / year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐	1 ☐ Date of start: __/__/____ (day / month / year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐
3. GRADE (1 - 4)	1 ☐ 2 ☐ 3 ☐ 4 ☐	1 ☐ 2 ☐ 3 ☐ 4 ☐
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ☐ No ☐	Yes ☐ No ☐
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
6. CORRECTIVE TREATMENT/THERAPY	Yes ☐ No ☐	Yes ☐ No ☐
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ☐ / 4 ☐ Date: __/__/____ (day / month / year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __/__/____ (day / month / year) 6 ☐	1 ☐ / 4 ☐ Date: __/__/____ (day / month / year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __/__/____ (day / month / year) 6 ☐
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ☐ No ☐ ➲ IF YES: - Date event became serious: __/__/____ (day / month / year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐	Yes ☐ No ☐ ➲ IF YES: - Date event became serious: __/__/____ (day / month / year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐
Investigator's name, date of report and signature:		Monitoring representative's name, date of receipt:

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 04-07 AE ref. no: __-__	AE form no: 04-08 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: __/__/__ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: __/__/__ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/__ (day/month/year) 6 ❑	1 ❑ / 4 ❑ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/__ (day/month/year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES: - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES: - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:		Monitoring representative's name, date of receipt:

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 04-09 AE ref. no: __-__	AE form no: 04-10 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: __/__/____ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: __/__/____ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: __/__/____ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/____ (day/month/year) 6 ❑	1 ❑ / 4 ❑ Date: __/__/____ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/____ (day/month/year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __/__/____ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __/__/____ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:	

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 04-11 AE ref. no: __-__	AE form no: 04-12 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: __/__/____ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: __/__/____ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: __/__/____ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/____ (day/month/year) 6 ❑	1 ❑ / 4 ❑ Date: __/__/____ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/____ (day/month/year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __/__/____ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __/__/____ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:	

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: ␣␣-␣␣ AE ref. no: ␣␣-␣␣	AE form no: ␣␣-␣␣ AE ref. no: ␣␣-␣␣
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) 6 ❑	1 ❑ / 4 ❑ Date: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES - Date event became serious: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES - Date event became serious: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:		Monitoring representative's name, date of receipt:

** Is there a reasonable possibility that the AE was caused by study treatment?*

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PHYSICAL EXAMINATION

PHYSEXAM_2

NONE ❑

Date performed: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
day month year

- Were there any clinically significant changes from the previous evaluation? Yes* ❑ No ❑

**If yes, please complete Adverse Event form.*

See Page 27

VITAL SIGNS

VITAL_1

NOT DONE ❑

Weight: ⌊_⌋⌊_⌋⌊_⌋ . ⌊_⌋ kg

- Blood pressure: Systolic ⌊_⌋⌊_⌋⌊_⌋ mmHg / Diastolic ⌊_⌋⌊_⌋⌊_⌋ mmHg

- Heart rate: ⌊_⌋⌊_⌋⌊_⌋ beats/min

- Temperature: ⌊_⌋⌊_⌋ . ⌊_⌋ °C

(tick appropriate box): Oral ❑ Rectal ❑ Auricular ❑

ECOG Performance Status

0	1	2	3	4
❑	❑	❑	❑	❑

See Page 24

HEMATOLOGY

LABH_1

Date of sampling: ☐☐ ☐☐☐ ☐☐☐☐
day month year

TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
WBC		10^9/L	
RBC		10^6/mm^3	
Neutrophils		10^9/L	
Eosinophils		10^9/L	
Basophils		10^9/L	
Monocytes		10^9/L	
Lymphocytes		10^9/L	
Platelets		10^9/L	
Hemoglobin		g/dL	

See Page 26

PSA

LABH_1

DATE OF SAMPLING (day month year)	TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
☐☐ ☐☐☐ ☐☐☐☐	PSA		ng/mL	

See Page 25

BIOCHEMISTRY

LABB_1

Date of sampling: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
day month year

TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
Sodium		mmol/L	
Potassium		mmol/L	
SGOT (AST)		U/L	
SGPT (ALT)		U/L	
Alkaline phosphatase		U/L	
Total bilirubin		mg/dL	
BUN		mg/dL	
Creatinine		mg/dL	
Glucose		mg/dL	
Chloride		mmol/L	
Bicarbonate		mmol/L	

See Page 24

HEMATOLOGY

LABH_1

Date of sampling: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
day month year

TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
WBC		10^9/L	
RBC		10^6/mm^3	
Neutrophils		10^9/L	
Eosinophils		10^9/L	
Basophils		10^9/L	
Monocytes		10^9/L	
Lymphocytes		10^9/L	
Platelets		10^9/L	
Hemoglobin		g/dL	

See Page 24

HEMATOLOGY

LABH_1

Date of sampling: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
day month year

TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
WBC		10^9/L	
RBC		10^6/mm^3	
Neutrophils		10^9/L	
Eosinophils		10^9/L	
Basophils		10^9/L	
Monocytes		10^9/L	
Lymphocytes		10^9/L	
Platelets		10^9/L	
Hemoglobin		g/dL	

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SPECIFIC CONCOMITANT MEDICATION *SPMED_1*

None ❑

- Please record all premedication administered prior to study drug XRP6258 or Mitoxantrone infusion or tick "None".

	MEDICATION	DOSAGE		START DATE	END DATE
		Number of Units	Unit	day month year	day month year
1				␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣
2				␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣
3				␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣
4				␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣
5				␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣
6				␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣
7				␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣
8				␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣
9				␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣
10				␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣

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INVESTIGATIONAL PRODUCT ADMINISTRATION *ADMIN_1*

TREATMENT NAME	DATE AND TIME OF DOSING day month year 24-hour clock	INTENDED DOSE (mg/m^2)	ACTUAL DOSE GIVEN (mg)
❑ XRP6258 ❑ Mitoxantrone	Start ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋ : ⌊_⌋⌊_⌋ End ⌊_⌋⌊_⌋ : ⌊_⌋⌊_⌋		
IF DOSE DELAYED AND/OR REDUCED AND/OR INTERRUPTED, SPECIFY REASON:			
❑ AE: Specify on AE form ❑ Other: _____			

IF DOSE INTERRUPTED, complete below:

TREATMENT NAME	DATE AND TIME OF DOSING day month year 24-hour clock	INTENDED DOSE (mg/m^2)	ACTUAL DOSE GIVEN (mg)
❑ XRP6258 ❑ Mitoxantrone	Start ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋ : ⌊_⌋⌊_⌋ End ⌊_⌋⌊_⌋ : ⌊_⌋⌊_⌋	NA	

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INVESTIGATIONAL PRODUCT ADMINISTRATION *ADMIN_1*

TREATMENT NAME	DATE OF DOSING (day month year)	INTENDED DOSE (mg)	ACTUAL DOSE GIVEN (mg)
❑ Prednisone ❑ Prednisolone	Start ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ End ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋		

IF DOSE DELAYED AND/OR REDUCED AND/OR INTERRUPTED, SPECIFY REASON:

❑ AE: Specify on AE form

❑ Other: _____

IF DOSE INTERRUPTED, complete below:

TREATMENT NAME	DATE OF DOSING (day month year)	INTENDED DOSE (mg)	ACTUAL DOSE GIVEN (mg)
❑ Prednisone ❑ Prednisolone	Start ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ End ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	NA	

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BATCH NUMBERS

O.BATCH_1

	DRUG NAME	BATCH NUMBER
1		
2		
3		
4		
5		

*** Location:**

01	Skin	12	Liver	22	Mediastinum
02	Muscle/Soft Tissue	13	Stomach	23	Uterus
03	Bone	14	Pancreas	24	Abdomen
04	Bone Marrow	15	Kidneys	25	Gastrointestinal Tract
05	Peripheral Blood Stream	16	Ovaries	26	Pelvis
06	Brain/CNS	16.01	Fallopian Tubes	27	Peritoneum
07	Head/Neck	17	Bladder	28	Testis
08	Esophagus	18	Prostate	29	Thorax
09	Breast	19	Cervix	29.01	Pleura
10	Lungs	20.10	Colon	30	Other
11.01	Regional Lymph Nodes	20.20	Rectum		
11.02	Distant Lymph Nodes	21	Adrenal		

**** Method of Measurement Codes:**

1 - CT Scan	3 - MRI	5 - Scintigraphy
2 - Spiral CT	4 - PET	7 - Ultrasound
8 - X-Ray	10 - Physical Exam	99 - Other

*****Response of Non-Target Codes:**

CR - Complete Response	IR/SD - Incomplete Response/Stable Disease	PD - Progressive Disease
NL - New Lesion	NE - Not Evaluable	

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TUMOR MEASUREMENTS

O.ASSESS_3

☐ NOT DONE

LESION NUMBER	LOCATION SITE*	DATE OF ASSESSMENT Day Month Year	METHOD OF MEASUREMENT**	MEASUREMENT OF TARGET LESION: longest diameter	RESPONSE OF NON-TARGET LESIONS***
1	☐☐.☐☐	☐☐ ☐☐☐ ☐☐☐☐ ☐ Not Done	☐☐	☐☐☐ mm	☐☐
2	☐☐.☐☐	☐☐ ☐☐☐ ☐☐☐☐ ☐ Not Done	☐☐	☐☐☐ mm	☐☐
3	☐☐.☐☐	☐☐ ☐☐☐ ☐☐☐☐ ☐ Not Done	☐☐	☐☐☐ mm	☐☐
4	☐☐.☐☐	☐☐ ☐☐☐ ☐☐☐☐ ☐ Not Done	☐☐	☐☐☐ mm	☐☐
5	☐☐.☐☐	☐☐ ☐☐☐ ☐☐☐☐ ☐ Not Done	☐☐	☐☐☐ mm	☐☐
6	☐☐.☐☐	☐☐ ☐☐☐ ☐☐☐☐ ☐ Not Done	☐☐	☐☐☐ mm	☐☐
7	☐☐.☐☐	☐☐ ☐☐☐ ☐☐☐☐ ☐ Not Done	☐☐	☐☐☐ mm	☐☐
8	☐☐.☐☐	☐☐ ☐☐☐ ☐☐☐☐ ☐ Not Done	☐☐	☐☐☐ mm	☐☐
9	☐☐.☐☐	☐☐ ☐☐☐ ☐☐☐☐ ☐ Not Done	☐☐	☐☐☐ mm	☐☐
10	☐☐.☐☐	☐☐ ☐☐☐ ☐☐☐☐ ☐ Not Done	☐☐	☐☐☐ mm	☐☐
11	☐☐.☐☐	☐☐ ☐☐☐ ☐☐☐☐ ☐ Not Done	☐☐	☐☐☐ mm	☐☐
12	☐☐.☐☐	☐☐ ☐☐☐ ☐☐☐☐ ☐ Not Done	☐☐	☐☐☐ mm	☐☐
13	☐☐.☐☐	☐☐ ☐☐☐ ☐☐☐☐ ☐ Not Done	☐☐	☐☐☐ mm	☐☐
14	☐☐.☐☐	☐☐ ☐☐☐ ☐☐☐☐ ☐ Not Done	☐☐	☐☐☐ mm	☐☐

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PAIN INTENSITY ASSESSMENT *PAINVAS1*

Date corresponds to current cycle (7 days prior to dosing Day 1)

Date (Day Month Year)	PPI	Analgesic Score
1. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
2. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
3. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
4. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
5. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
6. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
7. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣

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ECHOCARDIOGRAPHY *ECHOCARD_1*

NOT DONE ❑

- Date performed: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
  day month year

- **2D-Echocardiography:** Normal ❑ Abnormal* ❑

- Left ventricular ejection fraction (LVEF) ⌊_⌋⌊_⌋ . ⌊_⌋ %

- Lower Limit Normal of LVEF ⌊_⌋⌊_⌋ . ⌊_⌋ %

* ***If clinically relevant, please complete the Adverse Event form.***

RADIONUCLIDE VENTRICULOGRAPHY *MUGA_1*

NOT DONE ❑

- Date performed: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
  day month year

- **Radionuclide Ventriculographyy:** Normal ❑ Abnormal* ❑

- Left ventricular ejection fraction (LVEF) ⌊_⌋⌊_⌋ . ⌊_⌋ %

- Lower Limit Normal of LVEF ⌊_⌋⌊_⌋ . ⌊_⌋ %

* ***If clinically relevant, please complete the Adverse Event form.***

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CONCOMITANT MEDICATION

O.MED_9

❑ NONE

Tick the box if no medication(s) has been taken concomitantly with study drug.

	MEDICATION	START DATE Day Month Year	END DATE Day Month Year
1.		❑ Ongoing	❑ Ongoing
2.		❑ Ongoing	❑ Ongoing
3.		❑ Ongoing	❑ Ongoing
4.		❑ Ongoing	❑ Ongoing
5.		❑ Ongoing	❑ Ongoing
6.		❑ Ongoing	❑ Ongoing
7.		❑ Ongoing	❑ Ongoing
8.		❑ Ongoing	❑ Ongoing
9.		❑ Ongoing	❑ Ongoing
10.		❑ Ongoing	❑ Ongoing

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CONCOMITANT MEDICATION

O.MED_9

	MEDICATION	START DATE Day Month Year	END DATE Day Month Year
1.		❑ Ongoing	❑ Ongoing
2.		❑ Ongoing	❑ Ongoing
3.		❑ Ongoing	❑ Ongoing
4.		❑ Ongoing	❑ Ongoing
5.		❑ Ongoing	❑ Ongoing
6.		❑ Ongoing	❑ Ongoing
7.		❑ Ongoing	❑ Ongoing
8.		❑ Ongoing	❑ Ongoing
9.		❑ Ongoing	❑ Ongoing
10.		❑ Ongoing	❑ Ongoing

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ADVERSE EVENT FORM

O.1_AE_1

☐ NONE

1. ADVERSE EVENT DIAGNOSIS	AE form no: 05-01 AE ref. no: __-__	AE form no: 05-02 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ☐ Date of start: __/__/____ (day/month/year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐	1 ☐ Date of start: __/__/____ (day/month/year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐
3. GRADE (1 - 4)	1 ☐ 2 ☐ 3 ☐ 4 ☐	1 ☐ 2 ☐ 3 ☐ 4 ☐
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ☐ No ☐	Yes ☐ No ☐
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
6. CORRECTIVE TREATMENT/THERAPY	Yes ☐ No ☐	Yes ☐ No ☐
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ☐ / 4 ☐ Date: __/__/____ (day/month/year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __/__/____ (day/month/year) 6 ☐	1 ☐ / 4 ☐ Date: __/__/____ (day/month/year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __/__/____ (day/month/year) 6 ☐
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __/__/____ (day/month/year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __/__/____ (day/month/year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐
Investigator's name, date of report and signature:		Monitoring representative's name, date of receipt:

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 05-03 AE ref. no: __-__	AE form no: 05-04 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: __/__/__ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: __/__/__ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/__ (day/month/year) 6 ❑	1 ❑ / 4 ❑ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/__ (day/month/year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES: - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES: - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:	

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 05-05 AE ref. no: __-__	AE form no: 05-06 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ☐ Date of start: __/__/____ (day / month / year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐	1 ☐ Date of start: __/__/____ (day / month / year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐
3. GRADE (1 - 4)	1 ☐ 2 ☐ 3 ☐ 4 ☐	1 ☐ 2 ☐ 3 ☐ 4 ☐
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ☐ No ☐	Yes ☐ No ☐
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
6. CORRECTIVE TREATMENT/THERAPY	Yes ☐ No ☐	Yes ☐ No ☐
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ☐ / 4 ☐ Date: __/__/____ (day / month / year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __/__/____ (day / month / year) 6 ☐	1 ☐ / 4 ☐ Date: __/__/____ (day / month / year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __/__/____ (day / month / year) 6 ☐
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ☐ No ☐ ➲ IF YES: - Date event became serious: __/__/____ (day / month / year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐	Yes ☐ No ☐ ➲ IF YES: - Date event became serious: __/__/____ (day / month / year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐
Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:	

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 05-07 AE ref. no: __-__	AE form no: 05-08 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: __/__/__ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: __/__/__ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/__ (day/month/year) 6 ❑	1 ❑ / 4 ❑ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/__ (day/month/year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:		Monitoring representative's name, date of receipt:

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 05-09 AE ref. no: __-__	AE form no: 05-10 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: __/__/____ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: __/__/____ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: __/__/____ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/____ (day/month/year) 6 ❑	1 ❑ / 4 ❑ Date: __/__/____ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/____ (day/month/year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __/__/____ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __/__/____ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:	

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 05-11 AE ref. no: __-__	AE form no: 05-12 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: __/__/____ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: __/__/____ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: __/__/____ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/____ (day/month/year) 6 ❑	1 ❑ / 4 ❑ Date: __/__/____ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/____ (day/month/year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __/__/____ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __/__/____ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:	

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: ⌊_⌊_-⌊_⌊_ AE ref. no: ⌊_⌊_-⌊_⌊_	AE form no: ⌊_⌊_-⌊_⌊_ AE ref. no: ⌊_⌊_-⌊_⌊_
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: ⌊_⌊_ ⌊_⌊_⌊_ ⌊_⌊_⌊_⌊_ (day / month / year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: ⌊_⌊_ ⌊_⌊_⌊_ ⌊_⌊_⌊_⌊_ (day / month / year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: ⌊_⌊_ ⌊_⌊_⌊_ ⌊_⌊_⌊_⌊_ (day / month / year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: ⌊_⌊_ ⌊_⌊_⌊_ ⌊_⌊_⌊_⌊_ (day / month / year) 6 ❑	1 ❑ / 4 ❑ Date: ⌊_⌊_ ⌊_⌊_⌊_ ⌊_⌊_⌊_⌊_ (day / month / year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: ⌊_⌊_ ⌊_⌊_⌊_ ⌊_⌊_⌊_⌊_ (day / month / year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES - Date event became serious: ⌊_⌊_ ⌊_⌊_⌊_ ⌊_⌊_⌊_⌊_ (day / month / year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES - Date event became serious: ⌊_⌊_ ⌊_⌊_⌊_ ⌊_⌊_⌊_⌊_ (day / month / year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:		Monitoring representative's name, date of receipt:

** Is there a reasonable possibility that the AE was caused by study treatment?*

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PHYSICAL EXAMINATION

PHYSEXAM_2

NONE ❑

Date performed: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
day month year

- Were there any clinically significant changes from the previous evaluation? Yes* ❑ No ❑

**If yes, please complete Adverse Event form.*

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VITAL SIGNS

VITAL_1

NOT DONE ❑

Weight: ⌊_⌋⌊_⌋⌊_⌋ . ⌊_⌋ kg

- Blood pressure: Systolic ⌊_⌋⌊_⌋⌊_⌋ mmHg / Diastolic ⌊_⌋⌊_⌋⌊_⌋ mmHg

- Heart rate: ⌊_⌋⌊_⌋⌊_⌋ beats/min

- Temperature: ⌊_⌋⌊_⌋ . ⌊_⌋ °C

(tick appropriate box): Oral ❑ Rectal ❑ Auricular ❑

ECOG Performance Status

0	1	2	3	4
❑	❑	❑	❑	❑

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HEMATOLOGY

LABH_1

Date of sampling: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
day month year

TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
WBC		10^9/L	
RBC		10^6/mm^3	
Neutrophils		10^9/L	
Eosinophils		10^9/L	
Basophils		10^9/L	
Monocytes		10^9/L	
Lymphocytes		10^9/L	
Platelets		10^9/L	
Hemoglobin		g/dL	

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PSA

LABH_1

DATE OF SAMPLING (day month year)	TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	PSA		ng/mL	

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BIOCHEMISTRY

LABB_1

Date of sampling: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
day month year

TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
Sodium		mmol/L	
Potassium		mmol/L	
SGOT (AST)		U/L	
SGPT (ALT)		U/L	
Alkaline phosphatase		U/L	
Total bilirubin		mg/dL	
BUN		mg/dL	
Creatinine		mg/dL	
Glucose		mg/dL	
Chloride		mmol/L	
Bicarbonate		mmol/L	

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HEMATOLOGY

LABH_1

Date of sampling: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
day month year

TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
WBC		10^9/L	
RBC		10^6/mm^3	
Neutrophils		10^9/L	
Eosinophils		10^9/L	
Basophils		10^9/L	
Monocytes		10^9/L	
Lymphocytes		10^9/L	
Platelets		10^9/L	
Hemoglobin		g/dL	

See Page 24

HEMATOLOGY

LABH_1

Date of sampling: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
day month year

TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
WBC		10^9/L	
RBC		10^6/mm^3	
Neutrophils		10^9/L	
Eosinophils		10^9/L	
Basophils		10^9/L	
Monocytes		10^9/L	
Lymphocytes		10^9/L	
Platelets		10^9/L	
Hemoglobin		g/dL	

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SPECIFIC CONCOMITANT MEDICATION *SPMED_1*

None ❑

- Please record all premedication administered prior to study drug XRP6258 or Mitoxantrone infusion or tick "None".

	MEDICATION	DOSAGE		START DATE	END DATE
		Number of Units	Unit	day month year	day month year
1				␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣
2				␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣
3				␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣
4				␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣
5				␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣
6				␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣
7				␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣
8				␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣
9				␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣
10				␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣

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INVESTIGATIONAL PRODUCT ADMINISTRATION *ADMIN_1*

TREATMENT NAME	DATE AND TIME OF DOSING day month year 24-hour clock	INTENDED DOSE (mg/m^2)	ACTUAL DOSE GIVEN (mg)
❑ XRP6258 ❑ Mitoxantrone	Start ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋ : ⌊_⌋⌊_⌋ End ⌊_⌋⌊_⌋ : ⌊_⌋⌊_⌋		
IF DOSE DELAYED AND/OR REDUCED AND/OR INTERRUPTED, SPECIFY REASON:			
❑ AE: Specify on AE form ❑ Other: _____			

IF DOSE INTERRUPTED, complete below:

TREATMENT NAME	DATE AND TIME OF DOSING day month year 24-hour clock	INTENDED DOSE (mg/m^2)	ACTUAL DOSE GIVEN (mg)
❑ XRP6258 ❑ Mitoxantrone	Start ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋ : ⌊_⌋⌊_⌋ End ⌊_⌋⌊_⌋ : ⌊_⌋⌊_⌋	NA	

INVESTIGATIONAL PRODUCT ADMINISTRATION *ADMIN_1*

TREATMENT NAME	DATE OF DOSING (day month year)	INTENDED DOSE (mg)	ACTUAL DOSE GIVEN (mg)
❑ Prednisone ❑ Prednisolone	Start ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ End ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋		

IF DOSE DELAYED AND/OR REDUCED AND/OR INTERRUPTED, SPECIFY REASON:

❑ AE: Specify on AE form

❑ Other: _____

IF DOSE INTERRUPTED, complete below:

TREATMENT NAME	DATE OF DOSING (day month year)	INTENDED DOSE (mg)	ACTUAL DOSE GIVEN (mg)
❑ Prednisone ❑ Prednisolone	Start ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ End ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	NA	

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BATCH NUMBERS

O.BATCH_1

	DRUG NAME	BATCH NUMBER
1		
2		
3		
4		
5		

*** Location:**

01	Skin	12	Liver	22	Mediastinum
02	Muscle/Soft Tissue	13	Stomach	23	Uterus
03	Bone	14	Pancreas	24	Abdomen
04	Bone Marrow	15	Kidneys	25	Gastrointestinal Tract
05	Peripheral Blood Stream	16	Ovaries	26	Pelvis
06	Brain/CNS	16.01	Fallopian Tubes	27	Peritoneum
07	Head/Neck	17	Bladder	28	Testis
08	Esophagus	18	Prostate	29	Thorax
09	Breast	19	Cervix	29.01	Pleura
10	Lungs	20.10	Colon	30	Other
11.01	Regional Lymph Nodes	20.20	Rectum		
11.02	Distant Lymph Nodes	21	Adrenal		

**** Method of Measurement Codes:**

1 - CT Scan	3 - MRI	5 - Scintigraphy
2 - Spiral CT	4 - PET	7 - Ultrasound
8 - X-Ray	10 - Physical Exam	99 - Other

*****Response of Non-Target Codes:**

CR - Complete Response	IR/SD - Incomplete Response/Stable Disease	PD - Progressive Disease
NL - New Lesion	NE - Not Evaluable	

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TUMOR MEASUREMENTS

O.ASSESS_3

☐ NOT DONE

LESION NUMBER	LOCATION SITE*	DATE OF ASSESSMENT Day Month Year	METHOD OF MEASUREMENT**	MEASUREMENT OF TARGET LESION: longest diameter	RESPONSE OF NON-TARGET LESIONS***
1	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ☐ Not Done	␣␣	␣␣␣ mm	␣␣
2	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ☐ Not Done	␣␣	␣␣␣ mm	␣␣
3	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ☐ Not Done	␣␣	␣␣␣ mm	␣␣
4	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ☐ Not Done	␣␣	␣␣␣ mm	␣␣
5	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ☐ Not Done	␣␣	␣␣␣ mm	␣␣
6	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ☐ Not Done	␣␣	␣␣␣ mm	␣␣
7	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ☐ Not Done	␣␣	␣␣␣ mm	␣␣
8	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ☐ Not Done	␣␣	␣␣␣ mm	␣␣
9	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ☐ Not Done	␣␣	␣␣␣ mm	␣␣
10	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ☐ Not Done	␣␣	␣␣␣ mm	␣␣
11	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ☐ Not Done	␣␣	␣␣␣ mm	␣␣
12	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ☐ Not Done	␣␣	␣␣␣ mm	␣␣
13	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ☐ Not Done	␣␣	␣␣␣ mm	␣␣
14	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ☐ Not Done	␣␣	␣␣␣ mm	␣␣

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PAIN INTENSITY ASSESSMENT

PAINVAS1

Date corresponds to current cycle (7 days prior to dosing Day 1)

Date (Day Month Year)	PPI	Analgesic Score
1. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
2. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
3. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
4. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
5. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
6. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
7. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣

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ECHOCARDIOGRAPHY

ECHOCARD_1

NOT DONE ❑

- Date performed: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
  day month year

- **2D-Echocardiography:** Normal ❑ Abnormal* ❑

- Left ventricular ejection fraction (LVEF) ⌊_⌋⌊_⌋ . ⌊_⌋ %

- Lower Limit Normal of LVEF ⌊_⌋⌊_⌋ . ⌊_⌋ %

* ***If clinically relevant, please complete the Adverse Event form.***

RADIONUCLIDE VENTRICULOGRAPHY

MUGA_1

NOT DONE ❑

- Date performed: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
  day month year

- **Radionuclide Ventriculographyy:** Normal ❑ Abnormal* ❑

- Left ventricular ejection fraction (LVEF) ⌊_⌋⌊_⌋ . ⌊_⌋ %

- Lower Limit Normal of LVEF ⌊_⌋⌊_⌋ . ⌊_⌋ %

* ***If clinically relevant, please complete the Adverse Event form.***

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CONCOMITANT MEDICATION

O.MED_9

☐ NONE

Tick the box if no medication(s) has been taken concomitantly with study drug.

	MEDICATION	START DATE Day Month Year	END DATE Day Month Year
1.		☐ Ongoing	☐ Ongoing
2.		☐ Ongoing	☐ Ongoing
3.		☐ Ongoing	☐ Ongoing
4.		☐ Ongoing	☐ Ongoing
5.		☐ Ongoing	☐ Ongoing
6.		☐ Ongoing	☐ Ongoing
7.		☐ Ongoing	☐ Ongoing
8.		☐ Ongoing	☐ Ongoing
9.		☐ Ongoing	☐ Ongoing
10.		☐ Ongoing	☐ Ongoing

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CONCOMITANT MEDICATION

O.MED_9

	MEDICATION	START DATE Day Month Year	END DATE Day Month Year
1.		❑ Ongoing	❑ Ongoing
2.		❑ Ongoing	❑ Ongoing
3.		❑ Ongoing	❑ Ongoing
4.		❑ Ongoing	❑ Ongoing
5.		❑ Ongoing	❑ Ongoing
6.		❑ Ongoing	❑ Ongoing
7.		❑ Ongoing	❑ Ongoing
8.		❑ Ongoing	❑ Ongoing
9.		❑ Ongoing	❑ Ongoing
10.		❑ Ongoing	❑ Ongoing

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ADVERSE EVENT FORM

O.1_AE_1

❑ NONE

1. ADVERSE EVENT DIAGNOSIS	AE form no: 06-01 AE ref. no: __-__	AE form no: 06-02 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: __/__/____ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: __/__/____ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: __/__/____ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/____ (day/month/year) 6 ❑	1 ❑ / 4 ❑ Date: __/__/____ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/____ (day/month/year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __/__/____ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __/__/____ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:		Monitoring representative's name, date of receipt:

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 06-03 AE ref. no: __-__	AE form no: 06-04 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: __/__/__ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: __/__/__ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/__ (day/month/year) 6 ❑	1 ❑ / 4 ❑ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/__ (day/month/year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES: - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES: - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:	

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 06-05 AE ref. no: __-__	AE form no: 06-06 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ☐ Date of start: __ __ (day) __ __ __ (month) __ __ __ __ (year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐	1 ☐ Date of start: __ __ (day) __ __ __ (month) __ __ __ __ (year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐
3. GRADE (1 - 4)	1 ☐ 2 ☐ 3 ☐ 4 ☐	1 ☐ 2 ☐ 3 ☐ 4 ☐
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ☐ No ☐	Yes ☐ No ☐
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
6. CORRECTIVE TREATMENT/THERAPY	Yes ☐ No ☐	Yes ☐ No ☐
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ☐ / 4 ☐ Date: __ __ (day) __ __ __ (month) __ __ __ __ (year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __ __ (day) __ __ __ (month) __ __ __ __ (year) 6 ☐	1 ☐ / 4 ☐ Date: __ __ (day) __ __ __ (month) __ __ __ __ (year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __ __ (day) __ __ __ (month) __ __ __ __ (year) 6 ☐
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __ __ (day) __ __ __ (month) __ __ __ __ (year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __ __ (day) __ __ __ (month) __ __ __ __ (year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐
Investigator's name, date of report and signature:		Monitoring representative's name, date of receipt:

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 06-07 AE ref. no: __-__	AE form no: 06-08 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: __/__/__ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: __/__/__ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/__ (day/month/year) 6 ❑	1 ❑ / 4 ❑ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/__ (day/month/year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:	

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 06-09 AE ref. no: __-__	AE form no: 06-10 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: __/__/__ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: __/__/__ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/__ (day/month/year) 6 ❑	1 ❑ / 4 ❑ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/__ (day/month/year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:	

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 06-11 AE ref. no: __-__	AE form no: 06-12 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: __/__/____ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: __/__/____ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: __/__/____ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/____ (day/month/year) 6 ❑	1 ❑ / 4 ❑ Date: __/__/____ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/____ (day/month/year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __/__/____ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __/__/____ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:	

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: ⌊_⌊_-⌊_⌊_ AE ref. no: ⌊_⌊_-⌊_⌊_	AE form no: ⌊_⌊_-⌊_⌊_ AE ref. no: ⌊_⌊_-⌊_⌊_
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: ⌊_⌊_ ⌊_⌊_⌊_ ⌊_⌊_⌊_⌊_ (day / month / year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: ⌊_⌊_ ⌊_⌊_⌊_ ⌊_⌊_⌊_⌊_ (day / month / year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: ⌊_⌊_ ⌊_⌊_⌊_ ⌊_⌊_⌊_⌊_ (day / month / year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: ⌊_⌊_ ⌊_⌊_⌊_ ⌊_⌊_⌊_⌊_ (day / month / year) 6 ❑	1 ❑ / 4 ❑ Date: ⌊_⌊_ ⌊_⌊_⌊_ ⌊_⌊_⌊_⌊_ (day / month / year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: ⌊_⌊_ ⌊_⌊_⌊_ ⌊_⌊_⌊_⌊_ (day / month / year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES - Date event became serious: ⌊_⌊_ ⌊_⌊_⌊_ ⌊_⌊_⌊_⌊_ (day / month / year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES - Date event became serious: ⌊_⌊_ ⌊_⌊_⌊_ ⌊_⌊_⌊_⌊_ (day / month / year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:		Monitoring representative's name, date of receipt:

** Is there a reasonable possibility that the AE was caused by study treatment?*

See Page 43

PHYSICAL EXAMINATION

PHYSEXAM_2

NONE ❑

Date performed: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
day month year

- Were there any clinically significant changes from the previous evaluation? Yes* ❑ No ❑

**If yes, please complete Adverse Event form.*

See Page 27

VITAL SIGNS

VITAL_1

NOT DONE ❑

Weight: ⌊_⌋⌊_⌋⌊_⌋ . ⌊_⌋ kg

- Blood pressure: Systolic ⌊_⌋⌊_⌋⌊_⌋ mmHg / Diastolic ⌊_⌋⌊_⌋⌊_⌋ mmHg

- Heart rate: ⌊_⌋⌊_⌋⌊_⌋ beats/min

- Temperature: ⌊_⌋⌊_⌋ . ⌊_⌋ °C

(tick appropriate box): Oral ❑ Rectal ❑ Auricular ❑

ECOG Performance Status

0	1	2	3	4
❑	❑	❑	❑	❑

See Page 24

HEMATOLOGY

LABH_1

Date of sampling: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
day month year

TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
WBC		10^9/L	
RBC		10^6/mm^3	
Neutrophils		10^9/L	
Eosinophils		10^9/L	
Basophils		10^9/L	
Monocytes		10^9/L	
Lymphocytes		10^9/L	
Platelets		10^9/L	
Hemoglobin		g/dL	

See Page 26

PSA

LABH_1

DATE OF SAMPLING (day month year)	TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	PSA		ng/mL	

See Page 25

BIOCHEMISTRY

LABB_1

Date of sampling: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
day month year

TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
Sodium		mmol/L	
Potassium		mmol/L	
SGOT (AST)		U/L	
SGPT (ALT)		U/L	
Alkaline phosphatase		U/L	
Total bilirubin		mg/dL	
BUN		mg/dL	
Creatinine		mg/dL	
Glucose		mg/dL	
Chloride		mmol/L	
Bicarbonate		mmol/L	

See Page 24

HEMATOLOGY

LABH_1

Date of sampling: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
day month year

TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
WBC		10^9/L	
RBC		10^6/mm^3	
Neutrophils		10^9/L	
Eosinophils		10^9/L	
Basophils		10^9/L	
Monocytes		10^9/L	
Lymphocytes		10^9/L	
Platelets		10^9/L	
Hemoglobin		g/dL	

See Page 24

HEMATOLOGY

LABH_1

Date of sampling: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
day month year

TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
WBC		10^9/L	
RBC		10^6/mm^3	
Neutrophils		10^9/L	
Eosinophils		10^9/L	
Basophils		10^9/L	
Monocytes		10^9/L	
Lymphocytes		10^9/L	
Platelets		10^9/L	
Hemoglobin		g/dL	

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SPECIFIC CONCOMITANT MEDICATION *SPMED_1*

None ❑

- Please record all premedication administered prior to study drug XRP6258 or Mitoxantrone infusion or tick "None".

	MEDICATION	DOSAGE		START DATE	END DATE
		Number of Units	Unit	day month year	day month year
1				␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣
2				␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣
3				␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣
4				␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣
5				␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣
6				␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣
7				␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣
8				␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣
9				␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣
10				␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣

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INVESTIGATIONAL PRODUCT ADMINISTRATION *ADMIN_1*

TREATMENT NAME	DATE AND TIME OF DOSING (day, month, year, 24-hour clock)	INTENDED DOSE (mg/m^2)	ACTUAL DOSE GIVEN (mg)
❑ XRP6258 ❑ Mitoxantrone	Start ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋ : ⌊_⌋⌊_⌋ End ⌊_⌋⌊_⌋ : ⌊_⌋⌊_⌋		
IF DOSE DELAYED AND/OR REDUCED AND/OR INTERRUPTED, SPECIFY REASON:			
❑ AE: Specify on AE form ❑ Other: _____			

IF DOSE INTERRUPTED, complete below:

TREATMENT NAME	DATE AND TIME OF DOSING (day, month, year, 24-hour clock)	INTENDED DOSE (mg/m^2)	ACTUAL DOSE GIVEN (mg)
❑ XRP6258 ❑ Mitoxantrone	Start ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋ : ⌊_⌋⌊_⌋ End ⌊_⌋⌊_⌋ : ⌊_⌋⌊_⌋	NA	

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INVESTIGATIONAL PRODUCT ADMINISTRATION *ADMIN_1*

TREATMENT NAME	DATE OF DOSING (day month year)	INTENDED DOSE (mg)	ACTUAL DOSE GIVEN (mg)
❑ Prednisone ❑ Prednisolone	Start ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ End ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋		

IF DOSE DELAYED AND/OR REDUCED AND/OR INTERRUPTED, SPECIFY REASON:

❑ AE: Specify on AE form

❑ Other: _____

IF DOSE INTERRUPTED, complete below:

TREATMENT NAME	DATE OF DOSING (day month year)	INTENDED DOSE (mg)	ACTUAL DOSE GIVEN (mg)
❑ Prednisone ❑ Prednisolone	Start ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ End ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	NA	

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BATCH NUMBERS

O.BATCH_1

	DRUG NAME	BATCH NUMBER
1		
2		
3		
4		
5		

*** Location:**

01	Skin	12	Liver	22	Mediastinum
02	Muscle/Soft Tissue	13	Stomach	23	Uterus
03	Bone	14	Pancreas	24	Abdomen
04	Bone Marrow	15	Kidneys	25	Gastrointestinal Tract
05	Peripheral Blood Stream	16	Ovaries	26	Pelvis
06	Brain/CNS	16.01	Fallopian Tubes	27	Peritoneum
07	Head/Neck	17	Bladder	28	Testis
08	Esophagus	18	Prostate	29	Thorax
09	Breast	19	Cervix	29.01	Pleura
10	Lungs	20.10	Colon	30	Other
11.01	Regional Lymph Nodes	20.20	Rectum		
11.02	Distant Lymph Nodes	21	Adrenal		

**** Method of Measurement Codes:**

1 - CT Scan	3 - MRI	5 - Scintigraphy
2 - Spiral CT	4 - PET	7 - Ultrasound
8 - X-Ray	10 - Physical Exam	99 - Other

*****Response of Non-Target Codes:**

CR - Complete Response	IR/SD - Incomplete Response/Stable Disease	PD - Progressive Disease
NL - New Lesion	NE - Not Evaluable	

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TUMOR MEASUREMENTS

O.ASSESS_3

☐ NOT DONE

LESION NUMBER	LOCATION SITE*	DATE OF ASSESSMENT Day Month Year	METHOD OF MEASUREMENT**	MEASUREMENT OF TARGET LESION: longest diameter	RESPONSE OF NON-TARGET LESIONS***
1	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ☐ Not Done	␣␣	␣␣␣ mm	␣␣
2	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ☐ Not Done	␣␣	␣␣␣ mm	␣␣
3	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ☐ Not Done	␣␣	␣␣␣ mm	␣␣
4	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ☐ Not Done	␣␣	␣␣␣ mm	␣␣
5	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ☐ Not Done	␣␣	␣␣␣ mm	␣␣
6	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ☐ Not Done	␣␣	␣␣␣ mm	␣␣
7	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ☐ Not Done	␣␣	␣␣␣ mm	␣␣
8	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ☐ Not Done	␣␣	␣␣␣ mm	␣␣
9	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ☐ Not Done	␣␣	␣␣␣ mm	␣␣
10	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ☐ Not Done	␣␣	␣␣␣ mm	␣␣
11	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ☐ Not Done	␣␣	␣␣␣ mm	␣␣
12	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ☐ Not Done	␣␣	␣␣␣ mm	␣␣
13	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ☐ Not Done	␣␣	␣␣␣ mm	␣␣
14	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ☐ Not Done	␣␣	␣␣␣ mm	␣␣

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PAIN INTENSITY ASSESSMENT

PAINVAS1

Date corresponds to current cycle (7 days prior to dosing Day 1)

Date (Day Month Year)	PPI	Analgesic Score
1. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
2. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
3. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
4. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
5. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
6. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
7. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣

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ECHOCARDIOGRAPHY *ECHOCARD_1*

NOT DONE ❑

- Date performed: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
  day month year

- **2D-Echocardiography:** Normal ❑ Abnormal* ❑

- Left ventricular ejection fraction (LVEF) ⌊_⌋⌊_⌋ . ⌊_⌋ %

- Lower Limit Normal of LVEF ⌊_⌋⌊_⌋ . ⌊_⌋ %

* ***If clinically relevant, please complete the Adverse Event form.***

RADIONUCLIDE VENTRICULOGRAPHY *MUGA_1*

NOT DONE ❑

- Date performed: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
  day month year

- **Radionuclide Ventriculographyy:** Normal ❑ Abnormal* ❑

- Left ventricular ejection fraction (LVEF) ⌊_⌋⌊_⌋ . ⌊_⌋ %

- Lower Limit Normal of LVEF ⌊_⌋⌊_⌋ . ⌊_⌋ %

* ***If clinically relevant, please complete the Adverse Event form.***

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CONCOMITANT MEDICATION

O.MED_9

❑ NONE

Tick the box if no medication(s) has been taken concomitantly with study drug.

	MEDICATION	START DATE Day Month Year	END DATE Day Month Year
1.		❑ Ongoing	❑ Ongoing
2.		❑ Ongoing	❑ Ongoing
3.		❑ Ongoing	❑ Ongoing
4.		❑ Ongoing	❑ Ongoing
5.		❑ Ongoing	❑ Ongoing
6.		❑ Ongoing	❑ Ongoing
7.		❑ Ongoing	❑ Ongoing
8.		❑ Ongoing	❑ Ongoing
9.		❑ Ongoing	❑ Ongoing
10.		❑ Ongoing	❑ Ongoing

See Page 60

CONCOMITANT MEDICATION

O.MED_9

	MEDICATION	START DATE Day Month Year	END DATE Day Month Year
1.		❑ Ongoing	❑ Ongoing
2.		❑ Ongoing	❑ Ongoing
3.		❑ Ongoing	❑ Ongoing
4.		❑ Ongoing	❑ Ongoing
5.		❑ Ongoing	❑ Ongoing
6.		❑ Ongoing	❑ Ongoing
7.		❑ Ongoing	❑ Ongoing
8.		❑ Ongoing	❑ Ongoing
9.		❑ Ongoing	❑ Ongoing
10.		❑ Ongoing	❑ Ongoing

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ADVERSE EVENT FORM

O.1_AE_1

☐ NONE

1. ADVERSE EVENT DIAGNOSIS	AE form no: 07-01 AE ref. no: __-__	AE form no: 07-02 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ☐ Date of start: __ __ (day) __ __ __ (month) __ __ __ __ (year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐	1 ☐ Date of start: __ __ (day) __ __ __ (month) __ __ __ __ (year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐
3. GRADE (1 - 4)	1 ☐ 2 ☐ 3 ☐ 4 ☐	1 ☐ 2 ☐ 3 ☐ 4 ☐
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ☐ No ☐	Yes ☐ No ☐
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
6. CORRECTIVE TREATMENT/THERAPY	Yes ☐ No ☐	Yes ☐ No ☐
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ☐ / 4 ☐ Date: __ __ (day) __ __ __ (month) __ __ __ __ (year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __ __ (day) __ __ __ (month) __ __ __ __ (year) 6 ☐	1 ☐ / 4 ☐ Date: __ __ (day) __ __ __ (month) __ __ __ __ (year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __ __ (day) __ __ __ (month) __ __ __ __ (year) 6 ☐
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __ __ (day) __ __ __ (month) __ __ __ __ (year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __ __ (day) __ __ __ (month) __ __ __ __ (year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐
Investigator's name, date of report and signature:		Monitoring representative's name, date of receipt:

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 07-03 AE ref. no: __-__	AE form no: 07-04 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: __/__/__ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: __/__/__ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/__ (day/month/year) 6 ❑	1 ❑ / 4 ❑ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/__ (day/month/year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES: - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES: - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:	

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 07-05 AE ref. no: __-__	AE form no: 07-06 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ☐ Date of start: __ __ day __ __ __ month __ __ __ __ year 2 ☐ *(do not complete the remaining items in the column)* 3 ☐	1 ☐ Date of start: __ __ day __ __ __ month __ __ __ __ year 2 ☐ *(do not complete the remaining items in the column)* 3 ☐
3. GRADE (1 - 4)	1 ☐ 2 ☐ 3 ☐ 4 ☐	1 ☐ 2 ☐ 3 ☐ 4 ☐
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ☐ No ☐	Yes ☐ No ☐
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
6. CORRECTIVE TREATMENT/THERAPY	Yes ☐ No ☐	Yes ☐ No ☐
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ☐ / 4 ☐ Date: __ __ day __ __ __ month __ __ __ __ year Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __ __ day __ __ __ month __ __ __ __ year 6 ☐	1 ☐ / 4 ☐ Date: __ __ day __ __ __ month __ __ __ __ year Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __ __ day __ __ __ month __ __ __ __ year 6 ☐
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __ __ day __ __ __ month __ __ __ __ year - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __ __ day __ __ __ month __ __ __ __ year - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐
Investigator's name, date of report and signature:		Monitoring representative's name, date of receipt:

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 07-07 AE ref. no: __-__	AE form no: 07-08 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: __/__/__ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: __/__/__ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/__ (day/month/year) 6 ❑	1 ❑ / 4 ❑ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/__ (day/month/year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:	

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 07-09 AE ref. no: __-__	AE form no: 07-10 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: __/__/__ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: __/__/__ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/__ (day/month/year) 6 ❑	1 ❑ / 4 ❑ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/__ (day/month/year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:	

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 07-11 AE ref. no: __-__	AE form no: 07-12 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: __/__/____ (day / month / year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: __/__/____ (day / month / year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: __/__/____ (day / month / year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/____ (day / month / year) 6 ❑	1 ❑ / 4 ❑ Date: __/__/____ (day / month / year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/____ (day / month / year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __/__/____ (day / month / year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __/__/____ (day / month / year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:	

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: ⌊_⌊_-⌊_⌊_ AE ref. no: ⌊_⌊_-⌊_⌊_	AE form no: ⌊_⌊_-⌊_⌊_ AE ref. no: ⌊_⌊_-⌊_⌊_
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: ⌊_⌊_ ⌊_⌊_⌊_ ⌊_⌊_⌊_⌊_ (day / month / year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: ⌊_⌊_ ⌊_⌊_⌊_ ⌊_⌊_⌊_⌊_ (day / month / year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: ⌊_⌊_ ⌊_⌊_⌊_ ⌊_⌊_⌊_⌊_ (day / month / year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: ⌊_⌊_ ⌊_⌊_⌊_ ⌊_⌊_⌊_⌊_ (day / month / year) 6 ❑	1 ❑ / 4 ❑ Date: ⌊_⌊_ ⌊_⌊_⌊_ ⌊_⌊_⌊_⌊_ (day / month / year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: ⌊_⌊_ ⌊_⌊_⌊_ ⌊_⌊_⌊_⌊_ (day / month / year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES - Date event became serious: ⌊_⌊_ ⌊_⌊_⌊_ ⌊_⌊_⌊_⌊_ (day / month / year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES - Date event became serious: ⌊_⌊_ ⌊_⌊_⌊_ ⌊_⌊_⌊_⌊_ (day / month / year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:		Monitoring representative's name, date of receipt:

** Is there a reasonable possibility that the AE was caused by study treatment?*

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PHYSICAL EXAMINATION

PHYSEXAM_2

NONE ❑

Date performed: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
day month year

- Were there any clinically significant changes from the previous evaluation? Yes* ❑ No ❑

**If yes, please complete Adverse Event form.*

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VITAL SIGNS

VITAL_1

NOT DONE ❑

Weight: ⌊_⌋⌊_⌋⌊_⌋ . ⌊_⌋ kg

- Blood pressure: Systolic ⌊_⌋⌊_⌋⌊_⌋ mmHg / Diastolic ⌊_⌋⌊_⌋⌊_⌋ mmHg

- Heart rate: ⌊_⌋⌊_⌋⌊_⌋ beats/min

- Temperature: ⌊_⌋⌊_⌋ . ⌊_⌋ °C

(tick appropriate box): Oral ❑ Rectal ❑ Auricular ❑

ECOG Performance Status

0	1	2	3	4
❑	❑	❑	❑	❑

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HEMATOLOGY

LABH_1

Date of sampling: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
day month year

TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
WBC		10^9/L	
RBC		10^6/mm^3	
Neutrophils		10^9/L	
Eosinophils		10^9/L	
Basophils		10^9/L	
Monocytes		10^9/L	
Lymphocytes		10^9/L	
Platelets		10^9/L	
Hemoglobin		g/dL	

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PSA

LABH_1

DATE OF SAMPLING (day month year)	TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	PSA		ng/mL	

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BIOCHEMISTRY

LABB_1

Date of sampling: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
day month year

TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
Sodium		mmol/L	
Potassium		mmol/L	
SGOT (AST)		U/L	
SGPT (ALT)		U/L	
Alkaline phosphatase		U/L	
Total bilirubin		mg/dL	
BUN		mg/dL	
Creatinine		mg/dL	
Glucose		mg/dL	
Chloride		mmol/L	
Bicarbonate		mmol/L	

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HEMATOLOGY

LABH_1

Date of sampling: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
day month year

TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
WBC		10^9/L	
RBC		10^6/mm^3	
Neutrophils		10^9/L	
Eosinophils		10^9/L	
Basophils		10^9/L	
Monocytes		10^9/L	
Lymphocytes		10^9/L	
Platelets		10^9/L	
Hemoglobin		g/dL	

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HEMATOLOGY

LABH_1

Date of sampling: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
day month year

TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
WBC		10^9/L	
RBC		10^6/mm^3	
Neutrophils		10^9/L	
Eosinophils		10^9/L	
Basophils		10^9/L	
Monocytes		10^9/L	
Lymphocytes		10^9/L	
Platelets		10^9/L	
Hemoglobin		g/dL	

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SPECIFIC CONCOMITANT MEDICATION *SPMED_1*

None ❑

- Please record all premedication administered prior to study drug XRP6258 or Mitoxantrone infusion or tick "None".

	MEDICATION	DOSAGE		START DATE	END DATE
		Number of Units	Unit	day month year	day month year
1				␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣
2				␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣
3				␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣
4				␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣
5				␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣
6				␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣
7				␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣
8				␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣
9				␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣
10				␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣

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INVESTIGATIONAL PRODUCT ADMINISTRATION *ADMIN_1*

TREATMENT NAME	DATE AND TIME OF DOSING day month year 24-hour clock	INTENDED DOSE (mg/m^2)	ACTUAL DOSE GIVEN (mg)
❑ XRP6258 ❑ Mitoxantrone	Start ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋ : ⌊_⌋⌊_⌋ End ⌊_⌋⌊_⌋ : ⌊_⌋⌊_⌋		
IF DOSE DELAYED AND/OR REDUCED AND/OR INTERRUPTED, SPECIFY REASON:			
❑ AE: Specify on AE form ❑ Other: _____			

IF DOSE INTERRUPTED, complete below:

TREATMENT NAME	DATE AND TIME OF DOSING day month year 24-hour clock	INTENDED DOSE (mg/m^2)	ACTUAL DOSE GIVEN (mg)
❑ XRP6258 ❑ Mitoxantrone	Start ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋ : ⌊_⌋⌊_⌋ End ⌊_⌋⌊_⌋ : ⌊_⌋⌊_⌋	NA	

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INVESTIGATIONAL PRODUCT ADMINISTRATION

ADMIN_1

TREATMENT NAME	DATE OF DOSING (day month year)	INTENDED DOSE (mg)	ACTUAL DOSE GIVEN (mg)
❑ Prednisone ❑ Prednisolone	Start ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ End ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋		

IF DOSE DELAYED AND/OR REDUCED AND/OR INTERRUPTED, SPECIFY REASON:

❑ AE: Specify on AE form

❑ Other: _____

IF DOSE INTERRUPTED, complete below:

TREATMENT NAME	DATE OF DOSING (day month year)	INTENDED DOSE (mg)	ACTUAL DOSE GIVEN (mg)
❑ Prednisone ❑ Prednisolone	Start ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ End ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	NA	

See Page 51

BATCH NUMBERS

O.BATCH_1

	DRUG NAME	BATCH NUMBER
1		
2		
3		
4		
5		

*** Location:**

01	Skin	12	Liver	22	Mediastinum
02	Muscle/Soft Tissue	13	Stomach	23	Uterus
03	Bone	14	Pancreas	24	Abdomen
04	Bone Marrow	15	Kidneys	25	Gastrointestinal Tract
05	Peripheral Blood Stream	16	Ovaries	26	Pelvis
06	Brain/CNS	16.01	Fallopian Tubes	27	Peritoneum
07	Head/Neck	17	Bladder	28	Testis
08	Esophagus	18	Prostate	29	Thorax
09	Breast	19	Cervix	29.01	Pleura
10	Lungs	20.10	Colon	30	Other
11.01	Regional Lymph Nodes	20.20	Rectum		
11.02	Distant Lymph Nodes	21	Adrenal		

**** Method of Measurement Codes:**

1 - CT Scan	3 - MRI	5 - Scintigraphy
2 - Spiral CT	4 - PET	7 - Ultrasound
8 - X-Ray	10 - Physical Exam	99 - Other

*****Response of Non-Target Codes:**

CR - Complete Response	IR/SD - Incomplete Response/Stable Disease	PD - Progressive Disease
NL - New Lesion	NE - Not Evaluable	

See Page 55

TUMOR MEASUREMENTS

O.ASSESS_3

❑ NOT DONE

LESION NUMBER	LOCATION SITE*	DATE OF ASSESSMENT Day Month Year	METHOD OF MEASUREMENT**	MEASUREMENT OF TARGET LESION: longest diameter	RESPONSE OF NON-TARGET LESIONS***
1	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
2	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
3	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
4	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
5	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
6	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
7	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
8	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
9	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
10	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
11	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
12	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
13	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
14	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣

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PAIN INTENSITY ASSESSMENT

PAINVAS1

Date corresponds to current cycle (7 days prior to dosing Day 1)

Date (Day Month Year)	PPI	Analgesic Score
1. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
2. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
3. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
4. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
5. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
6. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
7. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣

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ECHOCARDIOGRAPHY

ECHOCARD_1

NOT DONE ❑

- Date performed: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
  day month year

- **2D-Echocardiography:** Normal ❑ Abnormal* ❑

- Left ventricular ejection fraction (LVEF) ⌊_⌋⌊_⌋ . ⌊_⌋ %

- Lower Limit Normal of LVEF ⌊_⌋⌊_⌋ . ⌊_⌋ %

* ***If clinically relevant, please complete the Adverse Event form.***

RADIONUCLIDE VENTRICULOGRAPHY

MUGA_1

NOT DONE ❑

- Date performed: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
  day month year

- **Radionuclide Ventriculographyy:** Normal ❑ Abnormal* ❑

- Left ventricular ejection fraction (LVEF) ⌊_⌋⌊_⌋ . ⌊_⌋ %

- Lower Limit Normal of LVEF ⌊_⌋⌊_⌋ . ⌊_⌋ %

* ***If clinically relevant, please complete the Adverse Event form.***

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CONCOMITANT MEDICATION

O.MED_9

❑ NONE

Tick the box if no medication(s) has been taken concomitantly with study drug.

	MEDICATION	START DATE Day Month Year	END DATE Day Month Year
1.		❑ Ongoing	❑ Ongoing
2.		❑ Ongoing	❑ Ongoing
3.		❑ Ongoing	❑ Ongoing
4.		❑ Ongoing	❑ Ongoing
5.		❑ Ongoing	❑ Ongoing
6.		❑ Ongoing	❑ Ongoing
7.		❑ Ongoing	❑ Ongoing
8.		❑ Ongoing	❑ Ongoing
9.		❑ Ongoing	❑ Ongoing
10.		❑ Ongoing	❑ Ongoing

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CONCOMITANT MEDICATION

O.MED_9

	MEDICATION	START DATE Day Month Year	END DATE Day Month Year
1.		❑ Ongoing	❑ Ongoing
2.		❑ Ongoing	❑ Ongoing
3.		❑ Ongoing	❑ Ongoing
4.		❑ Ongoing	❑ Ongoing
5.		❑ Ongoing	❑ Ongoing
6.		❑ Ongoing	❑ Ongoing
7.		❑ Ongoing	❑ Ongoing
8.		❑ Ongoing	❑ Ongoing
9.		❑ Ongoing	❑ Ongoing
10.		❑ Ongoing	❑ Ongoing

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ADVERSE EVENT FORM

O.1_AE_1

❑ NONE

1. ADVERSE EVENT DIAGNOSIS	AE form no: 08-01 AE ref. no: ___-___	AE form no: 08-02 AE ref. no: ___-___
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: ___ ___ ___ (day / month / year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: ___ ___ ___ (day / month / year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: ___ ___ ___ (day / month / year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: ___ ___ ___ (day / month / year) 6 ❑	1 ❑ / 4 ❑ Date: ___ ___ ___ (day / month / year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: ___ ___ ___ (day / month / year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES - Date event became serious: ___ ___ ___ (day / month / year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES - Date event became serious: ___ ___ ___ (day / month / year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:		Monitoring representative's name, date of receipt:

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 08-03 AE ref. no: __-__	AE form no: 08-04 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: __/__/__ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: __/__/__ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/__ (day/month/year) 6 ❑	1 ❑ / 4 ❑ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/__ (day/month/year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES: - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES: - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:	

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 08-05 AE ref. no: __-__	AE form no: 08-06 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: __/__/__ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: __/__/__ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/__ (day/month/year) 6 ❑	1 ❑ / 4 ❑ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/__ (day/month/year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES: - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES: - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:		Monitoring representative's name, date of receipt:

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 08-07 AE ref. no: __-__	AE form no: 08-08 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: __/__/__ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: __/__/__ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/__ (day/month/year) 6 ❑	1 ❑ / 4 ❑ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/__ (day/month/year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:	

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 08-09 AE ref. no: __-__	AE form no: 08-10 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: __/__/____ (day / month / year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: __/__/____ (day / month / year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: __/__/____ (day / month / year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/____ (day / month / year) 6 ❑	1 ❑ / 4 ❑ Date: __/__/____ (day / month / year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/____ (day / month / year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __/__/____ (day / month / year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __/__/____ (day / month / year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:	

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 08-11 AE ref. no: __-__	AE form no: 08-12 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: __/__/__ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: __/__/__ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/__ (day/month/year) 6 ❑	1 ❑ / 4 ❑ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/__ (day/month/year) 6 ❑
8. SERIOUSNESS CRITERIA IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:	

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: ␣␣-␣␣ AE ref. no: ␣␣-␣␣	AE form no: ␣␣-␣␣ AE ref. no: ␣␣-␣␣
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) 6 ❑	1 ❑ / 4 ❑ Date: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES - Date event became serious: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES - Date event became serious: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:	

** Is there a reasonable possibility that the AE was caused by study treatment?*

See Page 43

PHYSICAL EXAMINATION

PHYSEXAM_2

NONE ❑

Date performed: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
day month year

- Were there any clinically significant changes from the previous evaluation? Yes* ❑ No ❑

**If yes, please complete Adverse Event form.*

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VITAL SIGNS

VITAL_1

NOT DONE ❑

Weight: ⌊_⌋⌊_⌋⌊_⌋ . ⌊_⌋ kg

- Blood pressure: Systolic ⌊_⌋⌊_⌋⌊_⌋ mmHg / Diastolic ⌊_⌋⌊_⌋⌊_⌋ mmHg

- Heart rate: ⌊_⌋⌊_⌋⌊_⌋ beats/min

- Temperature: ⌊_⌋⌊_⌋ . ⌊_⌋ °C

(tick appropriate box): Oral ❑ Rectal ❑ Auricular ❑

ECOG Performance Status

0	1	2	3	4
❑	❑	❑	❑	❑

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HEMATOLOGY

LABH_1

Date of sampling: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
day month year

TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
WBC		10^9/L	
RBC		10^6/mm^3	
Neutrophils		10^9/L	
Eosinophils		10^9/L	
Basophils		10^9/L	
Monocytes		10^9/L	
Lymphocytes		10^9/L	
Platelets		10^9/L	
Hemoglobin		g/dL	

See Page 26

PSA

LABH_1

DATE OF SAMPLING (day month year)	TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	PSA		ng/mL	

See Page 25

BIOCHEMISTRY

LABB_1

Date of sampling: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
day month year

TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
Sodium		mmol/L	
Potassium		mmol/L	
SGOT (AST)		U/L	
SGPT (ALT)		U/L	
Alkaline phosphatase		U/L	
Total bilirubin		mg/dL	
BUN		mg/dL	
Creatinine		mg/dL	
Glucose		mg/dL	
Chloride		mmol/L	
Bicarbonate		mmol/L	

See Page 24

HEMATOLOGY

LABH_1

Date of sampling: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
day month year

TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
WBC		10^9/L	
RBC		10^6/mm^3	
Neutrophils		10^9/L	
Eosinophils		10^9/L	
Basophils		10^9/L	
Monocytes		10^9/L	
Lymphocytes		10^9/L	
Platelets		10^9/L	
Hemoglobin		g/dL	

See Page 24

HEMATOLOGY

LABH_1

Date of sampling: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
day month year

TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
WBC		10^9/L	
RBC		10^6/mm^3	
Neutrophils		10^9/L	
Eosinophils		10^9/L	
Basophils		10^9/L	
Monocytes		10^9/L	
Lymphocytes		10^9/L	
Platelets		10^9/L	
Hemoglobin		g/dL	

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SPECIFIC CONCOMITANT MEDICATION *SPMED_1*

None ❑

- Please record all premedication administered prior to study drug XRP6258 or Mitoxantrone infusion or tick "None".

	MEDICATION	DOSAGE		START DATE	END DATE
		Number of Units	Unit	day month year	day month year
1				␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣
2				␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣
3				␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣
4				␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣
5				␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣
6				␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣
7				␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣
8				␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣
9				␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣
10				␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣

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INVESTIGATIONAL PRODUCT ADMINISTRATION *ADMIN_1*

TREATMENT NAME	DATE AND TIME OF DOSING day month year 24-hour clock	INTENDED DOSE (mg/m^2)	ACTUAL DOSE GIVEN (mg)
❑ XRP6258 ❑ Mitoxantrone	Start ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋ : ⌊_⌋⌊_⌋ End ⌊_⌋⌊_⌋ : ⌊_⌋⌊_⌋		
IF DOSE DELAYED AND/OR REDUCED AND/OR INTERRUPTED, SPECIFY REASON:			
❑ AE: Specify on AE form ❑ Other: _____			

IF DOSE INTERRUPTED, complete below:

TREATMENT NAME	DATE AND TIME OF DOSING day month year 24-hour clock	INTENDED DOSE (mg/m^2)	ACTUAL DOSE GIVEN (mg)
❑ XRP6258 ❑ Mitoxantrone	Start ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋ : ⌊_⌋⌊_⌋ End ⌊_⌋⌊_⌋ : ⌊_⌋⌊_⌋	NA	

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INVESTIGATIONAL PRODUCT ADMINISTRATION *ADMIN_1*

TREATMENT NAME	DATE OF DOSING (day month year)	INTENDED DOSE (mg)	ACTUAL DOSE GIVEN (mg)
❑ Prednisone ❑ Prednisolone	Start ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ End ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋		

IF DOSE DELAYED AND/OR REDUCED AND/OR INTERRUPTED, SPECIFY REASON:

❑ AE: Specify on AE form

❑ Other: _____

IF DOSE INTERRUPTED, complete below:

TREATMENT NAME	DATE OF DOSING (day month year)	INTENDED DOSE (mg)	ACTUAL DOSE GIVEN (mg)
❑ Prednisone ❑ Prednisolone	Start ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ End ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	NA	

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BATCH NUMBERS

O.BATCH_1

	DRUG NAME	BATCH NUMBER
1		
2		
3		
4		
5		

*** Location:**

01	Skin	12	Liver	22	Mediastinum
02	Muscle/Soft Tissue	13	Stomach	23	Uterus
03	Bone	14	Pancreas	24	Abdomen
04	Bone Marrow	15	Kidneys	25	Gastrointestinal Tract
05	Peripheral Blood Stream	16	Ovaries	26	Pelvis
06	Brain/CNS	16.01	Fallopian Tubes	27	Peritoneum
07	Head/Neck	17	Bladder	28	Testis
08	Esophagus	18	Prostate	29	Thorax
09	Breast	19	Cervix	29.01	Pleura
10	Lungs	20.10	Colon	30	Other
11.01	Regional Lymph Nodes	20.20	Rectum		
11.02	Distant Lymph Nodes	21	Adrenal		

**** Method of Measurement Codes:**

1 - CT Scan	3 - MRI	5 - Scintigraphy
2 - Spiral CT	4 - PET	7 - Ultrasound
8 - X-Ray	10 - Physical Exam	99 - Other

*****Response of Non-Target Codes:**

CR - Complete Response	IR/SD - Incomplete Response/Stable Disease	PD - Progressive Disease
NL - New Lesion	NE - Not Evaluable	

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TUMOR MEASUREMENTS

O.ASSESS_3

❑ NOT DONE

LESION NUMBER	LOCATION SITE*	DATE OF ASSESSMENT Day Month Year	METHOD OF MEASUREMENT**	MEASUREMENT OF TARGET LESION: longest diameter	RESPONSE OF NON-TARGET LESIONS***
1	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
2	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
3	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
4	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
5	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
6	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
7	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
8	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
9	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
10	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
11	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
12	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
13	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
14	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣

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PAIN INTENSITY ASSESSMENT *PAINVAS1*

Date corresponds to current cycle (7 days prior to dosing Day 1)

Date (Day Month Year)	PPI	Analgesic Score
1. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
2. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
3. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
4. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
5. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
6. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
7. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣

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ECHOCARDIOGRAPHY *ECHOCARD_1*

NOT DONE ❑

- Date performed: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
  day month year

- **2D-Echocardiography:** Normal ❑ Abnormal* ❑

- Left ventricular ejection fraction (LVEF) ⌊_⌋⌊_⌋ . ⌊_⌋ %

- Lower Limit Normal of LVEF ⌊_⌋⌊_⌋ . ⌊_⌋ %

* ***If clinically relevant, please complete the Adverse Event form.***

RADIONUCLIDE VENTRICULOGRAPHY *MUGA_1*

NOT DONE ❑

- Date performed: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
  day month year

- **Radionuclide Ventriculographyy:** Normal ❑ Abnormal* ❑

- Left ventricular ejection fraction (LVEF) ⌊_⌋⌊_⌋ . ⌊_⌋ %

- Lower Limit Normal of LVEF ⌊_⌋⌊_⌋ . ⌊_⌋ %

* ***If clinically relevant, please complete the Adverse Event form.***

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CONCOMITANT MEDICATION

O.MED_9

❑ NONE

Tick the box if no medication(s) has been taken concomitantly with study drug.

	MEDICATION	START DATE Day Month Year	END DATE Day Month Year
1.		❑ Ongoing	❑ Ongoing
2.		❑ Ongoing	❑ Ongoing
3.		❑ Ongoing	❑ Ongoing
4.		❑ Ongoing	❑ Ongoing
5.		❑ Ongoing	❑ Ongoing
6.		❑ Ongoing	❑ Ongoing
7.		❑ Ongoing	❑ Ongoing
8.		❑ Ongoing	❑ Ongoing
9.		❑ Ongoing	❑ Ongoing
10.		❑ Ongoing	❑ Ongoing

See Page 60

CONCOMITANT MEDICATION

O.MED_9

	MEDICATION	START DATE Day Month Year	END DATE Day Month Year
1.		❑ Ongoing	❑ Ongoing
2.		❑ Ongoing	❑ Ongoing
3.		❑ Ongoing	❑ Ongoing
4.		❑ Ongoing	❑ Ongoing
5.		❑ Ongoing	❑ Ongoing
6.		❑ Ongoing	❑ Ongoing
7.		❑ Ongoing	❑ Ongoing
8.		❑ Ongoing	❑ Ongoing
9.		❑ Ongoing	❑ Ongoing
10.		❑ Ongoing	❑ Ongoing

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ADVERSE EVENT FORM

O.1_AE_1

❑ NONE

1. ADVERSE EVENT DIAGNOSIS	AE form no: 09-01 AE ref. no: __-__	AE form no: 09-02 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: __/__/____ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: __/__/____ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: __/__/____ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/____ (day/month/year) 6 ❑	1 ❑ / 4 ❑ Date: __/__/____ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/____ (day/month/year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __/__/____ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __/__/____ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:	

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 09-03 AE ref. no: __-__	AE form no: 09-04 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: __/__/__ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: __/__/__ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/__ (day/month/year) 6 ❑	1 ❑ / 4 ❑ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/__ (day/month/year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:	

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 09-05 AE ref. no: __-__	AE form no: 09-06 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: __/__/__ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: __/__/__ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/__ (day/month/year) 6 ❑	1 ❑ / 4 ❑ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/__ (day/month/year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES: - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES: - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:		Monitoring representative's name, date of receipt:

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 09-07 AE ref. no: __-__	AE form no: 09-08 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: __/__/__ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: __/__/__ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/__ (day/month/year) 6 ❑	1 ❑ / 4 ❑ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/__ (day/month/year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES: - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES: - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:		Monitoring representative's name, date of receipt:

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 09-09 AE ref. no: __-__	AE form no: 09-10 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: __/__/____ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: __/__/____ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: __/__/____ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/____ (day/month/year) 6 ❑	1 ❑ / 4 ❑ Date: __/__/____ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/____ (day/month/year) 6 ❑
8. SERIOUSNESS CRITERIA IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __/__/____ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __/__/____ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:	

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 09-11 AE ref. no: __-__	AE form no: 09-12 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ☐ Date of start: __/__/__ (day/month/year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐	1 ☐ Date of start: __/__/__ (day/month/year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐
3. GRADE (1 - 4)	1 ☐ 2 ☐ 3 ☐ 4 ☐	1 ☐ 2 ☐ 3 ☐ 4 ☐
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ☐ No ☐	Yes ☐ No ☐
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
6. CORRECTIVE TREATMENT/THERAPY	Yes ☐ No ☐	Yes ☐ No ☐
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ☐ / 4 ☐ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __/__/__ (day/month/year) 6 ☐	1 ☐ / 4 ☐ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __/__/__ (day/month/year) 6 ☐
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐

Investigator's name, date of report and signature:

Monitoring representative's name, date of receipt:

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: ␣␣-␣␣ AE ref. no: ␣␣-␣␣	AE form no: ␣␣-␣␣ AE ref. no: ␣␣-␣␣
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) 6 ❑	1 ❑ / 4 ❑ Date: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES - Date event became serious: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES - Date event became serious: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:	

** Is there a reasonable possibility that the AE was caused by study treatment?*

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PHYSICAL EXAMINATION

PHYSEXAM_2

NONE ❑

Date performed: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
day month year

- Were there any clinically significant changes from the previous evaluation? Yes* ❑ No ❑

**If yes, please complete Adverse Event form.*

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VITAL SIGNS

VITAL_1

NOT DONE ❑

Weight: ⌊_⌋⌊_⌋⌊_⌋ . ⌊_⌋ kg

- Blood pressure: Systolic ⌊_⌋⌊_⌋⌊_⌋ mmHg / Diastolic ⌊_⌋⌊_⌋⌊_⌋ mmHg

- Heart rate: ⌊_⌋⌊_⌋⌊_⌋ beats/min

- Temperature: ⌊_⌋⌊_⌋ . ⌊_⌋ °C

(tick appropriate box): Oral ❑ Rectal ❑ Auricular ❑

ECOG Performance Status

0	1	2	3	4
❑	❑	❑	❑	❑

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HEMATOLOGY

LABH_1

Date of sampling: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
day month year

TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
WBC		10^9/L	
RBC		10^6/mm^3	
Neutrophils		10^9/L	
Eosinophils		10^9/L	
Basophils		10^9/L	
Monocytes		10^9/L	
Lymphocytes		10^9/L	
Platelets		10^9/L	
Hemoglobin		g/dL	

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PSA

LABH_1

DATE OF SAMPLING (day month year)	TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	PSA		ng/mL	

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BIOCHEMISTRY

LABB_1

Date of sampling: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
day month year

TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
Sodium		mmol/L	
Potassium		mmol/L	
SGOT (AST)		U/L	
SGPT (ALT)		U/L	
Alkaline phosphatase		U/L	
Total bilirubin		mg/dL	
BUN		mg/dL	
Creatinine		mg/dL	
Glucose		mg/dL	
Chloride		mmol/L	
Bicarbonate		mmol/L	

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HEMATOLOGY

LABH_1

Date of sampling: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
day month year

TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
WBC		10^9/L	
RBC		10^6/mm^3	
Neutrophils		10^9/L	
Eosinophils		10^9/L	
Basophils		10^9/L	
Monocytes		10^9/L	
Lymphocytes		10^9/L	
Platelets		10^9/L	
Hemoglobin		g/dL	

See Page 24

HEMATOLOGY

LABH_1

Date of sampling: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
day month year

TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
WBC		10^9/L	
RBC		10^6/mm^3	
Neutrophils		10^9/L	
Eosinophils		10^9/L	
Basophils		10^9/L	
Monocytes		10^9/L	
Lymphocytes		10^9/L	
Platelets		10^9/L	
Hemoglobin		g/dL	

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SPECIFIC CONCOMITANT MEDICATION *SPMED_1*

None ❑

- Please record all premedication administered prior to study drug XRP6258 or Mitoxantrone infusion or tick "None".

	MEDICATION	DOSAGE		START DATE	END DATE
		Number of Units	Unit	day month year	day month year
1				␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣
2				␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣
3				␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣
4				␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣
5				␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣
6				␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣
7				␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣
8				␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣
9				␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣
10				␣␣ ␣␣␣␣ ␣␣␣␣	␣␣ ␣␣␣␣ ␣␣␣␣

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INVESTIGATIONAL PRODUCT ADMINISTRATION *ADMIN_1*

TREATMENT NAME	DATE AND TIME OF DOSING day month year 24-hour clock	INTENDED DOSE (mg/m^2)	ACTUAL DOSE GIVEN (mg)
❑ XRP6258 ❑ Mitoxantrone	Start ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋ : ⌊_⌋⌊_⌋ End ⌊_⌋⌊_⌋ : ⌊_⌋⌊_⌋		
IF DOSE DELAYED AND/OR REDUCED AND/OR INTERRUPTED, SPECIFY REASON:			
❑ AE: Specify on AE form ❑ Other: _____			

IF DOSE INTERRUPTED, complete below:

TREATMENT NAME	DATE AND TIME OF DOSING day month year 24-hour clock	INTENDED DOSE (mg/m^2)	ACTUAL DOSE GIVEN (mg)
❑ XRP6258 ❑ Mitoxantrone	Start ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋ : ⌊_⌋⌊_⌋ End ⌊_⌋⌊_⌋ : ⌊_⌋⌊_⌋	NA	

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INVESTIGATIONAL PRODUCT ADMINISTRATION *ADMIN_1*

TREATMENT NAME	DATE OF DOSING (day month year)	INTENDED DOSE (mg)	ACTUAL DOSE GIVEN (mg)
❑ Prednisone ❑ Prednisolone	Start ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ End ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋		
IF DOSE DELAYED AND/OR REDUCED AND/OR INTERRUPTED, SPECIFY REASON:			
❑ AE: Specify on AE form ❑ Other: _____			

IF DOSE INTERRUPTED, complete below:

TREATMENT NAME	DATE OF DOSING (day month year)	INTENDED DOSE (mg)	ACTUAL DOSE GIVEN (mg)
❑ Prednisone ❑ Prednisolone	Start ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ End ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	NA	

See Page 51

BATCH NUMBERS

O.BATCH_1

	DRUG NAME	BATCH NUMBER
1		
2		
3		
4		
5		

*** Location:**

01	Skin	12	Liver	22	Mediastinum
02	Muscle/Soft Tissue	13	Stomach	23	Uterus
03	Bone	14	Pancreas	24	Abdomen
04	Bone Marrow	15	Kidneys	25	Gastrointestinal Tract
05	Peripheral Blood Stream	16	Ovaries	26	Pelvis
06	Brain/CNS	16.01	Fallopian Tubes	27	Peritoneum
07	Head/Neck	17	Bladder	28	Testis
08	Esophagus	18	Prostate	29	Thorax
09	Breast	19	Cervix	29.01	Pleura
10	Lungs	20.10	Colon	30	Other
11.01	Regional Lymph Nodes	20.20	Rectum		
11.02	Distant Lymph Nodes	21	Adrenal		

**** Method of Measurement Codes:**

1 - CT Scan	3 - MRI	5 - Scintigraphy
2 - Spiral CT	4 - PET	7 - Ultrasound
8 - X-Ray	10 - Physical Exam	99 - Other

*****Response of Non-Target Codes:**

CR - Complete Response	IR/SD - Incomplete Response/Stable Disease	PD - Progressive Disease
NL - New Lesion	NE - Not Evaluable	

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TUMOR MEASUREMENTS

O.ASSESS_3

❑ NOT DONE

LESION NUMBER	LOCATION SITE*	DATE OF ASSESSMENT Day Month Year	METHOD OF MEASUREMENT**	MEASUREMENT OF TARGET LESION: longest diameter	RESPONSE OF NON-TARGET LESIONS***
1	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
2	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
3	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
4	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
5	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
6	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
7	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
8	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
9	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
10	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
11	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
12	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
13	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
14	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣

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PAIN INTENSITY ASSESSMENT

PAINVAS1

Date corresponds to current cycle (7 days prior to dosing Day 1)

Date (Day Month Year)	PPI	Analgesic Score
1. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
2. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
3. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
4. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
5. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
6. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
7. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣

See Page 29

ECHOCARDIOGRAPHY *ECHOCARD_1*

NOT DONE ❑

- Date performed: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
  day month year

- **2D-Echocardiography:** Normal ❑ Abnormal* ❑

- Left ventricular ejection fraction (LVEF) ⌊_⌋⌊_⌋ . ⌊_⌋ %

- Lower Limit Normal of LVEF ⌊_⌋⌊_⌋ . ⌊_⌋ %

* ***If clinically relevant, please complete the Adverse Event form.***

RADIONUCLIDE VENTRICULOGRAPHY *MUGA_1*

NOT DONE ❑

- Date performed: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
  day month year

- **Radionuclide Ventriculographyy:** Normal ❑ Abnormal* ❑

- Left ventricular ejection fraction (LVEF) ⌊_⌋⌊_⌋ . ⌊_⌋ %

- Lower Limit Normal of LVEF ⌊_⌋⌊_⌋ . ⌊_⌋ %

* ***If clinically relevant, please complete the Adverse Event form.***

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CONCOMITANT MEDICATION

O.MED_9

❑ NONE

Tick the box if no medication(s) has been taken concomitantly with study drug.

	MEDICATION	START DATE Day Month Year	END DATE Day Month Year
1.		❑ Ongoing	❑ Ongoing
2.		❑ Ongoing	❑ Ongoing
3.		❑ Ongoing	❑ Ongoing
4.		❑ Ongoing	❑ Ongoing
5.		❑ Ongoing	❑ Ongoing
6.		❑ Ongoing	❑ Ongoing
7.		❑ Ongoing	❑ Ongoing
8.		❑ Ongoing	❑ Ongoing
9.		❑ Ongoing	❑ Ongoing
10.		❑ Ongoing	❑ Ongoing

See Page 60

CONCOMITANT MEDICATION

O.MED_9

	MEDICATION	START DATE Day Month Year	END DATE Day Month Year
1.		❑ Ongoing	❑ Ongoing
2.		❑ Ongoing	❑ Ongoing
3.		❑ Ongoing	❑ Ongoing
4.		❑ Ongoing	❑ Ongoing
5.		❑ Ongoing	❑ Ongoing
6.		❑ Ongoing	❑ Ongoing
7.		❑ Ongoing	❑ Ongoing
8.		❑ Ongoing	❑ Ongoing
9.		❑ Ongoing	❑ Ongoing
10.		❑ Ongoing	❑ Ongoing

ADVERSE EVENT FORM

O.1_AE_1

☐ NONE

1. ADVERSE EVENT DIAGNOSIS	AE form no: 10-01 AE ref. no: __-__	AE form no: 10-02 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ☐ Date of start: __ __ (day) __ __ __ (month) __ __ __ __ (year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐	1 ☐ Date of start: __ __ (day) __ __ __ (month) __ __ __ __ (year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐
3. GRADE (1 - 4)	1 ☐ 2 ☐ 3 ☐ 4 ☐	1 ☐ 2 ☐ 3 ☐ 4 ☐
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ☐ No ☐	Yes ☐ No ☐
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
6. CORRECTIVE TREATMENT/THERAPY	Yes ☐ No ☐	Yes ☐ No ☐
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ☐ / 4 ☐ Date: __ __ (day) __ __ __ (month) __ __ __ __ (year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __ __ (day) __ __ __ (month) __ __ __ __ (year) 6 ☐	1 ☐ / 4 ☐ Date: __ __ (day) __ __ __ (month) __ __ __ __ (year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __ __ (day) __ __ __ (month) __ __ __ __ (year) 6 ☐
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __ __ (day) __ __ __ (month) __ __ __ __ (year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __ __ (day) __ __ __ (month) __ __ __ __ (year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐
Investigator's name, date of report and signature:		Monitoring representative's name, date of receipt:

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 10-03 AE ref. no: __-__	AE form no: 10-04 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: __/__/__ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: __/__/__ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/__ (day/month/year) 6 ❑	1 ❑ / 4 ❑ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/__ (day/month/year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES: - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES: - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:	

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 10-05 AE ref. no: ___-___	AE form no: 10-06 AE ref. no: ___-___
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: ___ ___ ___ (day / month / year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: ___ ___ ___ (day / month / year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: ___ ___ ___ (day / month / year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: ___ ___ ___ (day / month / year) 6 ❑	1 ❑ / 4 ❑ Date: ___ ___ ___ (day / month / year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: ___ ___ ___ (day / month / year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES: - Date event became serious: ___ ___ ___ (day / month / year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES: - Date event became serious: ___ ___ ___ (day / month / year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:	

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 10-07 AE ref. no: __-__	AE form no: 10-08 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: __/__/__ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: __/__/__ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/__ (day/month/year) 6 ❑	1 ❑ / 4 ❑ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/__ (day/month/year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES: - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES: - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:		Monitoring representative's name, date of receipt:

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 10-09 AE ref. no: ___-___	AE form no: 10-10 AE ref. no: ___-___
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: ___ ___ ___ (day / month / year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: ___ ___ ___ (day / month / year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: ___ ___ ___ (day / month / year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: ___ ___ ___ (day / month / year) 6 ❑	1 ❑ / 4 ❑ Date: ___ ___ ___ (day / month / year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: ___ ___ ___ (day / month / year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES - Date event became serious: ___ ___ ___ (day / month / year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES - Date event became serious: ___ ___ ___ (day / month / year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:	

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 10-11 AE ref. no: __-__	AE form no: 10-12 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ☐ Date of start: __ __ (day) __ __ __ (month) __ __ __ __ (year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐	1 ☐ Date of start: __ __ (day) __ __ __ (month) __ __ __ __ (year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐
3. GRADE (1 - 4)	1 ☐ 2 ☐ 3 ☐ 4 ☐	1 ☐ 2 ☐ 3 ☐ 4 ☐
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ☐ No ☐	Yes ☐ No ☐
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
6. CORRECTIVE TREATMENT/THERAPY	Yes ☐ No ☐	Yes ☐ No ☐
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ☐ / 4 ☐ Date: __ __ (day) __ __ __ (month) __ __ __ __ (year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __ __ (day) __ __ __ (month) __ __ __ __ (year) 6 ☐	1 ☐ / 4 ☐ Date: __ __ (day) __ __ __ (month) __ __ __ __ (year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __ __ (day) __ __ __ (month) __ __ __ __ (year) 6 ☐
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __ __ (day) __ __ __ (month) __ __ __ __ (year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __ __ (day) __ __ __ (month) __ __ __ __ (year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐
Investigator's name, date of report and signature:		Monitoring representative's name, date of receipt:

** Is there a reasonable possibility that the AE was caused by study treatment?*

See Page 62

ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: ␣␣-␣␣ AE ref. no: ␣␣-␣␣	AE form no: ␣␣-␣␣ AE ref. no: ␣␣-␣␣
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) 6 ❑	1 ❑ / 4 ❑ Date: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES - Date event became serious: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES - Date event became serious: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:		Monitoring representative's name, date of receipt:

** Is there a reasonable possibility that the AE was caused by study treatment?*

END OF TREATMENT *O.ENDTT_2*

Main reason for stopping treatment (tick "✓" one box only): <DSTERM>

- Completed study treatment period . . . . . ❑
- Lack of efficacy . . . . . ❑
- Disease progression* . . . . . ❑
- Adverse event* *(complete AE form)* . . . . . ❑
- Poor compliance to protocol . . . . . ❑
- Subject lost to follow-up . . . . . ❑
- Other reason . . . . . ❑

If other reason, specify: <DSTERM>

- Subject request . . . . . ❑

This box should be checked only if the subject withdraw his consent and none of the above reasons are present especially adverse event.

Specify : <DSTERM>

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

"I, the undersigned, certify that I have carefully examined all entries on the CRF for this subject. To the best of my knowledge, all information is correct."

Investigator signature: _____ Date: __ __ (day) __ __ __ (month) __ __ __ __ (year)

See Page 43

PHYSICAL EXAMINATION *PHYSEXAM_2*

NONE ❑

Date performed: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
day month year

- Were there any clinically significant changes from the previous evaluation? Yes* ❑ No ❑

**If yes, please complete the Adverse Event form.*

See Page 27

VITAL SIGNS *VITAL_1*

NOT DONE ❑

Weight: ⌊_⌋⌊_⌋⌊_⌋ . ⌊_⌋ kg

- Blood pressure: Systolic ⌊_⌋⌊_⌋⌊_⌋ mmHg / Diastolic ⌊_⌋⌊_⌋⌊_⌋ mmHg

- Heart rate: ⌊_⌋⌊_⌋⌊_⌋ beats/min

- Temperature: ⌊_⌋⌊_⌋ . ⌊_⌋ °C

(tick appropriate box): Oral ❑ Rectal ❑ Auricular ❑

ECOG Performance Status

0	1	2	3	4
❑	❑	❑	❑	❑

See Page 24

HEMATOLOGY

LABH_1

Date of sampling: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
day month year

TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
WBC		10^9/L	
RBC		10^6/mm^3	
Neutrophils		10^9/L	
Eosinophils		10^9/L	
Basophils		10^9/L	
Monocytes		10^9/L	
Lymphocytes		10^9/L	
Platelets		10^9/L	
Hemoglobin		g/dL	

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PSA

LABH_1

DATE OF SAMPLING (day month year)	TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	PSA		ng/mL	

See Page 25

BIOCHEMISTRY

LABB_1

Date of sampling: ☐☐ ☐☐☐ ☐☐☐☐ day month year

TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
Sodium		mmol/L	
Potassium		mmol/L	
SGOT (AST)		U/L	
SGPT (ALT)		U/L	
Alkaline phosphatase		U/L	
Total bilirubin		mg/dL	
BUN		mg/dL	
Creatinine		mg/dL	
Glucose		mg/dL	
Chloride		mmol/L	
Bicarbonate		mmol/L	

TESTOSTERONE

LABB_1

Date of sampling: ☐☐ ☐☐☐ ☐☐☐☐ day month year

TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
Testosterone		ng/dL	

*** Location:**

01	Skin	12	Liver	22	Mediastinum
02	Muscle/Soft Tissue	13	Stomach	23	Uterus
03	Bone	14	Pancreas	24	Abdomen
04	Bone Marrow	15	Kidneys	25	Gastrointestinal Tract
05	Peripheral Blood Stream	16	Ovaries	26	Pelvis
06	Brain/CNS	16.01	Fallopian Tubes	27	Peritoneum
07	Head/Neck	17	Bladder	28	Testis
08	Esophagus	18	Prostate	29	Thorax
09	Breast	19	Cervix	29.01	Pleura
10	Lungs	20.10	Colon	30	Other
11.01	Regional Lymph Nodes	20.20	Rectum		
11.02	Distant Lymph Nodes	21	Adrenal		

**** Method of Measurement Codes:**

1 - CT Scan	3 - MRI	5 - Scintigraphy
2 - Spiral CT	4 - PET	7 - Ultrasound
8 - X-Ray	10 - Physical Exam	99 - Other

*****Response of Non-Target Codes:**

CR - Complete Response	IR/SD - Incomplete Response/Stable Disease	PD - Progressive Disease
NL - New Lesion	NE - Not Evaluable	

See Page 55

TUMOR MEASUREMENTS

O.ASSESS_3

☐ NOT DONE

LESION NUMBER	LOCATION SITE*	DATE OF ASSESSMENT Day Month Year	METHOD OF MEASUREMENT**	MEASUREMENT OF TARGET LESION: longest diameter	RESPONSE OF NON-TARGET LESIONS***
1	☐☐.☐☐	☐☐ ☐☐☐ ☐☐☐☐ ☐ Not Done	☐☐	☐☐☐ mm	☐☐
2	☐☐.☐☐	☐☐ ☐☐☐ ☐☐☐☐ ☐ Not Done	☐☐	☐☐☐ mm	☐☐
3	☐☐.☐☐	☐☐ ☐☐☐ ☐☐☐☐ ☐ Not Done	☐☐	☐☐☐ mm	☐☐
4	☐☐.☐☐	☐☐ ☐☐☐ ☐☐☐☐ ☐ Not Done	☐☐	☐☐☐ mm	☐☐
5	☐☐.☐☐	☐☐ ☐☐☐ ☐☐☐☐ ☐ Not Done	☐☐	☐☐☐ mm	☐☐
6	☐☐.☐☐	☐☐ ☐☐☐ ☐☐☐☐ ☐ Not Done	☐☐	☐☐☐ mm	☐☐
7	☐☐.☐☐	☐☐ ☐☐☐ ☐☐☐☐ ☐ Not Done	☐☐	☐☐☐ mm	☐☐
8	☐☐.☐☐	☐☐ ☐☐☐ ☐☐☐☐ ☐ Not Done	☐☐	☐☐☐ mm	☐☐
9	☐☐.☐☐	☐☐ ☐☐☐ ☐☐☐☐ ☐ Not Done	☐☐	☐☐☐ mm	☐☐
10	☐☐.☐☐	☐☐ ☐☐☐ ☐☐☐☐ ☐ Not Done	☐☐	☐☐☐ mm	☐☐
11	☐☐.☐☐	☐☐ ☐☐☐ ☐☐☐☐ ☐ Not Done	☐☐	☐☐☐ mm	☐☐
12	☐☐.☐☐	☐☐ ☐☐☐ ☐☐☐☐ ☐ Not Done	☐☐	☐☐☐ mm	☐☐
13	☐☐.☐☐	☐☐ ☐☐☐ ☐☐☐☐ ☐ Not Done	☐☐	☐☐☐ mm	☐☐
14	☐☐.☐☐	☐☐ ☐☐☐ ☐☐☐☐ ☐ Not Done	☐☐	☐☐☐ mm	☐☐

See Page 53

PAIN INTENSITY ASSESSMENT

PAINVAS1

Date corresponds to End of Treatment visit (7 days prior to End of Treatment visit)

Date (Day Month Year)	PPI	Analgesic Score
1. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
2. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
3. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
4. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
5. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
6. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
7. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣

See Page 28

ECG

ECG_1

- Date performed: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
  day month year

- **ECG:** Normal ❑ Abnormal* ❑

If abnormal, specify: _____

_____

**** If clinically relevant, please report on the Adverse Event form.***

See Page 29

ECHOCARDIOGRAPHY *ECHOCARD_1*

NOT DONE ❑

- Date performed: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
  day month year

- **2D-Echocardiography:** Normal ❑ Abnormal* ❑

- Left ventricular ejection fraction (LVEF) ⌊_⌋⌊_⌋ . ⌊_⌋ %

- Lower Limit Normal of LVEF ⌊_⌋⌊_⌋ . ⌊_⌋ %

**** If clinically relevant, please complete the Adverse Event form.***

RADIONUCLIDE VENTRICULOGRAPHY *MUGA_1*

NOT DONE ❑

- Date performed: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
  day month year

- **Radionuclide Ventriculography:** Normal ❑ Abnormal* ❑

- Left ventricular ejection fraction (LVEF) ⌊_⌋⌊_⌋ . ⌊_⌋ %

- Lower Limit Normal of LVEF ⌊_⌋⌊_⌋ . ⌊_⌋ %

**** If clinically relevant, please complete the Adverse Event form.***

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CONCOMITANT MEDICATION

O.MED_9

☐ NONE

Tick the box if no medication(s) has been taken concomitantly with study drug.

	MEDICATION	START DATE Day Month Year	END DATE Day Month Year
1.		☐ Ongoing	☐ Ongoing
2.		☐ Ongoing	☐ Ongoing
3.		☐ Ongoing	☐ Ongoing
4.		☐ Ongoing	☐ Ongoing
5.		☐ Ongoing	☐ Ongoing
6.		☐ Ongoing	☐ Ongoing
7.		☐ Ongoing	☐ Ongoing
8.		☐ Ongoing	☐ Ongoing
9.		☐ Ongoing	☐ Ongoing
10.		☐ Ongoing	☐ Ongoing

END OF TREATMENT V 80

See Page 60

CONCOMITANT MEDICATION

O.MED_9

	MEDICATION	START DATE Day Month Year	END DATE Day Month Year
1.		❑ Ongoing	❑ Ongoing
2.		❑ Ongoing	❑ Ongoing
3.		❑ Ongoing	❑ Ongoing
4.		❑ Ongoing	❑ Ongoing
5.		❑ Ongoing	❑ Ongoing
6.		❑ Ongoing	❑ Ongoing
7.		❑ Ongoing	❑ Ongoing
8.		❑ Ongoing	❑ Ongoing
9.		❑ Ongoing	❑ Ongoing
10.		❑ Ongoing	❑ Ongoing

XRP6258
EFC6193

Country No. | Centre No. | Subject No. | NO 159 Page

FOLLOW-UP 1 V 8 1 | Date of visit: day / month / year

See Page 12

FOLLOW-UP 1

O.FOLLOWUP_2

Subject condition (tick "✓" one box only): <DSTERM>

- ❑ Alive
- ❑ Lost to follow-up
- ❑ Dead *(complete Death form)*

Progression <SUPPDS.QNAM=DSPROG>

Has the subject had disease progression? (tick "✓" one box only)

- ❑ Unknown
- ❑ Previously reported progression
- ❑ No *
- ❑ Yes **

* If ***NO***, please complete the Tumor Measurement page, PSA, Pain Intensity Assessment forms.

** If ***YES***, please complete the Tumor Measurement and Symptomatic Deterioration forms, PSA, Pain Intensity Assessment form appropriately.

POST TREATMENT ANTI-CANCER DRUG THERAPY *O.MED_2*

❑ NONE ❑ UNKNOWN <SUPPCM.QNAM=CMUNKTK>

<SUPPCM.QNAM=ENDTCOL>

DRUG/AGENT	START DATE Day Month Year	STOP DATE Day Month Year	ONGOING
1. <CMTRT>	<CMSTDTC> ␣␣ ␣␣␣ ␣␣␣␣	<CMENDTC> ␣␣ ␣␣␣ ␣␣␣␣	<SUPPCM.QNAM=CMONGO> ❑
2.	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣	❑
3.	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣	❑
4.	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣	❑
5.	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣	❑
6.	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣	❑
7.	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣	❑
8.	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣	❑
9.	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣	❑
10.	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣	❑

See Page 26

PSA

LABH_1

DATE OF SAMPLING day month year	TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
␣␣ ␣␣␣ ␣␣␣␣	PSA		ng/mL	

*** Location:**

01	Skin	12	Liver	22	Mediastinum
02	Muscle/Soft Tissue	13	Stomach	23	Uterus
03	Bone	14	Pancreas	24	Abdomen
04	Bone Marrow	15	Kidneys	25	Gastrointestinal Tract
05	Peripheral Blood Stream	16	Ovaries	26	Pelvis
06	Brain/CNS	16.01	Fallopian Tubes	27	Peritoneum
07	Head/Neck	17	Bladder	28	Testis
08	Esophagus	18	Prostate	29	Thorax
09	Breast	19	Cervix	29.01	Pleura
10	Lungs	20.10	Colon	30	Other
11.01	Regional Lymph Nodes	20.20	Rectum		
11.02	Distant Lymph Nodes	21	Adrenal		

**** METHOD OF MEASUREMENT CODES:**

1 - CT Scan	3 - MRI	5 - Scintigraphy
2 - Spiral CT	4 - PET	7 - Ultrasound
8 - X-Ray	10 - Physical Exam	99 - Other

*****RESPONSE OF NON-TARGET CODES:**

CR - Complete Response	IR/SD - Incomplete Response/Stable Disease	PD - Progressive Disease
NL - New Lesion	NE - Not Evaluable	

TUMOR MEASUREMENTS

O.ASSESS_3

☐ NOT DONE

LESION NUMBER	LOCATION SITE*	DATE OF ASSESSMENT Day Month Year	METHOD OF MEASUREMENT**	MEASUREMENT OF TARGET LESION: longest diameter	RESPONSE OF NON-TARGET LESIONS***
1	☐☐.☐☐	☐☐ ☐☐☐ ☐☐☐☐ ☐ Not Done	☐☐	☐☐☐ mm	☐☐
2	☐☐.☐☐	☐☐ ☐☐☐ ☐☐☐☐ ☐ Not Done	☐☐	☐☐☐ mm	☐☐
3	☐☐.☐☐	☐☐ ☐☐☐ ☐☐☐☐ ☐ Not Done	☐☐	☐☐☐ mm	☐☐
4	☐☐.☐☐	☐☐ ☐☐☐ ☐☐☐☐ ☐ Not Done	☐☐	☐☐☐ mm	☐☐
5	☐☐.☐☐	☐☐ ☐☐☐ ☐☐☐☐ ☐ Not Done	☐☐	☐☐☐ mm	☐☐
6	☐☐.☐☐	☐☐ ☐☐☐ ☐☐☐☐ ☐ Not Done	☐☐	☐☐☐ mm	☐☐
7	☐☐.☐☐	☐☐ ☐☐☐ ☐☐☐☐ ☐ Not Done	☐☐	☐☐☐ mm	☐☐
8	☐☐.☐☐	☐☐ ☐☐☐ ☐☐☐☐ ☐ Not Done	☐☐	☐☐☐ mm	☐☐
9	☐☐.☐☐	☐☐ ☐☐☐ ☐☐☐☐ ☐ Not Done	☐☐	☐☐☐ mm	☐☐
10	☐☐.☐☐	☐☐ ☐☐☐ ☐☐☐☐ ☐ Not Done	☐☐	☐☐☐ mm	☐☐
11	☐☐.☐☐	☐☐ ☐☐☐ ☐☐☐☐ ☐ Not Done	☐☐	☐☐☐ mm	☐☐
12	☐☐.☐☐	☐☐ ☐☐☐ ☐☐☐☐ ☐ Not Done	☐☐	☐☐☐ mm	☐☐
13	☐☐.☐☐	☐☐ ☐☐☐ ☐☐☐☐ ☐ Not Done	☐☐	☐☐☐ mm	☐☐
14	☐☐.☐☐	☐☐ ☐☐☐ ☐☐☐☐ ☐ Not Done	☐☐	☐☐☐ mm	☐☐

See Page 53

PAIN INTENSITY ASSESSMENT

PAINVAS1

Date corresponds to current visit (7 days prior to each follow-up visit)

Date (Day Month Year)	PPI	Analgesic Score
1. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
2. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
3. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
4. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
5. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
6. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
7. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣

See Page 62

ADVERSE EVENT FORM

O.1_AE_1

❑ NONE

1. ADVERSE EVENT DIAGNOSIS	AE form no: 81-01 AE ref. no: ___-___	AE form no: 81-02 AE ref. no: ___-___
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: ___ ___ ___ (day / month / year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: ___ ___ ___ (day / month / year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: ___ ___ ___ (day / month / year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: ___ ___ ___ (day / month / year) 6 ❑	1 ❑ / 4 ❑ Date: ___ ___ ___ (day / month / year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: ___ ___ ___ (day / month / year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES - Date event became serious: ___ ___ ___ (day / month / year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES - Date event became serious: ___ ___ ___ (day / month / year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:	

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 81-03 AE ref. no: __-__	AE form no: 81-04 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: __/__/__ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: __/__/__ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/__ (day/month/year) 6 ❑	1 ❑ / 4 ❑ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/__ (day/month/year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:	

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 81-05 AE ref. no: __-__	AE form no: 81-06 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ☐ Date of start: __/__/__ (day/month/year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐	1 ☐ Date of start: __/__/__ (day/month/year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐
3. GRADE (1 - 4)	1 ☐ 2 ☐ 3 ☐ 4 ☐	1 ☐ 2 ☐ 3 ☐ 4 ☐
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ☐ No ☐	Yes ☐ No ☐
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
6. CORRECTIVE TREATMENT/THERAPY	Yes ☐ No ☐	Yes ☐ No ☐
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ☐ / 4 ☐ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __/__/__ (day/month/year) 6 ☐	1 ☐ / 4 ☐ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __/__/__ (day/month/year) 6 ☐
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐
Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:	

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 81-07 AE ref. no: __-__	AE form no: 81-08 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: __/__/__ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: __/__/__ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/__ (day/month/year) 6 ❑	1 ❑ / 4 ❑ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/__ (day/month/year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:	

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 81-09 AE ref. no: __-__	AE form no: 81-10 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ☐ Date of start: __/__/____ (day/month/year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐	1 ☐ Date of start: __/__/____ (day/month/year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐
3. GRADE (1 - 4)	1 ☐ 2 ☐ 3 ☐ 4 ☐	1 ☐ 2 ☐ 3 ☐ 4 ☐
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ☐ No ☐	Yes ☐ No ☐
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
6. CORRECTIVE TREATMENT/THERAPY	Yes ☐ No ☐	Yes ☐ No ☐
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ☐ / 4 ☐ Date: __/__/____ (day/month/year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __/__/____ (day/month/year) 6 ☐	1 ☐ / 4 ☐ Date: __/__/____ (day/month/year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __/__/____ (day/month/year) 6 ☐
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __/__/____ (day/month/year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __/__/____ (day/month/year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐
Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:	

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 81-11 AE ref. no: __-__	AE form no: 81-12 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ☐ Date of start: __ __ __ __ __ __ (day / month / year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐	1 ☐ Date of start: __ __ __ __ __ __ (day / month / year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐
3. GRADE (1 - 4)	1 ☐ 2 ☐ 3 ☐ 4 ☐	1 ☐ 2 ☐ 3 ☐ 4 ☐
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ☐ No ☐	Yes ☐ No ☐
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
6. CORRECTIVE TREATMENT/THERAPY	Yes ☐ No ☐	Yes ☐ No ☐
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ☐ / 4 ☐ Date: __ __ __ __ __ __ (day / month / year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __ __ __ __ __ __ (day / month / year) 6 ☐	1 ☐ / 4 ☐ Date: __ __ __ __ __ __ (day / month / year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __ __ __ __ __ __ (day / month / year) 6 ☐
8. SERIOUSNESS CRITERIA IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __ __ __ __ __ __ (day / month / year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __ __ __ __ __ __ (day / month / year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐
Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:	

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: ⌊_⌊_-⌊_⌊_ AE ref. no: ⌊_⌊_-⌊_⌊_	AE form no: ⌊_⌊_-⌊_⌊_ AE ref. no: ⌊_⌊_-⌊_⌊_
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: ⌊_⌊_ ⌊_⌊_⌊_ ⌊_⌊_⌊_⌊_ (day / month / year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: ⌊_⌊_ ⌊_⌊_⌊_ ⌊_⌊_⌊_⌊_ (day / month / year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: ⌊_⌊_ ⌊_⌊_⌊_ ⌊_⌊_⌊_⌊_ (day / month / year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: ⌊_⌊_ ⌊_⌊_⌊_ ⌊_⌊_⌊_⌊_ (day / month / year) 6 ❑	1 ❑ / 4 ❑ Date: ⌊_⌊_ ⌊_⌊_⌊_ ⌊_⌊_⌊_⌊_ (day / month / year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: ⌊_⌊_ ⌊_⌊_⌊_ ⌊_⌊_⌊_⌊_ (day / month / year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES - Date event became serious: ⌊_⌊_ ⌊_⌊_⌊_ ⌊_⌊_⌊_⌊_ (day / month / year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES - Date event became serious: ⌊_⌊_ ⌊_⌊_⌊_ ⌊_⌊_⌊_⌊_ (day / month / year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:		Monitoring representative's name, date of receipt:

** Is there a reasonable possibility that the AE was caused by study treatment?*

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FOLLOW-UP 2

O.FOLLOWUP_2

Subject condition (tick "✓" one box only):

- ❑ Alive
- ❑ Lost to follow-up
- ❑ Dead *(complete Death form)*

Progression

Has the subject had disease progression? (tick "✓" one box only)

- ❑ Unknown
- ❑ Previously reported progression
- ❑ No *
- ❑ Yes **

* If ***NO***, please complete the Tumor Measurement page, PSA, Pain Intensity Assessment forms.

** If ***YES***, please complete the Tumor Measurement and Symptomatic Deterioration forms, PSA, Pain Intensity Assessment form appropriately.

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POST TREATMENT ANTI-CANCER DRUG THERAPY *O.MED_2*

❑ NONE ❑ UNKNOWN

DRUG/REGIMEN/AGENT	START DATE Day Month Year	STOP DATE Day Month Year	ONGOING
1.	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	❑
2.	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	❑
3.	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	❑
4.	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	❑
5.	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	❑
6.	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	❑
7.	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	❑
8.	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	❑
9.	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	❑
10.	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	❑

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PSA

LABH_1

DATE OF SAMPLING day month year	TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
␣␣ ␣␣␣ ␣␣␣␣	PSA		ng/mL	

*** Location:**

01	Skin	12	Liver	22	Mediastinum
02	Muscle/Soft Tissue	13	Stomach	23	Uterus
03	Bone	14	Pancreas	24	Abdomen
04	Bone Marrow	15	Kidneys	25	Gastrointestinal Tract
05	Peripheral Blood Stream	16	Ovaries	26	Pelvis
06	Brain/CNS	16.01	Fallopian Tubes	27	Peritoneum
07	Head/Neck	17	Bladder	28	Testis
08	Esophagus	18	Prostate	29	Thorax
09	Breast	19	Cervix	29.01	Pleura
10	Lungs	20.10	Colon	30	Other
11.01	Regional Lymph Nodes	20.20	Rectum		
11.02	Distant Lymph Nodes	21	Adrenal		

**** Method of Measurement Codes:**

1 - CT Scan	3 - MRI	5 - Scintigraphy
2 - Spiral CT	4 - PET	7 - Ultrasound
8 - X-Ray	10 - Physical Exam	99 - Other

*****Response of Non-Target Codes:**

CR - Complete Response	IR/SD - Incomplete Response/Stable Disease	PD - Progressive Disease
NL - New Lesion	NE - Not Evaluable	

See Page 55

TUMOR MEASUREMENTS

O.ASSESS_3

❑ NOT DONE

LESION NUMBER	LOCATION SITE*	DATE OF ASSESSMENT Day Month Year	METHOD OF MEASUREMENT**	MEASUREMENT OF TARGET LESION: longest diameter	RESPONSE OF NON-TARGET LESIONS***
1	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
2	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
3	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
4	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
5	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
6	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
7	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
8	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
9	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
10	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
11	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
12	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
13	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
14	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣

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PAIN INTENSITY ASSESSMENT

PAINVAS1

Date corresponds to current visit (7 days prior to each follow-up visit)

Date (Day Month Year)	PPI	Analgesic Score
1. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
2. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
3. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
4. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
5. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
6. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
7. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣

See Page 62

ADVERSE EVENT FORM

O.1_AE_1

❑ NONE

1. **ADVERSE EVENT DIAGNOSIS**	AE form no: 82-01 AE ref. no: ___-___	AE form no: 82-02 AE ref. no: ___-___
2. **STATUS OF AE** 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: ___ ___ ___ (day / month / year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: ___ ___ ___ (day / month / year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. **GRADE (1 - 4)**	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. **ACTION TAKEN WITH STUDY TREATMENT**	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. **OUTCOME** 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: ___ ___ ___ (day / month / year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: ___ ___ ___ (day / month / year) 6 ❑	1 ❑ / 4 ❑ Date: ___ ___ ___ (day / month / year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: ___ ___ ___ (day / month / year) 6 ❑
8. **SERIOUSNESS CRITERIA** **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES - Date event became serious: ___ ___ ___ (day / month / year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES - Date event became serious: ___ ___ ___ (day / month / year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:	

** Is there a reasonable possibility that the AE was caused by study treatment?*

See Page 62

ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 82-03 AE ref. no: __-__	AE form no: 82-04 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ☐ Date of start: __ __ (day) __ __ __ (month) __ __ __ __ (year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐	1 ☐ Date of start: __ __ (day) __ __ __ (month) __ __ __ __ (year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐
3. GRADE (1 - 4)	1 ☐ 2 ☐ 3 ☐ 4 ☐	1 ☐ 2 ☐ 3 ☐ 4 ☐
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ☐ No ☐	Yes ☐ No ☐
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
6. CORRECTIVE TREATMENT/THERAPY	Yes ☐ No ☐	Yes ☐ No ☐
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ☐ / 4 ☐ Date: __ __ (day) __ __ __ (month) __ __ __ __ (year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __ __ (day) __ __ __ (month) __ __ __ __ (year) 6 ☐	1 ☐ / 4 ☐ Date: __ __ (day) __ __ __ (month) __ __ __ __ (year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __ __ (day) __ __ __ (month) __ __ __ __ (year) 6 ☐
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __ __ (day) __ __ __ (month) __ __ __ __ (year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __ __ (day) __ __ __ (month) __ __ __ __ (year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐
Investigator's name, date of report and signature:		Monitoring representative's name, date of receipt:

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 82-05 AE ref. no: __-__	AE form no: 82-06 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ☐ Date of start: __/__/__ (day/month/year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐	1 ☐ Date of start: __/__/__ (day/month/year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐
3. GRADE (1 - 4)	1 ☐ 2 ☐ 3 ☐ 4 ☐	1 ☐ 2 ☐ 3 ☐ 4 ☐
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ☐ No ☐	Yes ☐ No ☐
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
6. CORRECTIVE TREATMENT/THERAPY	Yes ☐ No ☐	Yes ☐ No ☐
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ☐ / 4 ☐ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __/__/__ (day/month/year) 6 ☐	1 ☐ / 4 ☐ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __/__/__ (day/month/year) 6 ☐
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐
Investigator's name, date of report and signature:		Monitoring representative's name, date of receipt:

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 82-07 AE ref. no: __-__	AE form no: 81-08 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: __/__/____ (day / month / year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: __/__/____ (day / month / year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: __/__/____ (day / month / year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/____ (day / month / year) 6 ❑	1 ❑ / 4 ❑ Date: __/__/____ (day / month / year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/____ (day / month / year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __/__/____ (day / month / year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __/__/____ (day / month / year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:	

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 82-09 AE ref. no: __-__	AE form no: 82-10 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ☐ Date of start: __ __ day __ __ __ month __ __ __ __ year 2 ☐ *(do not complete the remaining items in the column)* 3 ☐	1 ☐ Date of start: __ __ day __ __ __ month __ __ __ __ year 2 ☐ *(do not complete the remaining items in the column)* 3 ☐
3. GRADE (1 - 4)	1 ☐ 2 ☐ 3 ☐ 4 ☐	1 ☐ 2 ☐ 3 ☐ 4 ☐
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ☐ No ☐	Yes ☐ No ☐
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
6. CORRECTIVE TREATMENT/THERAPY	Yes ☐ No ☐	Yes ☐ No ☐
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ☐ / 4 ☐ Date: __ __ day __ __ __ month __ __ __ __ year Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __ __ day __ __ __ month __ __ __ __ year 6 ☐	1 ☐ / 4 ☐ Date: __ __ day __ __ __ month __ __ __ __ year Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __ __ day __ __ __ month __ __ __ __ year 6 ☐
8. SERIOUSNESS CRITERIA IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __ __ day __ __ __ month __ __ __ __ year - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __ __ day __ __ __ month __ __ __ __ year - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐
Investigator's name, date of report and signature:		Monitoring representative's name, date of receipt:

** Is there a reasonable possibility that the AE was caused by study treatment?*

See Page 62

ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 82-11 AE ref. no: __-__	AE form no: 82-12 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: __/__/__ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: __/__/__ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/__ (day/month/year) 6 ❑	1 ❑ / 4 ❑ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/__ (day/month/year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:	

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: ␣␣-␣␣ AE ref. no: ␣␣-␣␣	AE form no: ␣␣-␣␣ AE ref. no: ␣␣-␣␣
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) 6 ❑	1 ❑ / 4 ❑ Date: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES - Date event became serious: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES - Date event became serious: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:		Monitoring representative's name, date of receipt:

** Is there a reasonable possibility that the AE was caused by study treatment?*

FOLLOW-UP 3

O.FOLLOWUP_2

Subject condition (tick "✓" one box only):

- ❑ Alive
- ❑ Lost to follow-up
- ❑ Dead *(complete Death form)*

Progression

Has the subject had disease progression? (tick "✓" one box only)

- ❑ Unknown
- ❑ Previously reported progression
- ❑ No *
- ❑ Yes **

* If ***NO***, please complete the Tumor Measurement page, PSA, Pain Intensity Assessment forms.

** If ***YES***, please complete the Tumor Measurement and Symptomatic Deterioration forms, PSA, Pain Intensity Assessment form appropriately.

See Page 279

POST TREATMENT ANTI-CANCER DRUG THERAPY *O.MED_2*

❑ NONE ❑ UNKNOWN

DRUG/REGIMEN/AGENT	START DATE Day Month Year	STOP DATE Day Month Year	ONGOING
1.	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣	❑
2.	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣	❑
3.	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣	❑
4.	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣	❑
5.	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣	❑
6.	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣	❑
7.	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣	❑
8.	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣	❑
9.	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣	❑
10.	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣	❑

See Page 26

PSA

LABH_1

DATE OF SAMPLING day month year	TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	PSA		ng/mL	

*** Location:**

01	Skin	12	Liver	22	Mediastinum
02	Muscle/Soft Tissue	13	Stomach	23	Uterus
03	Bone	14	Pancreas	24	Abdomen
04	Bone Marrow	15	Kidneys	25	Gastrointestinal Tract
05	Peripheral Blood Stream	16	Ovaries	26	Pelvis
06	Brain/CNS	16.01	Fallopian Tubes	27	Peritoneum
07	Head/Neck	17	Bladder	28	Testis
08	Esophagus	18	Prostate	29	Thorax
09	Breast	19	Cervix	29.01	Pleura
10	Lungs	20.10	Colon	30	Other
11.01	Regional Lymph Nodes	20.20	Rectum		
11.02	Distant Lymph Nodes	21	Adrenal		

**** Method of Measurement Codes:**

1 - CT Scan	3 - MRI	5 - Scintigraphy
2 - Spiral CT	4 - PET	7 - Ultrasound
8 - X-Ray	10 - Physical Exam	99 - Other

*****Response of Non-Target Codes:**

CR - Complete Response	IR/SD - Incomplete Response/Stable Disease	PD - Progressive Disease
NL - New Lesion	NE - Not Evaluable	

See Page 55

TUMOR MEASUREMENTS

O.ASSESS_3

❑ NOT DONE

LESION NUMBER	LOCATION SITE*	DATE OF ASSESSMENT Day Month Year	METHOD OF MEASUREMENT**	MEASUREMENT OF TARGET LESION: longest diameter	RESPONSE OF NON-TARGET LESIONS***
1	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
2	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
3	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
4	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
5	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
6	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
7	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
8	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
9	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
10	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
11	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
12	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
13	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
14	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣

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PAIN INTENSITY ASSESSMENT

PAINVAS1

Date corresponds to current visit (7 days prior to each follow-up visit)

Date (Day Month Year)	PPI	Analgesic Score
1. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
2. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
3. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
4. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
5. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
6. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
7. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣

See Page 62

ADVERSE EVENT FORM

O.1_AE_1

☐ NONE

1. ADVERSE EVENT DIAGNOSIS	AE form no: 83-01 AE ref. no: __-__	AE form no: 83-02 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ☐ Date of start: __/__/____ (day/month/year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐	1 ☐ Date of start: __/__/____ (day/month/year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐
3. GRADE (1 - 4)	1 ☐ 2 ☐ 3 ☐ 4 ☐	1 ☐ 2 ☐ 3 ☐ 4 ☐
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ☐ No ☐	Yes ☐ No ☐
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
6. CORRECTIVE TREATMENT/THERAPY	Yes ☐ No ☐	Yes ☐ No ☐
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ☐ / 4 ☐ Date: __/__/____ (day/month/year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __/__/____ (day/month/year) 6 ☐	1 ☐ / 4 ☐ Date: __/__/____ (day/month/year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __/__/____ (day/month/year) 6 ☐
8. SERIOUSNESS CRITERIA IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __/__/____ (day/month/year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __/__/____ (day/month/year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐
Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:	

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 83-03 AE ref. no: __-__	AE form no: 83-04 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ☐ Date of start: __/__/__ (day/month/year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐	1 ☐ Date of start: __/__/__ (day/month/year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐
3. GRADE (1 - 4)	1 ☐ 2 ☐ 3 ☐ 4 ☐	1 ☐ 2 ☐ 3 ☐ 4 ☐
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ☐ No ☐	Yes ☐ No ☐
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
6. CORRECTIVE TREATMENT/THERAPY	Yes ☐ No ☐	Yes ☐ No ☐
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ☐ / 4 ☐ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __/__/__ (day/month/year) 6 ☐	1 ☐ / 4 ☐ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __/__/__ (day/month/year) 6 ☐
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ☐ No ☐ ➲ IF YES: - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐	Yes ☐ No ☐ ➲ IF YES: - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐
Investigator's name, date of report and signature:		Monitoring representative's name, date of receipt:

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 83-05 AE ref. no: __-__	AE form no: 83-06 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ☐ Date of start: __/__/__ (day/month/year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐	1 ☐ Date of start: __/__/__ (day/month/year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐
3. GRADE (1 - 4)	1 ☐ 2 ☐ 3 ☐ 4 ☐	1 ☐ 2 ☐ 3 ☐ 4 ☐
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ☐ No ☐	Yes ☐ No ☐
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
6. CORRECTIVE TREATMENT/THERAPY	Yes ☐ No ☐	Yes ☐ No ☐
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ☐ / 4 ☐ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __/__/__ (day/month/year) 6 ☐	1 ☐ / 4 ☐ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __/__/__ (day/month/year) 6 ☐
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ☐ No ☐ ➲ IF YES: - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐	Yes ☐ No ☐ ➲ IF YES: - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐
Investigator's name, date of report and signature:		Monitoring representative's name, date of receipt:

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 83-07 AE ref. no: ___-___	AE form no: 83-08 AE ref. no: ___-___
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: ___ ___ ___ (day / month / year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: ___ ___ ___ (day / month / year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: ___ ___ ___ (day / month / year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: ___ ___ ___ (day / month / year) 6 ❑	1 ❑ / 4 ❑ Date: ___ ___ ___ (day / month / year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: ___ ___ ___ (day / month / year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES: - Date event became serious: ___ ___ ___ (day / month / year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES: - Date event became serious: ___ ___ ___ (day / month / year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:		Monitoring representative's name, date of receipt:

** Is there a reasonable possibility that the AE was caused by study treatment?*

See Page 62

ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 83-09 AE ref. no: __-__	AE form no: 83-10 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ☐ Date of start: __/__/____ (day/month/year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐	1 ☐ Date of start: __/__/____ (day/month/year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐
3. GRADE (1 - 4)	1 ☐ 2 ☐ 3 ☐ 4 ☐	1 ☐ 2 ☐ 3 ☐ 4 ☐
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ☐ No ☐	Yes ☐ No ☐
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
6. CORRECTIVE TREATMENT/THERAPY	Yes ☐ No ☐	Yes ☐ No ☐
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ☐ / 4 ☐ Date: __/__/____ (day/month/year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __/__/____ (day/month/year) 6 ☐	1 ☐ / 4 ☐ Date: __/__/____ (day/month/year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __/__/____ (day/month/year) 6 ☐
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __/__/____ (day/month/year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __/__/____ (day/month/year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐
Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:	

** Is there a reasonable possibility that the AE was caused by study treatment?*

See Page 62

ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 83-11 AE ref. no: __-__	AE form no: 83-12 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ☐ Date of start: __/__/__ (day/month/year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐	1 ☐ Date of start: __/__/__ (day/month/year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐
3. GRADE (1 - 4)	1 ☐ 2 ☐ 3 ☐ 4 ☐	1 ☐ 2 ☐ 3 ☐ 4 ☐
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ☐ No ☐	Yes ☐ No ☐
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
6. CORRECTIVE TREATMENT/THERAPY	Yes ☐ No ☐	Yes ☐ No ☐
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ☐ / 4 ☐ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __/__/__ (day/month/year) 6 ☐	1 ☐ / 4 ☐ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __/__/__ (day/month/year) 6 ☐
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐
Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:	

** Is there a reasonable possibility that the AE was caused by study treatment?*

See Page 62

ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: ⌊_⌊_-⌊_⌊_ AE ref. no: ⌊_⌊_-⌊_⌊_	AE form no: ⌊_⌊_-⌊_⌊_ AE ref. no: ⌊_⌊_-⌊_⌊_
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: ⌊_⌊_ ⌊_⌊_⌊_ ⌊_⌊_⌊_⌊_ (day / month / year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: ⌊_⌊_ ⌊_⌊_⌊_ ⌊_⌊_⌊_⌊_ (day / month / year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: ⌊_⌊_ ⌊_⌊_⌊_ ⌊_⌊_⌊_⌊_ (day / month / year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: ⌊_⌊_ ⌊_⌊_⌊_ ⌊_⌊_⌊_⌊_ (day / month / year) 6 ❑	1 ❑ / 4 ❑ Date: ⌊_⌊_ ⌊_⌊_⌊_ ⌊_⌊_⌊_⌊_ (day / month / year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: ⌊_⌊_ ⌊_⌊_⌊_ ⌊_⌊_⌊_⌊_ (day / month / year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES - Date event became serious: ⌊_⌊_ ⌊_⌊_⌊_ ⌊_⌊_⌊_⌊_ (day / month / year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES - Date event became serious: ⌊_⌊_ ⌊_⌊_⌊_ ⌊_⌊_⌊_⌊_ (day / month / year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:		Monitoring representative's name, date of receipt:

** Is there a reasonable possibility that the AE was caused by study treatment?*

See Page 278

FOLLOW-UP 4

O.FOLLOWUP_2

Subject condition (tick "✓" one box only):

- ❑ Alive
- ❑ Lost to follow-up
- ❑ Dead *(complete Death form)*

Progression

Has the subject had disease progression? (tick "✓" one box only)

- ❑ Unknown
- ❑ Previously reported progression
- ❑ No *
- ❑ Yes **

* If ***NO***, please complete the Tumor Measurement page, PSA, Pain Intensity Assessment forms.

** If ***YES***, please complete the Tumor Measurement and Symptomatic Deterioration forms, PSA, Pain Intensity Assessment form appropriately.

See Page 279

POST TREATMENT ANTI-CANCER DRUG THERAPY *O.MED_2*

❑ NONE ❑ UNKNOWN

DRUG/REGIMEN/AGENT	START DATE Day Month Year	STOP DATE Day Month Year	ONGOING
1.	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣	❑
2.	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣	❑
3.	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣	❑
4.	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣	❑
5.	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣	❑
6.	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣	❑
7.	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣	❑
8.	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣	❑
9.	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣	❑
10.	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣	❑

See Page 26

PSA

LABH_1

DATE OF SAMPLING day month year	TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	PSA		ng/mL	

*** Location:**

01	Skin	12	Liver	22	Mediastinum
02	Muscle/Soft Tissue	13	Stomach	23	Uterus
03	Bone	14	Pancreas	24	Abdomen
04	Bone Marrow	15	Kidneys	25	Gastrointestinal Tract
05	Peripheral Blood Stream	16	Ovaries	26	Pelvis
06	Brain/CNS	16.01	Fallopian Tubes	27	Peritoneum
07	Head/Neck	17	Bladder	28	Testis
08	Esophagus	18	Prostate	29	Thorax
09	Breast	19	Cervix	29.01	Pleura
10	Lungs	20.10	Colon	30	Other
11.01	Regional Lymph Nodes	20.20	Rectum		
11.02	Distant Lymph Nodes	21	Adrenal		

**** METHOD OF MEASUREMENT CODES:**

1 - CT Scan	3 - MRI	5 - Scintigraphy
2 - Spiral CT	4 - PET	7 - Ultrasound
8 - X-Ray	10 - Physical Exam	99 - Other

*****RESPONSE OF NON-TARGET CODES:**

CR - Complete Response	IR/SD - Incomplete Response/Stable Disease	PD - Progressive Disease
NL - New Lesion	NE - Not Evaluable	

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TUMOR MEASUREMENTS

O.ASSESS_3

☐ NOT DONE

LESION NUMBER	LOCATION SITE*	DATE OF ASSESSMENT Day Month Year	METHOD OF MEASUREMENT**	MEASUREMENT OF TARGET LESION: longest diameter	RESPONSE OF NON-TARGET LESIONS***
1	☐☐.☐☐	☐☐ ☐☐☐ ☐☐☐☐ ☐ Not Done	☐☐	☐☐☐ mm	☐☐
2	☐☐.☐☐	☐☐ ☐☐☐ ☐☐☐☐ ☐ Not Done	☐☐	☐☐☐ mm	☐☐
3	☐☐.☐☐	☐☐ ☐☐☐ ☐☐☐☐ ☐ Not Done	☐☐	☐☐☐ mm	☐☐
4	☐☐.☐☐	☐☐ ☐☐☐ ☐☐☐☐ ☐ Not Done	☐☐	☐☐☐ mm	☐☐
5	☐☐.☐☐	☐☐ ☐☐☐ ☐☐☐☐ ☐ Not Done	☐☐	☐☐☐ mm	☐☐
6	☐☐.☐☐	☐☐ ☐☐☐ ☐☐☐☐ ☐ Not Done	☐☐	☐☐☐ mm	☐☐
7	☐☐.☐☐	☐☐ ☐☐☐ ☐☐☐☐ ☐ Not Done	☐☐	☐☐☐ mm	☐☐
8	☐☐.☐☐	☐☐ ☐☐☐ ☐☐☐☐ ☐ Not Done	☐☐	☐☐☐ mm	☐☐
9	☐☐.☐☐	☐☐ ☐☐☐ ☐☐☐☐ ☐ Not Done	☐☐	☐☐☐ mm	☐☐
10	☐☐.☐☐	☐☐ ☐☐☐ ☐☐☐☐ ☐ Not Done	☐☐	☐☐☐ mm	☐☐
11	☐☐.☐☐	☐☐ ☐☐☐ ☐☐☐☐ ☐ Not Done	☐☐	☐☐☐ mm	☐☐
12	☐☐.☐☐	☐☐ ☐☐☐ ☐☐☐☐ ☐ Not Done	☐☐	☐☐☐ mm	☐☐
13	☐☐.☐☐	☐☐ ☐☐☐ ☐☐☐☐ ☐ Not Done	☐☐	☐☐☐ mm	☐☐
14	☐☐.☐☐	☐☐ ☐☐☐ ☐☐☐☐ ☐ Not Done	☐☐	☐☐☐ mm	☐☐

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PAIN INTENSITY ASSESSMENT

PAINVAS1

Date corresponds to current visit (7 days prior to each follow-up visit)

Date (Day Month Year)	PPI	Analgesic Score
1. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
2. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
3. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
4. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
5. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
6. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
7. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣

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ADVERSE EVENT FORM

O.1_AE_1

❑ NONE

1. **ADVERSE EVENT DIAGNOSIS**	AE form no: 84-01 AE ref. no: __-__	AE form no: 84-02 AE ref. no: __-__
2. **STATUS OF AE** 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: __ __ (day) __ __ __ (month) __ __ __ __ (year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: __ __ (day) __ __ __ (month) __ __ __ __ (year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. **GRADE (1 - 4)**	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. **ACTION TAKEN WITH STUDY TREATMENT**	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. **OUTCOME** 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: __ __ (day) __ __ __ (month) __ __ __ __ (year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __ __ (day) __ __ __ (month) __ __ __ __ (year) 6 ❑	1 ❑ / 4 ❑ Date: __ __ (day) __ __ __ (month) __ __ __ __ (year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __ __ (day) __ __ __ (month) __ __ __ __ (year) 6 ❑
8. **SERIOUSNESS CRITERIA** **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __ __ (day) __ __ __ (month) __ __ __ __ (year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __ __ (day) __ __ __ (month) __ __ __ __ (year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:		Monitoring representative's name, date of receipt:

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 84-03 AE ref. no: __-__	AE form no: 84-04 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ☐ Date of start: __/__/__ (day/month/year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐	1 ☐ Date of start: __/__/__ (day/month/year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐
3. GRADE (1 - 4)	1 ☐ 2 ☐ 3 ☐ 4 ☐	1 ☐ 2 ☐ 3 ☐ 4 ☐
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ☐ No ☐	Yes ☐ No ☐
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
6. CORRECTIVE TREATMENT/THERAPY	Yes ☐ No ☐	Yes ☐ No ☐
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ☐ / 4 ☐ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __/__/__ (day/month/year) 6 ☐	1 ☐ / 4 ☐ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __/__/__ (day/month/year) 6 ☐
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐
Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:	

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 84-05 AE ref. no: __-__	AE form no: 84-06 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ☐ Date of start: __/__/__ (day/month/year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐	1 ☐ Date of start: __/__/__ (day/month/year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐
3. GRADE (1 - 4)	1 ☐ 2 ☐ 3 ☐ 4 ☐	1 ☐ 2 ☐ 3 ☐ 4 ☐
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ☐ No ☐	Yes ☐ No ☐
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
6. CORRECTIVE TREATMENT/THERAPY	Yes ☐ No ☐	Yes ☐ No ☐
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ☐ / 4 ☐ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __/__/__ (day/month/year) 6 ☐	1 ☐ / 4 ☐ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __/__/__ (day/month/year) 6 ☐
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐
Investigator's name, date of report and signature:		Monitoring representative's name, date of receipt:

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 84-07 AE ref. no: __-__	AE form no: 84-08 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ☐ Date of start: __/__/__ (day/month/year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐	1 ☐ Date of start: __/__/__ (day/month/year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐
3. GRADE (1 - 4)	1 ☐ 2 ☐ 3 ☐ 4 ☐	1 ☐ 2 ☐ 3 ☐ 4 ☐
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ☐ No ☐	Yes ☐ No ☐
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
6. CORRECTIVE TREATMENT/THERAPY	Yes ☐ No ☐	Yes ☐ No ☐
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ☐ / 4 ☐ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __/__/__ (day/month/year) 6 ☐	1 ☐ / 4 ☐ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __/__/__ (day/month/year) 6 ☐
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐
Investigator's name, date of report and signature:		Monitoring representative's name, date of receipt:

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 84-09 AE ref. no: __-__	AE form no: 84-10 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ☐ Date of start: __/__/____ (day/month/year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐	1 ☐ Date of start: __/__/____ (day/month/year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐
3. GRADE (1 - 4)	1 ☐ 2 ☐ 3 ☐ 4 ☐	1 ☐ 2 ☐ 3 ☐ 4 ☐
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ☐ No ☐	Yes ☐ No ☐
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
6. CORRECTIVE TREATMENT/THERAPY	Yes ☐ No ☐	Yes ☐ No ☐
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ☐ / 4 ☐ Date: __/__/____ (day/month/year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __/__/____ (day/month/year) 6 ☐	1 ☐ / 4 ☐ Date: __/__/____ (day/month/year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __/__/____ (day/month/year) 6 ☐
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __/__/____ (day/month/year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __/__/____ (day/month/year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐
Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:	

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 84-11 AE ref. no: ___-___	AE form no: 84-12 AE ref. no: ___-___
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ☐ Date of start: ___ ___ ___ (day / month / year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐	1 ☐ Date of start: ___ ___ ___ (day / month / year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐
3. GRADE (1 - 4)	1 ☐ 2 ☐ 3 ☐ 4 ☐	1 ☐ 2 ☐ 3 ☐ 4 ☐
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ☐ No ☐	Yes ☐ No ☐
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
6. CORRECTIVE TREATMENT/THERAPY	Yes ☐ No ☐	Yes ☐ No ☐
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ☐ / 4 ☐ Date: ___ ___ ___ (day / month / year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: ___ ___ ___ (day / month / year) 6 ☐	1 ☐ / 4 ☐ Date: ___ ___ ___ (day / month / year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: ___ ___ ___ (day / month / year) 6 ☐
8. SERIOUSNESS CRITERIA IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM	Yes ☐ No ☐ ➲ IF YES - Date event became serious: ___ ___ ___ (day / month / year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐	Yes ☐ No ☐ ➲ IF YES - Date event became serious: ___ ___ ___ (day / month / year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐
Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:	

** Is there a reasonable possibility that the AE was caused by study treatment?*

See Page 62

ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: ␣␣-␣␣ AE ref. no: ␣␣-␣␣	AE form no: ␣␣-␣␣ AE ref. no: ␣␣-␣␣
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) 6 ❑	1 ❑ / 4 ❑ Date: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES - Date event became serious: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES - Date event became serious: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:		Monitoring representative's name, date of receipt:

** Is there a reasonable possibility that the AE was caused by study treatment?*

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FOLLOW-UP 5

O.FOLLOWUP_2

Subject condition (tick "✓" one box only):

- ❑ Alive
- ❑ Lost to follow-up
- ❑ Dead *(complete Death form)*

Progression

Has the subject had disease progression? (tick "✓" one box only)

- ❑ Unknown
- ❑ Previously reported progression
- ❑ No *
- ❑ Yes **

* If ***NO***, please complete the Tumor Measurement page, PSA, Pain Intensity Assessment forms.

** If ***YES***, please complete the Tumor Measurement and Symptomatic Deterioration forms, PSA, Pain Intensity Assessment form appropriately.

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POST TREATMENT ANTI-CANCER DRUG THERAPY *O.MED_2*

❑ NONE ❑ UNKNOWN

DRUG/REGIMEN/AGENT	START DATE Day Month Year	STOP DATE Day Month Year	ONGOING
1.	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	❑
2.	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	❑
3.	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	❑
4.	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	❑
5.	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	❑
6.	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	❑
7.	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	❑
8.	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	❑
9.	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	❑
10.	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	❑

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PSA

LABH_1

DATE OF SAMPLING day month year	TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
␣␣ ␣␣␣ ␣␣␣␣	PSA		ng/mL	

*** Location:**

01	Skin	12	Liver	22	Mediastinum
02	Muscle/Soft Tissue	13	Stomach	23	Uterus
03	Bone	14	Pancreas	24	Abdomen
04	Bone Marrow	15	Kidneys	25	Gastrointestinal Tract
05	Peripheral Blood Stream	16	Ovaries	26	Pelvis
06	Brain/CNS	16.01	Fallopian Tubes	27	Peritoneum
07	Head/Neck	17	Bladder	28	Testis
08	Esophagus	18	Prostate	29	Thorax
09	Breast	19	Cervix	29.01	Pleura
10	Lungs	20.10	Colon	30	Other
11.01	Regional Lymph Nodes	20.20	Rectum		
11.02	Distant Lymph Nodes	21	Adrenal		

**** Method of Measurement Codes:**

1 - CT Scan	3 - MRI	5 - Scintigraphy
2 - Spiral CT	4 - PET	7 - Ultrasound
8 - X-Ray	10 - Physical Exam	99 - Other

*****Response of Non-Target Codes:**

CR - Complete Response	IR/SD - Incomplete Response/Stable Disease	PD - Progressive Disease
NL - New Lesion	NE - Not Evaluable	

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TUMOR MEASUREMENTS

O.ASSESS_3

❑ NOT DONE

LESION NUMBER	LOCATION SITE*	DATE OF ASSESSMENT Day Month Year	METHOD OF MEASUREMENT**	MEASUREMENT OF TARGET LESION: longest diameter	RESPONSE OF NON-TARGET LESIONS***
1	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
2	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
3	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
4	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
5	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
6	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
7	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
8	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
9	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
10	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
11	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
12	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
13	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
14	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣

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PAIN INTENSITY ASSESSMENT

PAINVAS1

Date corresponds to current visit (7 days prior to each follow-up visit)

Date (Day Month Year)	PPI	Analgesic Score
1. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
2. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
3. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
4. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
5. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
6. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
7. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣

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ADVERSE EVENT FORM

O.1_AE_1

❑ NONE

1. ADVERSE EVENT DIAGNOSIS	AE form no: 85-01 AE ref. no: ⌊⌋⌊⌋-⌊⌋⌊⌋	AE form no: 85-02 AE ref. no: ⌊⌋⌊⌋-⌊⌋⌊⌋
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: ⌊⌋⌊⌋ ⌊⌋⌊⌋⌊⌋ ⌊⌋⌊⌋⌊⌋⌊⌋ (day / month / year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: ⌊⌋⌊⌋ ⌊⌋⌊⌋⌊⌋ ⌊⌋⌊⌋⌊⌋⌊⌋ (day / month / year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: ⌊⌋⌊⌋ ⌊⌋⌊⌋⌊⌋ ⌊⌋⌊⌋⌊⌋⌊⌋ (day / month / year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: ⌊⌋⌊⌋ ⌊⌋⌊⌋⌊⌋ ⌊⌋⌊⌋⌊⌋⌊⌋ (day / month / year) 6 ❑	1 ❑ / 4 ❑ Date: ⌊⌋⌊⌋ ⌊⌋⌊⌋⌊⌋ ⌊⌋⌊⌋⌊⌋⌊⌋ (day / month / year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: ⌊⌋⌊⌋ ⌊⌋⌊⌋⌊⌋ ⌊⌋⌊⌋⌊⌋⌊⌋ (day / month / year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES - Date event became serious: ⌊⌋⌊⌋ ⌊⌋⌊⌋⌊⌋ ⌊⌋⌊⌋⌊⌋⌊⌋ (day / month / year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES - Date event became serious: ⌊⌋⌊⌋ ⌊⌋⌊⌋⌊⌋ ⌊⌋⌊⌋⌊⌋⌊⌋ (day / month / year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:	

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 85-03 AE ref. no: __-__	AE form no: 85-04 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: __/__/____ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: __/__/____ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: __/__/____ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/____ (day/month/year) 6 ❑	1 ❑ / 4 ❑ Date: __/__/____ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/____ (day/month/year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES: - Date event became serious: __/__/____ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES: - Date event became serious: __/__/____ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:		Monitoring representative's name, date of receipt:

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 85-05 AE ref. no: __-__	AE form no: 85-06 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ☐ Date of start: __ __ (day) __ __ __ (month) __ __ __ __ (year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐	1 ☐ Date of start: __ __ (day) __ __ __ (month) __ __ __ __ (year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐
3. GRADE (1 - 4)	1 ☐ 2 ☐ 3 ☐ 4 ☐	1 ☐ 2 ☐ 3 ☐ 4 ☐
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ☐ No ☐	Yes ☐ No ☐
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
6. CORRECTIVE TREATMENT/THERAPY	Yes ☐ No ☐	Yes ☐ No ☐
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ☐ / 4 ☐ Date: __ __ (day) __ __ __ (month) __ __ __ __ (year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __ __ (day) __ __ __ (month) __ __ __ __ (year) 6 ☐	1 ☐ / 4 ☐ Date: __ __ (day) __ __ __ (month) __ __ __ __ (year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __ __ (day) __ __ __ (month) __ __ __ __ (year) 6 ☐
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __ __ (day) __ __ __ (month) __ __ __ __ (year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __ __ (day) __ __ __ (month) __ __ __ __ (year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐
Investigator's name, date of report and signature:		Monitoring representative's name, date of receipt:

** Is there a reasonable possibility that the AE was caused by study treatment?*

See Page 62

ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 85-07 AE ref. no: __-__	AE form no: 85-08 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: __/__/____ (day / month / year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: __/__/____ (day / month / year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: __/__/____ (day / month / year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/____ (day / month / year) 6 ❑	1 ❑ / 4 ❑ Date: __/__/____ (day / month / year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/____ (day / month / year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __/__/____ (day / month / year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __/__/____ (day / month / year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:	

** Is there a reasonable possibility that the AE was caused by study treatment?*

See Page 62

ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 85-09 AE ref. no: __-__	AE form no: 85-10 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ☐ Date of start: __ __ (day) __ __ __ (month) __ __ __ __ (year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐	1 ☐ Date of start: __ __ (day) __ __ __ (month) __ __ __ __ (year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐
3. GRADE (1 - 4)	1 ☐ 2 ☐ 3 ☐ 4 ☐	1 ☐ 2 ☐ 3 ☐ 4 ☐
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ☐ No ☐	Yes ☐ No ☐
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
6. CORRECTIVE TREATMENT/THERAPY	Yes ☐ No ☐	Yes ☐ No ☐
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ☐ / 4 ☐ Date: __ __ (day) __ __ __ (month) __ __ __ __ (year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __ __ (day) __ __ __ (month) __ __ __ __ (year) 6 ☐	1 ☐ / 4 ☐ Date: __ __ (day) __ __ __ (month) __ __ __ __ (year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __ __ (day) __ __ __ (month) __ __ __ __ (year) 6 ☐
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __ __ (day) __ __ __ (month) __ __ __ __ (year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __ __ (day) __ __ __ (month) __ __ __ __ (year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐
Investigator's name, date of report and signature:		Monitoring representative's name, date of receipt:

** Is there a reasonable possibility that the AE was caused by study treatment?*

See Page 62

ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 85-11 AE ref. no: __-__	AE form no: 85-12 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ☐ Date of start: __/__/____ (day/month/year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐	1 ☐ Date of start: __/__/____ (day/month/year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐
3. GRADE (1 - 4)	1 ☐ 2 ☐ 3 ☐ 4 ☐	1 ☐ 2 ☐ 3 ☐ 4 ☐
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ☐ No ☐	Yes ☐ No ☐
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
6. CORRECTIVE TREATMENT/THERAPY	Yes ☐ No ☐	Yes ☐ No ☐
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ☐ / 4 ☐ Date: __/__/____ (day/month/year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __/__/____ (day/month/year) 6 ☐	1 ☐ / 4 ☐ Date: __/__/____ (day/month/year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __/__/____ (day/month/year) 6 ☐
8. SERIOUSNESS CRITERIA IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __/__/____ (day/month/year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __/__/____ (day/month/year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐
Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:	

** Is there a reasonable possibility that the AE was caused by study treatment?*

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FOLLOW-UP 6

O.FOLLOWUP_2

Subject condition (tick "✓" one box only):

- ❑ Alive
- ❑ Lost to follow-up
- ❑ Dead *(complete Death form)*

Progression

Has the subject had disease progression? (tick "✓" one box only)

- ❑ Unknown
- ❑ Previously reported progression
- ❑ No *
- ❑ Yes **

* If ***NO***, please complete the Tumor Measurement page, PSA, Pain Intensity Assessment forms.

** If ***YES***, please complete the Tumor Measurement and Symptomatic Deterioration forms, PSA, Pain Intensity Assessment form appropriately.

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POST TREATMENT ANTI-CANCER DRUG THERAPY *O.MED_2*

❑ NONE ❑ UNKNOWN

DRUG/REGIMEN/AGENT	START DATE Day Month Year	STOP DATE Day Month Year	ONGOING
1.	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣	❑
2.	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣	❑
3.	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣	❑
4.	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣	❑
5.	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣	❑
6.	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣	❑
7.	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣	❑
8.	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣	❑
9.	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣	❑
10.	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣	❑

See Page 26

PSA

LABH_1

DATE OF SAMPLING day month year	TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	PSA		ng/mL	

*** Location:**

01	Skin	12	Liver	22	Mediastinum
02	Muscle/Soft Tissue	13	Stomach	23	Uterus
03	Bone	14	Pancreas	24	Abdomen
04	Bone Marrow	15	Kidneys	25	Gastrointestinal Tract
05	Peripheral Blood Stream	16	Ovaries	26	Pelvis
06	Brain/CNS	16.01	Fallopian Tubes	27	Peritoneum
07	Head/Neck	17	Bladder	28	Testis
08	Esophagus	18	Prostate	29	Thorax
09	Breast	19	Cervix	29.01	Pleura
10	Lungs	20.10	Colon	30	Other
11.01	Regional Lymph Nodes	20.20	Rectum		
11.02	Distant Lymph Nodes	21	Adrenal		

**** Method of Measurement Codes:**

1 - CT Scan	3 - MRI	5 - Scintigraphy
2 - Spiral CT	4 - PET	7 - Ultrasound
8 - X-Ray	10 - Physical Exam	99 - Other

*****Response of Non-Target Codes:**

CR - Complete Response	IR/SD - Incomplete Response/Stable Disease	PD - Progressive Disease
NL - New Lesion	NE - Not Evaluable	

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TUMOR MEASUREMENTS

O.ASSESS_3

❑ NOT DONE

LESION NUMBER	LOCATION SITE*	DATE OF ASSESSMENT Day Month Year	METHOD OF MEASUREMENT**	MEASUREMENT OF TARGET LESION: longest diameter	RESPONSE OF NON-TARGET LESIONS***
1	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
2	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
3	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
4	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
5	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
6	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
7	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
8	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
9	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
10	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
11	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
12	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
13	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
14	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣

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PAIN INTENSITY ASSESSMENT

PAINVAS1

Date corresponds to current visit (7 days prior to each follow-up visit)

Date (Day Month Year)	PPI	Analgesic Score
1. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
2. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
3. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
4. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
5. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
6. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
7. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣

See Page 62

ADVERSE EVENT FORM

O.1_AE_1

❑ NONE

1. ADVERSE EVENT DIAGNOSIS	AE form no: 86-01 AE ref. no: ␣␣-␣␣	AE form no: 86-02 AE ref. no: ␣␣-␣␣
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑ If grade changes, date of change: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year)	1 ❑ Date of start: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑ If grade changes, date of change: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year)
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) 6 ❑	1 ❑ / 4 ❑ Date: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES - Date event became serious: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES - Date event became serious: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:		Monitoring representative's name, date of receipt:

** Is there a reasonable possibility that the AE was caused by study treatment?*

See Page 62

ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 86-03 AE ref. no: __-__	AE form no: 86-04 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: __/__/__ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: __/__/__ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/__ (day/month/year) 6 ❑	1 ❑ / 4 ❑ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/__ (day/month/year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:	

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 86-05 AE ref. no: __-__	AE form no: 86-06 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: __/__/__ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: __/__/__ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/__ (day/month/year) 6 ❑	1 ❑ / 4 ❑ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/__ (day/month/year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES: - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES: - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:		Monitoring representative's name, date of receipt:

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 86-07 AE ref. no: ___-___	AE form no: 86-08 AE ref. no: ___-___
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: ___ ___ ___ (day / month / year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: ___ ___ ___ (day / month / year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: ___ ___ ___ (day / month / year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: ___ ___ ___ (day / month / year) 6 ❑	1 ❑ / 4 ❑ Date: ___ ___ ___ (day / month / year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: ___ ___ ___ (day / month / year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES: - Date event became serious: ___ ___ ___ (day / month / year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES: - Date event became serious: ___ ___ ___ (day / month / year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:		Monitoring representative's name, date of receipt:

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 86-09 AE ref. no: __-__	AE form no: 86-10 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ☐ Date of start: __ __ day __ __ __ month __ __ __ __ year 2 ☐ *(do not complete the remaining items in the column)* 3 ☐	1 ☐ Date of start: __ __ day __ __ __ month __ __ __ __ year 2 ☐ *(do not complete the remaining items in the column)* 3 ☐
3. GRADE (1 - 4)	1 ☐ 2 ☐ 3 ☐ 4 ☐	1 ☐ 2 ☐ 3 ☐ 4 ☐
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ☐ No ☐	Yes ☐ No ☐
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
6. CORRECTIVE TREATMENT/THERAPY	Yes ☐ No ☐	Yes ☐ No ☐
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ☐ / 4 ☐ Date: __ __ day __ __ __ month __ __ __ __ year Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __ __ day __ __ __ month __ __ __ __ year 6 ☐	1 ☐ / 4 ☐ Date: __ __ day __ __ __ month __ __ __ __ year Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __ __ day __ __ __ month __ __ __ __ year 6 ☐
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __ __ day __ __ __ month __ __ __ __ year - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __ __ day __ __ __ month __ __ __ __ year - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐
Investigator's name, date of report and signature:		Monitoring representative's name, date of receipt:

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 86-11 AE ref. no: __-__	AE form no: 86-12 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ☐ Date of start: __ __ (day) __ __ __ (month) __ __ __ __ (year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐	1 ☐ Date of start: __ __ (day) __ __ __ (month) __ __ __ __ (year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐
3. GRADE (1 - 4)	1 ☐ 2 ☐ 3 ☐ 4 ☐	1 ☐ 2 ☐ 3 ☐ 4 ☐
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ☐ No ☐	Yes ☐ No ☐
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
6. CORRECTIVE TREATMENT/THERAPY	Yes ☐ No ☐	Yes ☐ No ☐
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ☐ / 4 ☐ Date: __ __ (day) __ __ __ (month) __ __ __ __ (year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __ __ (day) __ __ __ (month) __ __ __ __ (year) 6 ☐	1 ☐ / 4 ☐ Date: __ __ (day) __ __ __ (month) __ __ __ __ (year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __ __ (day) __ __ __ (month) __ __ __ __ (year) 6 ☐
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __ __ (day) __ __ __ (month) __ __ __ __ (year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __ __ (day) __ __ __ (month) __ __ __ __ (year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐
Investigator's name, date of report and signature:		Monitoring representative's name, date of receipt:

** Is there a reasonable possibility that the AE was caused by study treatment?*

FOLLOW-UP 7

O.FOLLOWUP_2

Subject condition (tick "✓" one box only):

- ❑ Alive
- ❑ Lost to follow-up
- ❑ Dead *(complete Death form)*

Progression

Has the subject had disease progression? (tick "✓" one box only)

- ❑ Unknown
- ❑ Previously reported progression
- ❑ No *
- ❑ Yes **

* If ***NO***, please complete the Tumor Measurement page, PSA, Pain Intensity Assessment forms.

** If ***YES***, please complete the Tumor Measurement and Symptomatic Deterioration forms, PSA, Pain Intensity Assessment form appropriately.

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POST TREATMENT ANTI-CANCER DRUG THERAPY *O.MED_2*

❑ NONE ❑ UNKNOWN

DRUG/REGIMEN/AGENT	START DATE Day Month Year	STOP DATE Day Month Year	ONGOING
1.	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣	❑
2.	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣	❑
3.	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣	❑
4.	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣	❑
5.	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣	❑
6.	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣	❑
7.	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣	❑
8.	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣	❑
9.	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣	❑
10.	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣	❑

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PSA

LABH_1

DATE OF SAMPLING day month year	TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	PSA		ng/mL	

*** Location:**

01	Skin	12	Liver	22	Mediastinum
02	Muscle/Soft Tissue	13	Stomach	23	Uterus
03	Bone	14	Pancreas	24	Abdomen
04	Bone Marrow	15	Kidneys	25	Gastrointestinal Tract
05	Peripheral Blood Stream	16	Ovaries	26	Pelvis
06	Brain/CNS	16.01	Fallopian Tubes	27	Peritoneum
07	Head/Neck	17	Bladder	28	Testis
08	Esophagus	18	Prostate	29	Thorax
09	Breast	19	Cervix	29.01	Pleura
10	Lungs	20.10	Colon	30	Other
11.01	Regional Lymph Nodes	20.20	Rectum		
11.02	Distant Lymph Nodes	21	Adrenal		

**** Method of Measurement Codes:**

1 - CT Scan	3 - MRI	5 - Scintigraphy
2 - Spiral CT	4 - PET	7 - Ultrasound
8 - X-Ray	10 - Physical Exam	99 - Other

*****Response of Non-Target Codes:**

CR - Complete Response	IR/SD - Incomplete Response/Stable Disease	PD - Progressive Disease
NL - New Lesion	NE - Not Evaluable	

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TUMOR MEASUREMENTS

O.ASSESS_3

❑ NOT DONE

LESION NUMBER	LOCATION SITE*	DATE OF ASSESSMENT Day Month Year	METHOD OF MEASUREMENT**	MEASUREMENT OF TARGET LESION: longest diameter	RESPONSE OF NON-TARGET LESIONS***
1	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋
2	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋
3	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋
4	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋
5	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋
6	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋
7	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋
8	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋
9	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋
10	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋
11	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋
12	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋
13	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋
14	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋

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PAIN INTENSITY ASSESSMENT

PAINVAS1

Date corresponds to current visit (7 days prior to each follow-up visit)

Date (Day Month Year)	PPI	Analgesic Score
1. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
2. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
3. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
4. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
5. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
6. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
7. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣

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ADVERSE EVENT FORM

O.1_AE_1

❑ NONE

1. ADVERSE EVENT DIAGNOSIS	AE form no: 87-01 AE ref. no: ␣␣-␣␣	AE form no: 87-02 AE ref. no: ␣␣-␣␣
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑ If grade changes, date of change: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year)	1 ❑ Date of start: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑ If grade changes, date of change: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year)
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) 6 ❑	1 ❑ / 4 ❑ Date: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES: - Date event became serious: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES: - Date event became serious: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:		Monitoring representative's name, date of receipt:

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 87-03 AE ref. no: __-__	AE form no: 87-04 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ☐ Date of start: __/__/__ (day/month/year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐	1 ☐ Date of start: __/__/__ (day/month/year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐
3. GRADE (1 - 4)	1 ☐ 2 ☐ 3 ☐ 4 ☐	1 ☐ 2 ☐ 3 ☐ 4 ☐
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ☐ No ☐	Yes ☐ No ☐
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
6. CORRECTIVE TREATMENT/THERAPY	Yes ☐ No ☐	Yes ☐ No ☐
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ☐ / 4 ☐ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __/__/__ (day/month/year) 6 ☐	1 ☐ / 4 ☐ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __/__/__ (day/month/year) 6 ☐
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐
Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:	

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

0.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 87-05 AE ref. no: __-__	AE form no: 87-06 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ☐ Date of start: __/__/__ (day/month/year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐	1 ☐ Date of start: __/__/__ (day/month/year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐
3. GRADE (1 - 4)	1 ☐ 2 ☐ 3 ☐ 4 ☐	1 ☐ 2 ☐ 3 ☐ 4 ☐
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ☐ No ☐	Yes ☐ No ☐
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
6. CORRECTIVE TREATMENT/THERAPY	Yes ☐ No ☐	Yes ☐ No ☐
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ☐ / 4 ☐ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __/__/__ (day/month/year) 6 ☐	1 ☐ / 4 ☐ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __/__/__ (day/month/year) 6 ☐
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐
Investigator's name, date of report and signature:		Monitoring representative's name, date of receipt:

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 87-07 AE ref. no: __-__	AE form no: 87-08 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: __/__/__ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: __/__/__ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/__ (day/month/year) 6 ❑	1 ❑ / 4 ❑ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/__ (day/month/year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:		Monitoring representative's name, date of receipt:

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 87-09 AE ref. no: __-__	AE form no: 87-10 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ☐ Date of start: __/__/____ (day/month/year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐	1 ☐ Date of start: __/__/____ (day/month/year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐
3. GRADE (1 - 4)	1 ☐ 2 ☐ 3 ☐ 4 ☐	1 ☐ 2 ☐ 3 ☐ 4 ☐
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ☐ No ☐	Yes ☐ No ☐
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
6. CORRECTIVE TREATMENT/THERAPY	Yes ☐ No ☐	Yes ☐ No ☐
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ☐ / 4 ☐ Date: __/__/____ (day/month/year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __/__/____ (day/month/year) 6 ☐	1 ☐ / 4 ☐ Date: __/__/____ (day/month/year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __/__/____ (day/month/year) 6 ☐
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __/__/____ (day/month/year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __/__/____ (day/month/year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐
Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:	

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 87-11 AE ref. no: __-__	AE form no: 87-12 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: __/__/____ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: __/__/____ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: __/__/____ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/____ (day/month/year) 6 ❑	1 ❑ / 4 ❑ Date: __/__/____ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/____ (day/month/year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __/__/____ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __/__/____ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:	

** Is there a reasonable possibility that the AE was caused by study treatment?*

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FOLLOW-UP 8

O.FOLLOWUP_2

Subject condition (tick "✓" one box only):

- ❑ Alive
- ❑ Lost to follow-up
- ❑ Dead *(complete Death form)*

Progression

Has the subject had disease progression? (tick "✓" one box only)

- ❑ Unknown
- ❑ Previously reported progression
- ❑ No *
- ❑ Yes **

* If ***NO***, please complete the Tumor Measurement page, PSA, Pain Intensity Assessment forms.

** If ***YES***, please complete the Tumor Measurement and Symptomatic Deterioration forms, PSA, Pain Intensity Assessment form appropriately.

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POST TREATMENT ANTI-CANCER DRUG THERAPY *O.MED_2*

❑ NONE ❑ UNKNOWN

DRUG/REGIMEN/AGENT	START DATE Day Month Year	STOP DATE Day Month Year	ONGOING
1.	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣	❑
2.	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣	❑
3.	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣	❑
4.	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣	❑
5.	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣	❑
6.	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣	❑
7.	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣	❑
8.	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣	❑
9.	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣	❑
10.	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣	❑

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PSA

LABH_1

DATE OF SAMPLING day month year	TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
␣␣ ␣␣␣ ␣␣␣␣	PSA		ng/mL	

*** Location:**

01	Skin	12	Liver	22	Mediastinum
02	Muscle/Soft Tissue	13	Stomach	23	Uterus
03	Bone	14	Pancreas	24	Abdomen
04	Bone Marrow	15	Kidneys	25	Gastrointestinal Tract
05	Peripheral Blood Stream	16	Ovaries	26	Pelvis
06	Brain/CNS	16.01	Fallopian Tubes	27	Peritoneum
07	Head/Neck	17	Bladder	28	Testis
08	Esophagus	18	Prostate	29	Thorax
09	Breast	19	Cervix	29.01	Pleura
10	Lungs	20.10	Colon	30	Other
11.01	Regional Lymph Nodes	20.20	Rectum		
11.02	Distant Lymph Nodes	21	Adrenal		

**** METHOD OF MEASUREMENT CODES:**

1 - CT Scan	3 - MRI	5 - Scintigraphy
2 - Spiral CT	4 - PET	7 - Ultrasound
8 - X-Ray	10 - Physical Exam	99 - Other

*****RESPONSE OF NON-TARGET CODES:**

CR - Complete Response	IR/SD - Incomplete Response/Stable Disease	PD - Progressive Disease
NL - New Lesion	NE - Not Evaluable	

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TUMOR MEASUREMENTS

O.ASSESS_3

❑ NOT DONE

LESION NUMBER	LOCATION SITE*	DATE OF ASSESSMENT Day Month Year	METHOD OF MEASUREMENT**	MEASUREMENT OF TARGET LESION: longest diameter	RESPONSE OF NON-TARGET LESIONS***
1	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋
2	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋
3	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋
4	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋
5	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋
6	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋
7	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋
8	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋
9	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋
10	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋
11	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋
12	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋
13	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋
14	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋

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PAIN INTENSITY ASSESSMENT

PAINVAS1

Date corresponds to current visit (7 days prior to each follow-up visit)

Date (Day Month Year)	PPI	Analgesic Score
1. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
2. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
3. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
4. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
5. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
6. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
7. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣

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ADVERSE EVENT FORM

O.1_AE_1

❑ NONE

1. ADVERSE EVENT DIAGNOSIS	AE form no: 88-01 AE ref. no: ␣␣-␣␣	AE form no: 88-02 AE ref. no: ␣␣-␣␣
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑ If grade changes, date of change: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year)	1 ❑ Date of start: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑ If grade changes, date of change: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year)
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) 6 ❑	1 ❑ / 4 ❑ Date: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES - Date event became serious: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES - Date event became serious: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:		Monitoring representative's name, date of receipt:

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 88-03 AE ref. no: __-__	AE form no: 88-04 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: __/__/__ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: __/__/__ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/__ (day/month/year) 6 ❑	1 ❑ / 4 ❑ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/__ (day/month/year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:	

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 88-05 AE ref. no: __-__	AE form no: 88-06 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: __/__/__ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: __/__/__ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/__ (day/month/year) 6 ❑	1 ❑ / 4 ❑ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/__ (day/month/year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:	

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 88-07 AE ref. no: __-__	AE form no: 88-08 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: __/__/__ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: __/__/__ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/__ (day/month/year) 6 ❑	1 ❑ / 4 ❑ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/__ (day/month/year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:		Monitoring representative's name, date of receipt:

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 88-09 AE ref. no: __-__	AE form no: 88-10 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ☐ Date of start: __/__/____ (day / month / year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐	1 ☐ Date of start: __/__/____ (day / month / year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐
3. GRADE (1 - 4)	1 ☐ 2 ☐ 3 ☐ 4 ☐	1 ☐ 2 ☐ 3 ☐ 4 ☐
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ☐ No ☐	Yes ☐ No ☐
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
6. CORRECTIVE TREATMENT/THERAPY	Yes ☐ No ☐	Yes ☐ No ☐
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ☐ / 4 ☐ Date: __/__/____ (day / month / year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __/__/____ (day / month / year) 6 ☐	1 ☐ / 4 ☐ Date: __/__/____ (day / month / year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __/__/____ (day / month / year) 6 ☐
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __/__/____ (day / month / year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __/__/____ (day / month / year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐
Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:	

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 88-11 AE ref. no: __-__	AE form no: 88-12 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: __ __ (day) __ __ __ (month) __ __ __ __ (year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: __ __ (day) __ __ __ (month) __ __ __ __ (year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: __ __ (day) __ __ __ (month) __ __ __ __ (year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __ __ (day) __ __ __ (month) __ __ __ __ (year) 6 ❑	1 ❑ / 4 ❑ Date: __ __ (day) __ __ __ (month) __ __ __ __ (year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __ __ (day) __ __ __ (month) __ __ __ __ (year) 6 ❑
8. SERIOUSNESS CRITERIA IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __ __ (day) __ __ __ (month) __ __ __ __ (year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __ __ (day) __ __ __ (month) __ __ __ __ (year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:		Monitoring representative's name, date of receipt:

** Is there a reasonable possibility that the AE was caused by study treatment?*

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FOLLOW-UP 9

O.FOLLOWUP_2

Subject condition (tick "✓" one box only):

- ❑ Alive
- ❑ Lost to follow-up
- ❑ Dead *(complete Death form)*

Progression

Has the subject had disease progression? (tick "✓" one box only)

- ❑ Unknown
- ❑ Previously reported progression
- ❑ No *
- ❑ Yes **

* If ***NO***, please complete the Tumor Measurement page, PSA, Pain Intensity Assessment forms.

** If ***YES***, please complete the Tumor Measurement and Symptomatic Deterioration forms, PSA, Pain Intensity Assessment form appropriately.

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POST TREATMENT ANTI-CANCER DRUG THERAPY *O.MED_2*

❑ NONE ❑ UNKNOWN

DRUG/REGIMEN/AGENT	START DATE Day Month Year	STOP DATE Day Month Year	ONGOING
1.	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣	❑
2.	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣	❑
3.	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣	❑
4.	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣	❑
5.	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣	❑
6.	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣	❑
7.	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣	❑
8.	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣	❑
9.	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣	❑
10.	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣	❑

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PSA

LABH_1

DATE OF SAMPLING day month year	TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
␣␣ ␣␣␣ ␣␣␣␣	PSA		ng/mL	

*** Location:**

01	Skin	12	Liver	22	Mediastinum
02	Muscle/Soft Tissue	13	Stomach	23	Uterus
03	Bone	14	Pancreas	24	Abdomen
04	Bone Marrow	15	Kidneys	25	Gastrointestinal Tract
05	Peripheral Blood Stream	16	Ovaries	26	Pelvis
06	Brain/CNS	16.01	Fallopian Tubes	27	Peritoneum
07	Head/Neck	17	Bladder	28	Testis
08	Esophagus	18	Prostate	29	Thorax
09	Breast	19	Cervix	29.01	Pleura
10	Lungs	20.10	Colon	30	Other
11.01	Regional Lymph Nodes	20.20	Rectum		
11.02	Distant Lymph Nodes	21	Adrenal		

**** Method of Measurement Codes:**

1 - CT Scan	3 - MRI	5 - Scintigraphy
2 - Spiral CT	4 - PET	7 - Ultrasound
8 - X-Ray	10 - Physical Exam	99 - Other

*****Response of Non-Target Codes:**

CR - Complete Response	IR/SD - Incomplete Response/Stable Disease	PD - Progressive Disease
NL - New Lesion	NE - Not Evaluable	

TUMOR MEASUREMENTS

O.ASSESS_3

☐ NOT DONE

LESION NUMBER	LOCATION SITE*	DATE OF ASSESSMENT Day Month Year	METHOD OF MEASUREMENT**	MEASUREMENT OF TARGET LESION: longest diameter	RESPONSE OF NON-TARGET LESIONS***
1	☐☐.☐☐	☐☐ ☐☐☐ ☐☐☐☐ ☐ Not Done	☐☐	☐☐☐ mm	☐☐
2	☐☐.☐☐	☐☐ ☐☐☐ ☐☐☐☐ ☐ Not Done	☐☐	☐☐☐ mm	☐☐
3	☐☐.☐☐	☐☐ ☐☐☐ ☐☐☐☐ ☐ Not Done	☐☐	☐☐☐ mm	☐☐
4	☐☐.☐☐	☐☐ ☐☐☐ ☐☐☐☐ ☐ Not Done	☐☐	☐☐☐ mm	☐☐
5	☐☐.☐☐	☐☐ ☐☐☐ ☐☐☐☐ ☐ Not Done	☐☐	☐☐☐ mm	☐☐
6	☐☐.☐☐	☐☐ ☐☐☐ ☐☐☐☐ ☐ Not Done	☐☐	☐☐☐ mm	☐☐
7	☐☐.☐☐	☐☐ ☐☐☐ ☐☐☐☐ ☐ Not Done	☐☐	☐☐☐ mm	☐☐
8	☐☐.☐☐	☐☐ ☐☐☐ ☐☐☐☐ ☐ Not Done	☐☐	☐☐☐ mm	☐☐
9	☐☐.☐☐	☐☐ ☐☐☐ ☐☐☐☐ ☐ Not Done	☐☐	☐☐☐ mm	☐☐
10	☐☐.☐☐	☐☐ ☐☐☐ ☐☐☐☐ ☐ Not Done	☐☐	☐☐☐ mm	☐☐
11	☐☐.☐☐	☐☐ ☐☐☐ ☐☐☐☐ ☐ Not Done	☐☐	☐☐☐ mm	☐☐
12	☐☐.☐☐	☐☐ ☐☐☐ ☐☐☐☐ ☐ Not Done	☐☐	☐☐☐ mm	☐☐
13	☐☐.☐☐	☐☐ ☐☐☐ ☐☐☐☐ ☐ Not Done	☐☐	☐☐☐ mm	☐☐
14	☐☐.☐☐	☐☐ ☐☐☐ ☐☐☐☐ ☐ Not Done	☐☐	☐☐☐ mm	☐☐

See Page 53

PAIN INTENSITY ASSESSMENT

PAINVAS1

Date corresponds to current visit (7 days prior to each follow-up visit)

Date (Day Month Year)	PPI	Analgesic Score
1. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
2. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
3. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
4. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
5. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
6. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
7. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣

See Page 62

ADVERSE EVENT FORM

O.1_AE_1

❑ NONE

1. ADVERSE EVENT DIAGNOSIS	AE form no: 89-01 AE ref. no: ␣␣-␣␣	AE form no: 89-02 AE ref. no: ␣␣-␣␣
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑ If grade changes, date of change: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year)	1 ❑ Date of start: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑ If grade changes, date of change: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year)
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) 6 ❑	1 ❑ / 4 ❑ Date: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES - Date event became serious: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES - Date event became serious: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:		Monitoring representative's name, date of receipt:

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 89-03 AE ref. no: __-__	AE form no: 89-04 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: __/__/__ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: __/__/__ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/__ (day/month/year) 6 ❑	1 ❑ / 4 ❑ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/__ (day/month/year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:	

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

0.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 89-05 AE ref. no: __-__	AE form no: 89-06 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: __/__/__ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: __/__/__ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/__ (day/month/year) 6 ❑	1 ❑ / 4 ❑ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/__ (day/month/year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:	

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 89-07 AE ref. no: __-__	AE form no: 89-08 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: __/__/__ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: __/__/__ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/__ (day/month/year) 6 ❑	1 ❑ / 4 ❑ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/__ (day/month/year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:		Monitoring representative's name, date of receipt:

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 89-09 AE ref. no: __-__	AE form no: 89-10 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: __ __ (day) __ __ __ (month) __ __ __ __ (year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: __ __ (day) __ __ __ (month) __ __ __ __ (year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: __ __ (day) __ __ __ (month) __ __ __ __ (year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __ __ (day) __ __ __ (month) __ __ __ __ (year) 6 ❑	1 ❑ / 4 ❑ Date: __ __ (day) __ __ __ (month) __ __ __ __ (year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __ __ (day) __ __ __ (month) __ __ __ __ (year) 6 ❑
8. SERIOUSNESS CRITERIA IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __ __ (day) __ __ __ (month) __ __ __ __ (year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __ __ (day) __ __ __ (month) __ __ __ __ (year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:		Monitoring representative's name, date of receipt:

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 89-11 AE ref. no: __-__	AE form no: 89-12 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ☐ Date of start: __/__/____ (day/month/year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐	1 ☐ Date of start: __/__/____ (day/month/year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐
3. GRADE (1 - 4)	1 ☐ 2 ☐ 3 ☐ 4 ☐	1 ☐ 2 ☐ 3 ☐ 4 ☐
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ☐ No ☐	Yes ☐ No ☐
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
6. CORRECTIVE TREATMENT/THERAPY	Yes ☐ No ☐	Yes ☐ No ☐
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ☐ / 4 ☐ Date: __/__/____ (day/month/year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __/__/____ (day/month/year) 6 ☐	1 ☐ / 4 ☐ Date: __/__/____ (day/month/year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __/__/____ (day/month/year) 6 ☐
8. SERIOUSNESS CRITERIA IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __/__/____ (day/month/year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __/__/____ (day/month/year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐
Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:	

** Is there a reasonable possibility that the AE was caused by study treatment?*

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FOLLOW-UP 10

O.FOLLOWUP_2

Subject condition (tick "✓" one box only):

- ❑ Alive
- ❑ Lost to follow-up
- ❑ Dead *(complete Death form)*

Progression

Has the subject had disease progression? (tick "✓" one box only)

- ❑ Unknown
- ❑ Previously reported progression
- ❑ No *
- ❑ Yes **

* If ***NO***, please complete the Tumor Measurement page, PSA, Pain Intensity Assessment forms.

** If ***YES***, please complete the Tumor Measurement and Symptomatic Deterioration forms, PSA, Pain Intensity Assessment form appropriately.

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POST TREATMENT ANTI-CANCER DRUG THERAPY *O.MED_2*

❑ NONE ❑ UNKNOWN

DRUG/REGIMEN/AGENT	START DATE Day Month Year	STOP DATE Day Month Year	ONGOING
1.	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣	❑
2.	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣	❑
3.	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣	❑
4.	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣	❑
5.	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣	❑
6.	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣	❑
7.	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣	❑
8.	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣	❑
9.	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣	❑
10.	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣	❑

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PSA

LABH_1

DATE OF SAMPLING day month year	TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
␣␣ ␣␣␣ ␣␣␣␣	PSA		ng/mL	

*** Location:**

01	Skin	12	Liver	22	Mediastinum
02	Muscle/Soft Tissue	13	Stomach	23	Uterus
03	Bone	14	Pancreas	24	Abdomen
04	Bone Marrow	15	Kidneys	25	Gastrointestinal Tract
05	Peripheral Blood Stream	16	Ovaries	26	Pelvis
06	Brain/CNS	16.01	Fallopian Tubes	27	Peritoneum
07	Head/Neck	17	Bladder	28	Testis
08	Esophagus	18	Prostate	29	Thorax
09	Breast	19	Cervix	29.01	Pleura
10	Lungs	20.10	Colon	30	Other
11.01	Regional Lymph Nodes	20.20	Rectum		
11.02	Distant Lymph Nodes	21	Adrenal		

**** Method of Measurement Codes:**

1 - CT Scan	3 - MRI	5 - Scintigraphy
2 - Spiral CT	4 - PET	7 - Ultrasound
8 - X-Ray	10 - Physical Exam	99 - Other

*****Response of Non-Target Codes:**

CR - Complete Response	IR/SD - Incomplete Response/Stable Disease	PD - Progressive Disease
NL - New Lesion	NE - Not Evaluable	

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TUMOR MEASUREMENTS

O.ASSESS_3

❑ NOT DONE

LESION NUMBER	LOCATION SITE*	DATE OF ASSESSMENT Day Month Year	METHOD OF MEASUREMENT**	MEASUREMENT OF TARGET LESION: longest diameter	RESPONSE OF NON-TARGET LESIONS***
1	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
2	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
3	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
4	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
5	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
6	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
7	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
8	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
9	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
10	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
11	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
12	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
13	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
14	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣

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PAIN INTENSITY ASSESSMENT

PAINVAS1

Date corresponds to current visit (7 days prior to each follow-up visit)

Date (Day Month Year)	PPI	Analgesic Score
1. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
2. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
3. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
4. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
5. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
6. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
7. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣

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ADVERSE EVENT FORM

O.1_AE_1

❑ NONE

1. ADVERSE EVENT DIAGNOSIS	AE form no: 90-01 AE ref. no: ⌴⌴-⌴⌴	AE form no: 90-02 AE ref. no: ⌴⌴-⌴⌴
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: ⌴⌴ ⌴⌴⌴ ⌴⌴⌴⌴ (day / month / year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑ If grade changes, date of change: ⌴⌴ ⌴⌴⌴ ⌴⌴⌴⌴ (day / month / year)	1 ❑ Date of start: ⌴⌴ ⌴⌴⌴ ⌴⌴⌴⌴ (day / month / year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑ If grade changes, date of change: ⌴⌴ ⌴⌴⌴ ⌴⌴⌴⌴ (day / month / year)
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: ⌴⌴ ⌴⌴⌴ ⌴⌴⌴⌴ (day / month / year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: ⌴⌴ ⌴⌴⌴ ⌴⌴⌴⌴ (day / month / year) 6 ❑	1 ❑ / 4 ❑ Date: ⌴⌴ ⌴⌴⌴ ⌴⌴⌴⌴ (day / month / year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: ⌴⌴ ⌴⌴⌴ ⌴⌴⌴⌴ (day / month / year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES - Date event became serious: ⌴⌴ ⌴⌴⌴ ⌴⌴⌴⌴ (day / month / year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES - Date event became serious: ⌴⌴ ⌴⌴⌴ ⌴⌴⌴⌴ (day / month / year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:	

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 90-03 AE ref. no: __-__	AE form no: 90-04 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: __/__/____ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: __/__/____ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: __/__/____ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/____ (day/month/year) 6 ❑	1 ❑ / 4 ❑ Date: __/__/____ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/____ (day/month/year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES: - Date event became serious: __/__/____ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES: - Date event became serious: __/__/____ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:		Monitoring representative's name, date of receipt:

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 90-05 AE ref. no: __-__	AE form no: 90-06 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ☐ Date of start: __/__/__ (day/month/year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐	1 ☐ Date of start: __/__/__ (day/month/year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐
3. GRADE (1 - 4)	1 ☐ 2 ☐ 3 ☐ 4 ☐	1 ☐ 2 ☐ 3 ☐ 4 ☐
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ☐ No ☐	Yes ☐ No ☐
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
6. CORRECTIVE TREATMENT/THERAPY	Yes ☐ No ☐	Yes ☐ No ☐
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ☐ / 4 ☐ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __/__/__ (day/month/year) 6 ☐	1 ☐ / 4 ☐ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __/__/__ (day/month/year) 6 ☐
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐
Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:	

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 90-07 AE ref. no: __-__	AE form no: 90-08 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: __/__/__ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: __/__/__ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/__ (day/month/year) 6 ❑	1 ❑ / 4 ❑ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/__ (day/month/year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:	

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 90-09 AE ref. no: ___-___	AE form no: 90-10 AE ref. no: ___-___
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: ___ ___ ___ (day / month / year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: ___ ___ ___ (day / month / year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: ___ ___ ___ (day / month / year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: ___ ___ ___ (day / month / year) 6 ❑	1 ❑ / 4 ❑ Date: ___ ___ ___ (day / month / year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: ___ ___ ___ (day / month / year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES - Date event became serious: ___ ___ ___ (day / month / year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES - Date event became serious: ___ ___ ___ (day / month / year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:	

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 90-11 AE ref. no: ___-___	AE form no: 90-12 AE ref. no: ___-___
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ☐ Date of start: ___ ___ ___ (day / month / year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐	1 ☐ Date of start: ___ ___ ___ (day / month / year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐
3. GRADE (1 - 4)	1 ☐ 2 ☐ 3 ☐ 4 ☐	1 ☐ 2 ☐ 3 ☐ 4 ☐
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ☐ No ☐	Yes ☐ No ☐
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
6. CORRECTIVE TREATMENT/THERAPY	Yes ☐ No ☐	Yes ☐ No ☐
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ☐ / 4 ☐ Date: ___ ___ ___ (day / month / year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: ___ ___ ___ (day / month / year) 6 ☐	1 ☐ / 4 ☐ Date: ___ ___ ___ (day / month / year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: ___ ___ ___ (day / month / year) 6 ☐
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ☐ No ☐ ➲ IF YES - Date event became serious: ___ ___ ___ (day / month / year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐	Yes ☐ No ☐ ➲ IF YES - Date event became serious: ___ ___ ___ (day / month / year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐
Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:	

** Is there a reasonable possibility that the AE was caused by study treatment?*

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FOLLOW-UP 11

O.FOLLOWUP_2

Subject condition (tick "✓" one box only):

- ❑ Alive
- ❑ Lost to follow-up
- ❑ Dead *(complete Death form)*

Progression

Has the subject had disease progression? (tick "✓" one box only)

- ❑ Unknown
- ❑ Previously reported progression
- ❑ No *
- ❑ Yes **

* If ***NO***, please complete the Tumor Measurement page, PSA, Pain Intensity Assessment forms.

** If ***YES***, please complete the Tumor Measurement and Symptomatic Deterioration forms, PSA, Pain Intensity Assessment form appropriately.

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POST TREATMENT ANTI-CANCER DRUG THERAPY *O.MED_2*

❑ NONE ❑ UNKNOWN

DRUG/REGIMEN/AGENT	START DATE Day Month Year	STOP DATE Day Month Year	ONGOING
1.	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	❑
2.	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	❑
3.	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	❑
4.	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	❑
5.	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	❑
6.	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	❑
7.	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	❑
8.	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	❑
9.	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	❑
10.	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	❑

See Page 26

PSA

LABH_1

DATE OF SAMPLING day month year	TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
__/__/____	PSA		ng/mL	

*** Location:**

01	Skin	12	Liver	22	Mediastinum
02	Muscle/Soft Tissue	13	Stomach	23	Uterus
03	Bone	14	Pancreas	24	Abdomen
04	Bone Marrow	15	Kidneys	25	Gastrointestinal Tract
05	Peripheral Blood Stream	16	Ovaries	26	Pelvis
06	Brain/CNS	16.01	Fallopian Tubes	27	Peritoneum
07	Head/Neck	17	Bladder	28	Testis
08	Esophagus	18	Prostate	29	Thorax
09	Breast	19	Cervix	29.01	Pleura
10	Lungs	20.10	Colon	30	Other
11.01	Regional Lymph Nodes	20.20	Rectum		
11.02	Distant Lymph Nodes	21	Adrenal		

**** Method of Measurement Codes:**

1 - CT Scan	3 - MRI	5 - Scintigraphy
2 - Spiral CT	4 - PET	7 - Ultrasound
8 - X-Ray	10 - Physical Exam	99 - Other

*****Response of Non-Target Codes:**

CR - Complete Response	IR/SD - Incomplete Response/Stable Disease	PD - Progressive Disease
NL - New Lesion	NE - Not Evaluable	

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TUMOR MEASUREMENTS

O.ASSESS_3

❑ NOT DONE

LESION NUMBER	LOCATION SITE*	DATE OF ASSESSMENT Day Month Year	METHOD OF MEASUREMENT**	MEASUREMENT OF TARGET LESION: longest diameter	RESPONSE OF NON-TARGET LESIONS***
1	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
2	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
3	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
4	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
5	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
6	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
7	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
8	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
9	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
10	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
11	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
12	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
13	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
14	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣

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PAIN INTENSITY ASSESSMENT

PAINVAS1

Date corresponds to current visit (7 days prior to each follow-up visit)

Date (Day Month Year)	PPI	Analgesic Score
1. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
2. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
3. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
4. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
5. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
6. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
7. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣

See Page 62

ADVERSE EVENT FORM

O.1_AE_1

❑ NONE

1. **ADVERSE EVENT DIAGNOSIS**	AE form no: 91-01 AE ref. no: ___-___	AE form no: 91-02 AE ref. no: ___-___
2. **STATUS OF AE** 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: ___ ___ ___ (day / month / year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: ___ ___ ___ (day / month / year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. **GRADE (1 - 4)**	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. **ACTION TAKEN WITH STUDY TREATMENT**	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. **OUTCOME** 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: ___ ___ ___ (day / month / year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: ___ ___ ___ (day / month / year) 6 ❑	1 ❑ / 4 ❑ Date: ___ ___ ___ (day / month / year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: ___ ___ ___ (day / month / year) 6 ❑
8. **SERIOUSNESS CRITERIA** **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES - Date event became serious: ___ ___ ___ (day / month / year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES - Date event became serious: ___ ___ ___ (day / month / year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:		Monitoring representative's name, date of receipt:

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 91-03 AE ref. no: __-__	AE form no: 91-04 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: __/__/__ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: __/__/__ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/__ (day/month/year) 6 ❑	1 ❑ / 4 ❑ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/__ (day/month/year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:	

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 91-05 AE ref. no: __-__	AE form no: 91-06 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ☐ Date of start: __/__/__ (day/month/year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐	1 ☐ Date of start: __/__/__ (day/month/year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐
3. GRADE (1 - 4)	1 ☐ 2 ☐ 3 ☐ 4 ☐	1 ☐ 2 ☐ 3 ☐ 4 ☐
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ☐ No ☐	Yes ☐ No ☐
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
6. CORRECTIVE TREATMENT/THERAPY	Yes ☐ No ☐	Yes ☐ No ☐
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ☐ / 4 ☐ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __/__/__ (day/month/year) 6 ☐	1 ☐ / 4 ☐ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __/__/__ (day/month/year) 6 ☐
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐
Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:	

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 91-07 AE ref. no: ___-___	AE form no: 91-08 AE ref. no: ___-___
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: ___ ___ ___ (day / month / year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: ___ ___ ___ (day / month / year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: ___ ___ ___ (day / month / year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: ___ ___ ___ (day / month / year) 6 ❑	1 ❑ / 4 ❑ Date: ___ ___ ___ (day / month / year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: ___ ___ ___ (day / month / year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES - Date event became serious: ___ ___ ___ (day / month / year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES - Date event became serious: ___ ___ ___ (day / month / year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:	

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 91-09 AE ref. no: __-__	AE form no: 91-10 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ☐ Date of start: __/__/____ (day/month/year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐	1 ☐ Date of start: __/__/____ (day/month/year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐
3. GRADE (1 - 4)	1 ☐ 2 ☐ 3 ☐ 4 ☐	1 ☐ 2 ☐ 3 ☐ 4 ☐
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ☐ No ☐	Yes ☐ No ☐
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
6. CORRECTIVE TREATMENT/THERAPY	Yes ☐ No ☐	Yes ☐ No ☐
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ☐ / 4 ☐ Date: __/__/____ (day/month/year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __/__/____ (day/month/year) 6 ☐	1 ☐ / 4 ☐ Date: __/__/____ (day/month/year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __/__/____ (day/month/year) 6 ☐
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __/__/____ (day/month/year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __/__/____ (day/month/year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐
Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:	

** Is there a reasonable possibility that the AE was caused by study treatment?*

See Page 62

ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 91-11 AE ref. no: ___-___	AE form no: 91-12 AE ref. no: ___-___
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ☐ Date of start: ___ ___ ___ (day / month / year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐	1 ☐ Date of start: ___ ___ ___ (day / month / year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐
3. GRADE (1 - 4)	1 ☐ 2 ☐ 3 ☐ 4 ☐	1 ☐ 2 ☐ 3 ☐ 4 ☐
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ☐ No ☐	Yes ☐ No ☐
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
6. CORRECTIVE TREATMENT/THERAPY	Yes ☐ No ☐	Yes ☐ No ☐
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ☐ / 4 ☐ Date: ___ ___ ___ (day / month / year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: ___ ___ ___ (day / month / year) 6 ☐	1 ☐ / 4 ☐ Date: ___ ___ ___ (day / month / year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: ___ ___ ___ (day / month / year) 6 ☐
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ☐ No ☐ ➲ IF YES: - Date event became serious: ___ ___ ___ (day / month / year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐	Yes ☐ No ☐ ➲ IF YES: - Date event became serious: ___ ___ ___ (day / month / year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐
Investigator's name, date of report and signature:		Monitoring representative's name, date of receipt:

** Is there a reasonable possibility that the AE was caused by study treatment?*

FOLLOW-UP 12

O.FOLLOWUP_2

Subject condition (tick "✓" one box only):

- ❑ Alive
- ❑ Lost to follow-up
- ❑ Dead *(complete Death form)*

Progression

Has the subject had disease progression? (tick "✓" one box only)

- ❑ Unknown
- ❑ Previously reported progression
- ❑ No *
- ❑ Yes **

* If ***NO***, please complete the Tumor Measurement page, PSA, Pain Intensity Assessment forms.

** If ***YES***, please complete the Tumor Measurement and Symptomatic Deterioration forms, PSA, Pain Intensity Assessment form appropriately.

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POST TREATMENT ANTI-CANCER DRUG THERAPY *O.MED_2*

❑ NONE ❑ UNKNOWN

DRUG/REGIMEN/AGENT	START DATE Day Month Year	STOP DATE Day Month Year	ONGOING
1.	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	❑
2.	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	❑
3.	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	❑
4.	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	❑
5.	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	❑
6.	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	❑
7.	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	❑
8.	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	❑
9.	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	❑
10.	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	❑

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PSA

LABH_1

DATE OF SAMPLING day month year	TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
␣␣ ␣␣␣ ␣␣␣␣	PSA		ng/mL	

*** Location:**

01	Skin	12	Liver	22	Mediastinum
02	Muscle/Soft Tissue	13	Stomach	23	Uterus
03	Bone	14	Pancreas	24	Abdomen
04	Bone Marrow	15	Kidneys	25	Gastrointestinal Tract
05	Peripheral Blood Stream	16	Ovaries	26	Pelvis
06	Brain/CNS	16.01	Fallopian Tubes	27	Peritoneum
07	Head/Neck	17	Bladder	28	Testis
08	Esophagus	18	Prostate	29	Thorax
09	Breast	19	Cervix	29.01	Pleura
10	Lungs	20.10	Colon	30	Other
11.01	Regional Lymph Nodes	20.20	Rectum		
11.02	Distant Lymph Nodes	21	Adrenal		

**** Method of Measurement Codes:**

1 - CT Scan	3 - MRI	5 - Scintigraphy
2 - Spiral CT	4 - PET	7 - Ultrasound
8 - X-Ray	10 - Physical Exam	99 - Other

*****Response of Non-Target Codes:**

CR - Complete Response	IR/SD - Incomplete Response/Stable Disease	PD - Progressive Disease
NL - New Lesion	NE - Not Evaluable	

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TUMOR MEASUREMENTS

O.ASSESS_3

❑ NOT DONE

LESION NUMBER	LOCATION SITE*	DATE OF ASSESSMENT Day Month Year	METHOD OF MEASUREMENT**	MEASUREMENT OF TARGET LESION: longest diameter	RESPONSE OF NON-TARGET LESIONS***
1	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
2	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
3	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
4	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
5	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
6	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
7	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
8	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
9	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
10	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
11	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
12	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
13	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
14	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣

PAIN INTENSITY ASSESSMENT

PAINVAS1

Date corresponds to current visit (7 days prior to each follow-up visit)

Date (Day Month Year)	PPI	Analgesic Score
1. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
2. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
3. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
4. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
5. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
6. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
7. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣

See Page 62

ADVERSE EVENT FORM

O.1_AE_1

❑ NONE

1. ADVERSE EVENT DIAGNOSIS	AE form no: 92-01 AE ref. no: ___-___	AE form no: 92-02 AE ref. no: ___-___
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: ___ ___ ___ (day / month / year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑ If grade changes, date of change: ___ ___ ___ (day / month / year)	1 ❑ Date of start: ___ ___ ___ (day / month / year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑ If grade changes, date of change: ___ ___ ___ (day / month / year)
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: ___ ___ ___ (day / month / year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: ___ ___ ___ (day / month / year) 6 ❑	1 ❑ / 4 ❑ Date: ___ ___ ___ (day / month / year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: ___ ___ ___ (day / month / year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES - Date event became serious: ___ ___ ___ (day / month / year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES - Date event became serious: ___ ___ ___ (day / month / year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:	

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 92-03 AE ref. no: __-__	AE form no: 92-04 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: __/__/____ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: __/__/____ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: __/__/____ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/____ (day/month/year) 6 ❑	1 ❑ / 4 ❑ Date: __/__/____ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/____ (day/month/year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __/__/____ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __/__/____ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:	

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 92-05 AE ref. no: __-__	AE form no: 92-06 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ☐ Date of start: __ __ day __ __ __ month __ __ __ __ year 2 ☐ *(do not complete the remaining items in the column)* 3 ☐	1 ☐ Date of start: __ __ day __ __ __ month __ __ __ __ year 2 ☐ *(do not complete the remaining items in the column)* 3 ☐
3. GRADE (1 - 4)	1 ☐ 2 ☐ 3 ☐ 4 ☐	1 ☐ 2 ☐ 3 ☐ 4 ☐
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ☐ No ☐	Yes ☐ No ☐
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
6. CORRECTIVE TREATMENT/THERAPY	Yes ☐ No ☐	Yes ☐ No ☐
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ☐ / 4 ☐ Date: __ __ day __ __ __ month __ __ __ __ year Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __ __ day __ __ __ month __ __ __ __ year 6 ☐	1 ☐ / 4 ☐ Date: __ __ day __ __ __ month __ __ __ __ year Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __ __ day __ __ __ month __ __ __ __ year 6 ☐
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __ __ day __ __ __ month __ __ __ __ year - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __ __ day __ __ __ month __ __ __ __ year - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐
Investigator's name, date of report and signature:		Monitoring representative's name, date of receipt:

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 92-07 AE ref. no: __-__	AE form no: 92-08 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: __/__/__ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: __/__/__ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/__ (day/month/year) 6 ❑	1 ❑ / 4 ❑ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/__ (day/month/year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:	

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 92-09 AE ref. no: __-__	AE form no: 92-10 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ☐ Date of start: __/__/____ (day/month/year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐	1 ☐ Date of start: __/__/____ (day/month/year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐
3. GRADE (1 - 4)	1 ☐ 2 ☐ 3 ☐ 4 ☐	1 ☐ 2 ☐ 3 ☐ 4 ☐
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ☐ No ☐	Yes ☐ No ☐
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
6. CORRECTIVE TREATMENT/THERAPY	Yes ☐ No ☐	Yes ☐ No ☐
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ☐ / 4 ☐ Date: __/__/____ (day/month/year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __/__/____ (day/month/year) 6 ☐	1 ☐ / 4 ☐ Date: __/__/____ (day/month/year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __/__/____ (day/month/year) 6 ☐
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __/__/____ (day/month/year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __/__/____ (day/month/year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐
Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:	

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 92-11 AE ref. no: __-__	AE form no: 92-12 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ☐ Date of start: __/__/____ (day / month / year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐	1 ☐ Date of start: __/__/____ (day / month / year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐
3. GRADE (1 - 4)	1 ☐ 2 ☐ 3 ☐ 4 ☐	1 ☐ 2 ☐ 3 ☐ 4 ☐
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ☐ No ☐	Yes ☐ No ☐
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
6. CORRECTIVE TREATMENT/THERAPY	Yes ☐ No ☐	Yes ☐ No ☐
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ☐ / 4 ☐ Date: __/__/____ (day / month / year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __/__/____ (day / month / year) 6 ☐	1 ☐ / 4 ☐ Date: __/__/____ (day / month / year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __/__/____ (day / month / year) 6 ☐
8. SERIOUSNESS CRITERIA IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __/__/____ (day / month / year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __/__/____ (day / month / year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐
Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:	

** Is there a reasonable possibility that the AE was caused by study treatment?*

See Page 12

See Page 278

FOLLOW-UP 13

O.FOLLOWUP_2

Subject condition (tick "✓" one box only):

- ❑ Alive
- ❑ Lost to follow-up
- ❑ Dead *(complete Death form)*

Progression

Has the subject had disease progression? (tick "✓" one box only)

- ❑ Unknown
- ❑ Previously reported progression
- ❑ No *
- ❑ Yes **

* If ***NO***, please complete the Tumor Measurement page, PSA, Pain Intensity Assessment forms.

** If ***YES***, please complete the Tumor Measurement and Symptomatic Deterioration forms, PSA, Pain Intensity Assessment form appropriately.

See Page 279

POST TREATMENT ANTI-CANCER DRUG THERAPY *O.MED_2*

❑ NONE ❑ UNKNOWN

DRUG/REGIMEN/AGENT	START DATE Day Month Year	STOP DATE Day Month Year	ONGOING
1.	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	❑
2.	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	❑
3.	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	❑
4.	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	❑
5.	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	❑
6.	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	❑
7.	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	❑
8.	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	❑
9.	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	❑
10.	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	❑

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PSA

LABH_1

DATE OF SAMPLING day month year	TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	PSA		ng/mL	

*** Location:**

01	Skin	12	Liver	22	Mediastinum
02	Muscle/Soft Tissue	13	Stomach	23	Uterus
03	Bone	14	Pancreas	24	Abdomen
04	Bone Marrow	15	Kidneys	25	Gastrointestinal Tract
05	Peripheral Blood Stream	16	Ovaries	26	Pelvis
06	Brain/CNS	16.01	Fallopian Tubes	27	Peritoneum
07	Head/Neck	17	Bladder	28	Testis
08	Esophagus	18	Prostate	29	Thorax
09	Breast	19	Cervix	29.01	Pleura
10	Lungs	20.10	Colon	30	Other
11.01	Regional Lymph Nodes	20.20	Rectum		
11.02	Distant Lymph Nodes	21	Adrenal		

**** Method of Measurement Codes:**

1 - CT Scan	3 - MRI	5 - Scintigraphy
2 - Spiral CT	4 - PET	7 - Ultrasound
8 - X-Ray	10 - Physical Exam	99 - Other

*****Response of Non-Target Codes:**

CR - Complete Response	IR/SD - Incomplete Response/Stable Disease	PD - Progressive Disease
NL - New Lesion	NE - Not Evaluable	

TUMOR MEASUREMENTS

O.ASSESS_3

❑ NOT DONE

LESION NUMBER	LOCATION SITE*	DATE OF ASSESSMENT Day Month Year	METHOD OF MEASUREMENT**	MEASUREMENT OF TARGET LESION: longest diameter	RESPONSE OF NON-TARGET LESIONS***
1	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
2	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
3	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
4	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
5	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
6	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
7	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
8	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
9	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
10	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
11	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
12	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
13	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
14	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣

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PAIN INTENSITY ASSESSMENT

PAINVAS1

Date corresponds to current visit (7 days prior to each follow-up visit)

Date (Day Month Year)	PPI	Analgesic Score
1. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
2. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
3. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
4. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
5. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
6. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
7. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣

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ADVERSE EVENT FORM

O.1_AE_1

❑ NONE

1. ADVERSE EVENT DIAGNOSIS	AE form no: 93-01 AE ref. no: ␣␣-␣␣	AE form no: 93-02 AE ref. no: ␣␣-␣␣
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑ If grade changes, date of change: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year)	1 ❑ Date of start: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑ If grade changes, date of change: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year)
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) 6 ❑	1 ❑ / 4 ❑ Date: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES - Date event became serious: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES - Date event became serious: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:		Monitoring representative's name, date of receipt:

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. **ADVERSE EVENT DIAGNOSIS**	AE form no: 93-03 AE ref. no: __-__	AE form no: 93-04 AE ref. no: __-__
2. **STATUS OF AE** 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ☐ Date of start: __ __ (day) __ __ __ (month) __ __ __ __ (year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐	1 ☐ Date of start: __ __ (day) __ __ __ (month) __ __ __ __ (year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐
3. **GRADE (1 - 4)**	1 ☐ 2 ☐ 3 ☐ 4 ☐	1 ☐ 2 ☐ 3 ☐ 4 ☐
4. **RELATIONSHIP TO STUDY TREATMENT***	Yes ☐ No ☐	Yes ☐ No ☐
5. **ACTION TAKEN WITH STUDY TREATMENT**	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
6. **CORRECTIVE TREATMENT/THERAPY**	Yes ☐ No ☐	Yes ☐ No ☐
7. **OUTCOME** 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ☐ / 4 ☐ Date: __ __ (day) __ __ __ (month) __ __ __ __ (year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __ __ (day) __ __ __ (month) __ __ __ __ (year) 6 ☐	1 ☐ / 4 ☐ Date: __ __ (day) __ __ __ (month) __ __ __ __ (year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __ __ (day) __ __ __ (month) __ __ __ __ (year) 6 ☐
8. **SERIOUSNESS CRITERIA** **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ☐ No ☐ ➲ **IF YES** - Date event became serious: __ __ (day) __ __ __ (month) __ __ __ __ (year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐	Yes ☐ No ☐ ➲ **IF YES** - Date event became serious: __ __ (day) __ __ __ (month) __ __ __ __ (year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐
Investigator's name, date of report and signature:		Monitoring representative's name, date of receipt:

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

0.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 93-05 AE ref. no: __-__	AE form no: 93-06 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ☐ Date of start: __/__/____ (day/month/year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐	1 ☐ Date of start: __/__/____ (day/month/year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐
3. GRADE (1 - 4)	1 ☐ 2 ☐ 3 ☐ 4 ☐	1 ☐ 2 ☐ 3 ☐ 4 ☐
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ☐ No ☐	Yes ☐ No ☐
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
6. CORRECTIVE TREATMENT/THERAPY	Yes ☐ No ☐	Yes ☐ No ☐
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ☐ / 4 ☐ Date: __/__/____ (day/month/year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __/__/____ (day/month/year) 6 ☐	1 ☐ / 4 ☐ Date: __/__/____ (day/month/year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __/__/____ (day/month/year) 6 ☐
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __/__/____ (day/month/year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __/__/____ (day/month/year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐
Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:	

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 93-07 AE ref. no: __-__	AE form no: 93-08 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ☐ Date of start: __/__/__ (day/month/year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐	1 ☐ Date of start: __/__/__ (day/month/year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐
3. GRADE (1 - 4)	1 ☐ 2 ☐ 3 ☐ 4 ☐	1 ☐ 2 ☐ 3 ☐ 4 ☐
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ☐ No ☐	Yes ☐ No ☐
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
6. CORRECTIVE TREATMENT/THERAPY	Yes ☐ No ☐	Yes ☐ No ☐
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ☐ / 4 ☐ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __/__/__ (day/month/year) 6 ☐	1 ☐ / 4 ☐ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __/__/__ (day/month/year) 6 ☐
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐
Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:	

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 93-09 AE ref. no: __-__	AE form no: 93-10 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ☐ Date of start: __ __ day __ __ __ month __ __ __ __ year 2 ☐ *(do not complete the remaining items in the column)* 3 ☐	1 ☐ Date of start: __ __ day __ __ __ month __ __ __ __ year 2 ☐ *(do not complete the remaining items in the column)* 3 ☐
3. GRADE (1 - 4)	1 ☐ 2 ☐ 3 ☐ 4 ☐	1 ☐ 2 ☐ 3 ☐ 4 ☐
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ☐ No ☐	Yes ☐ No ☐
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
6. CORRECTIVE TREATMENT/THERAPY	Yes ☐ No ☐	Yes ☐ No ☐
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ☐ / 4 ☐ Date: __ __ day __ __ __ month __ __ __ __ year Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __ __ day __ __ __ month __ __ __ __ year 6 ☐	1 ☐ / 4 ☐ Date: __ __ day __ __ __ month __ __ __ __ year Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __ __ day __ __ __ month __ __ __ __ year 6 ☐
8. SERIOUSNESS CRITERIA IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __ __ day __ __ __ month __ __ __ __ year - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __ __ day __ __ __ month __ __ __ __ year - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐
Investigator's name, date of report and signature:		Monitoring representative's name, date of receipt:

** Is there a reasonable possibility that the AE was caused by study treatment?*

See Page 62

ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 93-11 AE ref. no: __-__	AE form no: 93-12 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ☐ Date of start: __/__/__ (day/month/year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐	1 ☐ Date of start: __/__/__ (day/month/year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐
3. GRADE (1 - 4)	1 ☐ 2 ☐ 3 ☐ 4 ☐	1 ☐ 2 ☐ 3 ☐ 4 ☐
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ☐ No ☐	Yes ☐ No ☐
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
6. CORRECTIVE TREATMENT/THERAPY	Yes ☐ No ☐	Yes ☐ No ☐
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ☐ / 4 ☐ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __/__/__ (day/month/year) 6 ☐	1 ☐ / 4 ☐ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __/__/__ (day/month/year) 6 ☐
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐
Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:	

** Is there a reasonable possibility that the AE was caused by study treatment?*

See Page 278

FOLLOW-UP 14

O.FOLLOWUP_2

Subject condition (tick "✓" one box only):

- ❑ Alive
- ❑ Lost to follow-up
- ❑ Dead *(complete Death form)*

Progression

Has the subject had disease progression? (tick "✓" one box only)

- ❑ Unknown
- ❑ Previously reported progression
- ❑ No *
- ❑ Yes **

* If ***NO***, please complete the Tumor Measurement page, PSA, Pain Intensity Assessment forms.

** If ***YES***, please complete the Tumor Measurement and Symptomatic Deterioration forms, PSA, Pain Intensity Assessment form appropriately.

See Page 279

POST TREATMENT ANTI-CANCER DRUG THERAPY *O.MED_2*

❑ NONE ❑ UNKNOWN

DRUG/REGIMEN/AGENT	START DATE Day Month Year	STOP DATE Day Month Year	ONGOING
1.	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	❑
2.	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	❑
3.	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	❑
4.	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	❑
5.	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	❑
6.	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	❑
7.	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	❑
8.	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	❑
9.	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	❑
10.	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	❑

See Page 26

PSA

LABH_1

DATE OF SAMPLING day month year	TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	PSA		ng/mL	

*** Location:**

01	Skin	12	Liver	22	Mediastinum
02	Muscle/Soft Tissue	13	Stomach	23	Uterus
03	Bone	14	Pancreas	24	Abdomen
04	Bone Marrow	15	Kidneys	25	Gastrointestinal Tract
05	Peripheral Blood Stream	16	Ovaries	26	Pelvis
06	Brain/CNS	16.01	Fallopian Tubes	27	Peritoneum
07	Head/Neck	17	Bladder	28	Testis
08	Esophagus	18	Prostate	29	Thorax
09	Breast	19	Cervix	29.01	Pleura
10	Lungs	20.10	Colon	30	Other
11.01	Regional Lymph Nodes	20.20	Rectum		
11.02	Distant Lymph Nodes	21	Adrenal		

**** Method of Measurement Codes:**

1 - CT Scan	3 - MRI	5 - Scintigraphy
2 - Spiral CT	4 - PET	7 - Ultrasound
8 - X-Ray	10 - Physical Exam	99 - Other

*****Response of Non-Target Codes:**

CR - Complete Response	IR/SD - Incomplete Response/Stable Disease	PD - Progressive Disease
NL - New Lesion	NE - Not Evaluable	

See Page 55

TUMOR MEASUREMENTS

O.ASSESS_3

❑ NOT DONE

LESION NUMBER	LOCATION SITE*	DATE OF ASSESSMENT Day Month Year	METHOD OF MEASUREMENT**	MEASUREMENT OF TARGET LESION: longest diameter	RESPONSE OF NON-TARGET LESIONS***
1	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋
2	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋
3	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋
4	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋
5	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋
6	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋
7	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋
8	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋
9	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋
10	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋
11	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋
12	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋
13	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋
14	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋

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PAIN INTENSITY ASSESSMENT

PAINVAS1

Date corresponds to current visit (7 days prior to each follow-up visit)

Date (Day Month Year)	PPI	Analgesic Score
1. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
2. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
3. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
4. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
5. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
6. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
7. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣

See Page 62

ADVERSE EVENT FORM

O.1_AE_1

❑ NONE

1. ADVERSE EVENT DIAGNOSIS	AE form no: 94-01 AE ref. no: ⌴⌴-⌴⌴	AE form no: 94-02 AE ref. no: ⌴⌴-⌴⌴
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: ⌴⌴ ⌴⌴⌴ ⌴⌴⌴⌴ (day / month / year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑ If grade changes, date of change: ⌴⌴ ⌴⌴⌴ ⌴⌴⌴⌴ (day / month / year)	1 ❑ Date of start: ⌴⌴ ⌴⌴⌴ ⌴⌴⌴⌴ (day / month / year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑ If grade changes, date of change: ⌴⌴ ⌴⌴⌴ ⌴⌴⌴⌴ (day / month / year)
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: ⌴⌴ ⌴⌴⌴ ⌴⌴⌴⌴ (day / month / year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: ⌴⌴ ⌴⌴⌴ ⌴⌴⌴⌴ (day / month / year) 6 ❑	1 ❑ / 4 ❑ Date: ⌴⌴ ⌴⌴⌴ ⌴⌴⌴⌴ (day / month / year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: ⌴⌴ ⌴⌴⌴ ⌴⌴⌴⌴ (day / month / year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES - Date event became serious: ⌴⌴ ⌴⌴⌴ ⌴⌴⌴⌴ (day / month / year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES - Date event became serious: ⌴⌴ ⌴⌴⌴ ⌴⌴⌴⌴ (day / month / year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:	

** Is there a reasonable possibility that the AE was caused by study treatment?*

See Page 62

ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 94-03 AE ref. no: __-__	AE form no: 94-04 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: __/__/__ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: __/__/__ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/__ (day/month/year) 6 ❑	1 ❑ / 4 ❑ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/__ (day/month/year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES: - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES: - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:		Monitoring representative's name, date of receipt:

** Is there a reasonable possibility that the AE was caused by study treatment?*

FOLLOW-UP 14 V 94

See Page 62

ADVERSE EVENT FORM

O.1_AE_1

1. **ADVERSE EVENT DIAGNOSIS**	AE form no: 94-05 AE ref. no: __-__	AE form no: 94-06 AE ref. no: __-__
2. **STATUS OF AE** 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: __ __ day __ __ __ month __ __ __ __ year 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: __ __ day __ __ __ month __ __ __ __ year 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. **GRADE (1 - 4)**	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. **ACTION TAKEN WITH STUDY TREATMENT**	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. **OUTCOME** 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: __ __ day __ __ __ month __ __ __ __ year Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __ __ day __ __ __ month __ __ __ __ year 6 ❑	1 ❑ / 4 ❑ Date: __ __ day __ __ __ month __ __ __ __ year Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __ __ day __ __ __ month __ __ __ __ year 6 ❑
8. **SERIOUSNESS CRITERIA** **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ **IF YES** - Date event became serious: __ __ day __ __ __ month __ __ __ __ year - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ **IF YES** - Date event became serious: __ __ day __ __ __ month __ __ __ __ year - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:		Monitoring representative's name, date of receipt:

** Is there a reasonable possibility that the AE was caused by study treatment?*

See Page 62

ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 94-07 AE ref. no: __-__	AE form no: 94-08 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ☐ Date of start: __/__/__ (day/month/year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐	1 ☐ Date of start: __/__/__ (day/month/year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐
3. GRADE (1 - 4)	1 ☐ 2 ☐ 3 ☐ 4 ☐	1 ☐ 2 ☐ 3 ☐ 4 ☐
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ☐ No ☐	Yes ☐ No ☐
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
6. CORRECTIVE TREATMENT/THERAPY	Yes ☐ No ☐	Yes ☐ No ☐
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ☐ / 4 ☐ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __/__/__ (day/month/year) 6 ☐	1 ☐ / 4 ☐ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __/__/__ (day/month/year) 6 ☐
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐
Investigator's name, date of report and signature:		Monitoring representative's name, date of receipt:

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 94-09 AE ref. no: __-__	AE form no: 94-10 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ☐ Date of start: __ __ (day) __ __ __ (month) __ __ __ __ (year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐	1 ☐ Date of start: __ __ (day) __ __ __ (month) __ __ __ __ (year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐
3. GRADE (1 - 4)	1 ☐ 2 ☐ 3 ☐ 4 ☐	1 ☐ 2 ☐ 3 ☐ 4 ☐
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ☐ No ☐	Yes ☐ No ☐
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
6. CORRECTIVE TREATMENT/THERAPY	Yes ☐ No ☐	Yes ☐ No ☐
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ☐ / 4 ☐ Date: __ __ (day) __ __ __ (month) __ __ __ __ (year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __ __ (day) __ __ __ (month) __ __ __ __ (year) 6 ☐	1 ☐ / 4 ☐ Date: __ __ (day) __ __ __ (month) __ __ __ __ (year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __ __ (day) __ __ __ (month) __ __ __ __ (year) 6 ☐
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __ __ (day) __ __ __ (month) __ __ __ __ (year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __ __ (day) __ __ __ (month) __ __ __ __ (year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐
Investigator's name, date of report and signature:		Monitoring representative's name, date of receipt:

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 94-11 AE ref. no: __-__	AE form no: 94-12 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ☐ Date of start: __/__/____ (day/month/year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐	1 ☐ Date of start: __/__/____ (day/month/year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐
3. GRADE (1 - 4)	1 ☐ 2 ☐ 3 ☐ 4 ☐	1 ☐ 2 ☐ 3 ☐ 4 ☐
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ☐ No ☐	Yes ☐ No ☐
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
6. CORRECTIVE TREATMENT/THERAPY	Yes ☐ No ☐	Yes ☐ No ☐
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ☐ / 4 ☐ Date: __/__/____ (day/month/year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __/__/____ (day/month/year) 6 ☐	1 ☐ / 4 ☐ Date: __/__/____ (day/month/year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __/__/____ (day/month/year) 6 ☐
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __/__/____ (day/month/year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __/__/____ (day/month/year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐
Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:	

** Is there a reasonable possibility that the AE was caused by study treatment?*

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FOLLOW-UP 15

O.FOLLOWUP_2

Subject condition (tick "✓" one box only):

- ❑ Alive
- ❑ Lost to follow-up
- ❑ Dead *(complete Death form)*

Progression

Has the subject had disease progression? (tick "✓" one box only)

- ❑ Unknown
- ❑ Previously reported progression
- ❑ No *
- ❑ Yes **

* If ***NO***, please complete the Tumor Measurement page, PSA, Pain Intensity Assessment forms.

** If ***YES***, please complete the Tumor Measurement and Symptomatic Deterioration forms, PSA, Pain Intensity Assessment form appropriately.

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POST TREATMENT ANTI-CANCER DRUG THERAPY *O.MED_2*

❑ NONE ❑ UNKNOWN

DRUG/REGIMEN/AGENT	START DATE Day Month Year	STOP DATE Day Month Year	ONGOING
1.	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣	❑
2.	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣	❑
3.	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣	❑
4.	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣	❑
5.	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣	❑
6.	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣	❑
7.	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣	❑
8.	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣	❑
9.	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣	❑
10.	␣␣ ␣␣␣ ␣␣␣␣	␣␣ ␣␣␣ ␣␣␣␣	❑

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PSA

LABH_1

DATE OF SAMPLING day month year	TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	PSA		ng/mL	

*** Location:**

01	Skin	12	Liver	22	Mediastinum
02	Muscle/Soft Tissue	13	Stomach	23	Uterus
03	Bone	14	Pancreas	24	Abdomen
04	Bone Marrow	15	Kidneys	25	Gastrointestinal Tract
05	Peripheral Blood Stream	16	Ovaries	26	Pelvis
06	Brain/CNS	16.01	Fallopian Tubes	27	Peritoneum
07	Head/Neck	17	Bladder	28	Testis
08	Esophagus	18	Prostate	29	Thorax
09	Breast	19	Cervix	29.01	Pleura
10	Lungs	20.10	Colon	30	Other
11.01	Regional Lymph Nodes	20.20	Rectum		
11.02	Distant Lymph Nodes	21	Adrenal		

**** Method of Measurement Codes:**

1 - CT Scan	3 - MRI	5 - Scintigraphy
2 - Spiral CT	4 - PET	7 - Ultrasound
8 - X-Ray	10 - Physical Exam	99 - Other

*****Response of Non-Target Codes:**

CR - Complete Response	IR/SD - Incomplete Response/Stable Disease	PD - Progressive Disease
NL - New Lesion	NE - Not Evaluable	

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TUMOR MEASUREMENTS

O.ASSESS_3

❑ NOT DONE

LESION NUMBER	LOCATION SITE*	DATE OF ASSESSMENT Day Month Year	METHOD OF MEASUREMENT**	MEASUREMENT OF TARGET LESION: longest diameter	RESPONSE OF NON-TARGET LESIONS***
1	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋
2	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋
3	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋
4	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋
5	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋
6	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋
7	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋
8	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋
9	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋
10	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋
11	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋
12	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋
13	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋
14	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋

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PAIN INTENSITY ASSESSMENT

PAINVAS1

Date corresponds to current visit (7 days prior to each follow-up visit)

Date (Day Month Year)	PPI	Analgesic Score
1. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
2. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
3. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
4. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
5. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
6. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
7. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣

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ADVERSE EVENT FORM

O.1_AE_1

❑ NONE

1. ADVERSE EVENT DIAGNOSIS	AE form no: 95-01 AE ref. no: ␣␣-␣␣	AE form no: 95-02 AE ref. no: ␣␣-␣␣
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑ If grade changes, date of change: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year)	1 ❑ Date of start: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑ If grade changes, date of change: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year)
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) 6 ❑	1 ❑ / 4 ❑ Date: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES - Date event became serious: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES - Date event became serious: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:		Monitoring representative's name, date of receipt:

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 95-03 AE ref. no: __-__	AE form no: 95-04 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: __/__/__ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: __/__/__ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/__ (day/month/year) 6 ❑	1 ❑ / 4 ❑ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/__ (day/month/year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:		Monitoring representative's name, date of receipt:

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 95-05 AE ref. no: __-__	AE form no: 95-06 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: __/__/__ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: __/__/__ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/__ (day/month/year) 6 ❑	1 ❑ / 4 ❑ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/__ (day/month/year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:	

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 95-07 AE ref. no: __-__	AE form no: 95-08 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ☐ Date of start: __/__/__ (day/month/year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐	1 ☐ Date of start: __/__/__ (day/month/year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐
3. GRADE (1 - 4)	1 ☐ 2 ☐ 3 ☐ 4 ☐	1 ☐ 2 ☐ 3 ☐ 4 ☐
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ☐ No ☐	Yes ☐ No ☐
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
6. CORRECTIVE TREATMENT/THERAPY	Yes ☐ No ☐	Yes ☐ No ☐
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ☐ / 4 ☐ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __/__/__ (day/month/year) 6 ☐	1 ☐ / 4 ☐ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __/__/__ (day/month/year) 6 ☐
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐
Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:	

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 95-09 AE ref. no: __-__	AE form no: 95-10 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ☐ Date of start: __/__/____ (day/month/year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐	1 ☐ Date of start: __/__/____ (day/month/year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐
3. GRADE (1 - 4)	1 ☐ 2 ☐ 3 ☐ 4 ☐	1 ☐ 2 ☐ 3 ☐ 4 ☐
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ☐ No ☐	Yes ☐ No ☐
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
6. CORRECTIVE TREATMENT/THERAPY	Yes ☐ No ☐	Yes ☐ No ☐
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ☐ / 4 ☐ Date: __/__/____ (day/month/year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __/__/____ (day/month/year) 6 ☐	1 ☐ / 4 ☐ Date: __/__/____ (day/month/year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __/__/____ (day/month/year) 6 ☐
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __/__/____ (day/month/year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __/__/____ (day/month/year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐
Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:	

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 95-11 AE ref. no: __-__	AE form no: 95-12 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ☐ Date of start: __/__/____ (day/month/year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐	1 ☐ Date of start: __/__/____ (day/month/year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐
3. GRADE (1 - 4)	1 ☐ 2 ☐ 3 ☐ 4 ☐	1 ☐ 2 ☐ 3 ☐ 4 ☐
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ☐ No ☐	Yes ☐ No ☐
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
6. CORRECTIVE TREATMENT/THERAPY	Yes ☐ No ☐	Yes ☐ No ☐
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ☐ / 4 ☐ Date: __/__/____ (day/month/year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __/__/____ (day/month/year) 6 ☐	1 ☐ / 4 ☐ Date: __/__/____ (day/month/year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __/__/____ (day/month/year) 6 ☐
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __/__/____ (day/month/year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __/__/____ (day/month/year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐
Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:	

** Is there a reasonable possibility that the AE was caused by study treatment?*

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FOLLOW-UP 16

O.FOLLOWUP_2

Subject condition (tick "✓" one box only):

- ❑ Alive
- ❑ Lost to follow-up
- ❑ Dead *(complete Death form)*

Progression

Has the subject had disease progression? (tick "✓" one box only)

- ❑ Unknown
- ❑ Previously reported progression
- ❑ No *
- ❑ Yes **

* If ***NO***, please complete the Tumor Measurement page, PSA, Pain Intensity Assessment forms.

** If ***YES***, please complete the Tumor Measurement and Symptomatic Deterioration forms, PSA, Pain Intensity Assessment form appropriately.

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POST TREATMENT ANTI-CANCER DRUG THERAPY *O.MED_2*

❑ NONE ❑ UNKNOWN

DRUG/REGIMEN/AGENT	START DATE Day Month Year	STOP DATE Day Month Year	ONGOING
1.	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	❑
2.	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	❑
3.	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	❑
4.	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	❑
5.	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	❑
6.	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	❑
7.	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	❑
8.	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	❑
9.	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	❑
10.	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	❑

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PSA

LABH_1

DATE OF SAMPLING day month year	TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
␣␣ ␣␣␣ ␣␣␣␣	PSA		ng/mL	

*** Location:**

01	Skin	12	Liver	22	Mediastinum
02	Muscle/Soft Tissue	13	Stomach	23	Uterus
03	Bone	14	Pancreas	24	Abdomen
04	Bone Marrow	15	Kidneys	25	Gastrointestinal Tract
05	Peripheral Blood Stream	16	Ovaries	26	Pelvis
06	Brain/CNS	16.01	Fallopian Tubes	27	Peritoneum
07	Head/Neck	17	Bladder	28	Testis
08	Esophagus	18	Prostate	29	Thorax
09	Breast	19	Cervix	29.01	Pleura
10	Lungs	20.10	Colon	30	Other
11.01	Regional Lymph Nodes	20.20	Rectum		
11.02	Distant Lymph Nodes	21	Adrenal		

**** Method of Measurement Codes:**

1 - CT Scan	3 - MRI	5 - Scintigraphy
2 - Spiral CT	4 - PET	7 - Ultrasound
8 - X-Ray	10 - Physical Exam	99 - Other

*****Response of Non-Target Codes:**

CR - Complete Response	IR/SD - Incomplete Response/Stable Disease	PD - Progressive Disease
NL - New Lesion	NE - Not Evaluable	

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TUMOR MEASUREMENTS

O.ASSESS_3

❑ NOT DONE

LESION NUMBER	LOCATION SITE*	DATE OF ASSESSMENT Day Month Year	METHOD OF MEASUREMENT**	MEASUREMENT OF TARGET LESION: longest diameter	RESPONSE OF NON-TARGET LESIONS***
1	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
2	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
3	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
4	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
5	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
6	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
7	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
8	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
9	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
10	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
11	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
12	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
13	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
14	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣

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PAIN INTENSITY ASSESSMENT

PAINVAS1

Date corresponds to current visit (7 days prior to each follow-up visit)

Date (Day Month Year)	PPI	Analgesic Score
1. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
2. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
3. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
4. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
5. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
6. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
7. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣

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ADVERSE EVENT FORM

O.1_AE_1

❑ NONE

1. ADVERSE EVENT DIAGNOSIS	AE form no: 96-01 AE ref. no: ␣␣-␣␣	AE form no: 96-02 AE ref. no: ␣␣-␣␣
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑ If grade changes, date of change: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year)	1 ❑ Date of start: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑ If grade changes, date of change: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year)
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) 6 ❑	1 ❑ / 4 ❑ Date: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES: - Date event became serious: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES: - Date event became serious: ␣␣ ␣␣␣ ␣␣␣␣ (day / month / year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:		Monitoring representative's name, date of receipt:

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 96-03 AE ref. no: __-__	AE form no: 96-04 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: __/__/__ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: __/__/__ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/__ (day/month/year) 6 ❑	1 ❑ / 4 ❑ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/__ (day/month/year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES: - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES: - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:	

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 96-05 AE ref. no: __-__	AE form no: 96-06 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ☐ Date of start: __/__/__ (day/month/year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐	1 ☐ Date of start: __/__/__ (day/month/year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐
3. GRADE (1 - 4)	1 ☐ 2 ☐ 3 ☐ 4 ☐	1 ☐ 2 ☐ 3 ☐ 4 ☐
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ☐ No ☐	Yes ☐ No ☐
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
6. CORRECTIVE TREATMENT/THERAPY	Yes ☐ No ☐	Yes ☐ No ☐
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ☐ / 4 ☐ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __/__/__ (day/month/year) 6 ☐	1 ☐ / 4 ☐ Date: __/__/__ (day/month/year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: __/__/__ (day/month/year) 6 ☐
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐	Yes ☐ No ☐ ➲ IF YES - Date event became serious: __/__/__ (day/month/year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐
Investigator's name, date of report and signature:		Monitoring representative's name, date of receipt:

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 96-07 AE ref. no: __-__	AE form no: 96-08 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: __/__/____ (day / month / year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: __/__/____ (day / month / year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: __/__/____ (day / month / year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/____ (day / month / year) 6 ❑	1 ❑ / 4 ❑ Date: __/__/____ (day / month / year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/____ (day / month / year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __/__/____ (day / month / year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __/__/____ (day / month / year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:	

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 96-09 AE ref. no: __-__	AE form no: 96-10 AE ref. no: __-__
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: __/__/____ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: __/__/____ (day/month/year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: __/__/____ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/____ (day/month/year) 6 ❑	1 ❑ / 4 ❑ Date: __/__/____ (day/month/year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: __/__/____ (day/month/year) 6 ❑
8. SERIOUSNESS CRITERIA IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __/__/____ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES - Date event became serious: __/__/____ (day/month/year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:	

** Is there a reasonable possibility that the AE was caused by study treatment?*

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ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 96-11 AE ref. no: ___-___	AE form no: 96-12 AE ref. no: ___-___
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ☐ Date of start: ___ ___ ___ (day / month / year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐	1 ☐ Date of start: ___ ___ ___ (day / month / year) 2 ☐ *(do not complete the remaining items in the column)* 3 ☐
3. GRADE (1 - 4)	1 ☐ 2 ☐ 3 ☐ 4 ☐	1 ☐ 2 ☐ 3 ☐ 4 ☐
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ☐ No ☐	Yes ☐ No ☐
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
6. CORRECTIVE TREATMENT/THERAPY	Yes ☐ No ☐	Yes ☐ No ☐
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ☐ / 4 ☐ Date: ___ ___ ___ (day / month / year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: ___ ___ ___ (day / month / year) 6 ☐	1 ☐ / 4 ☐ Date: ___ ___ ___ (day / month / year) Specify sequelae: _____ 2 ☐ 3 ☐ 5 ☐ Date of death: ___ ___ ___ (day / month / year) 6 ☐
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ☐ No ☐ ➲ IF YES - Date event became serious: ___ ___ ___ (day / month / year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐	Yes ☐ No ☐ ➲ IF YES - Date event became serious: ___ ___ ___ (day / month / year) - Tick below all criteria that apply: Resulting in death ☐ Life-threatening ☐ Requiring/prolonging hospitalization ☐ Persistent/significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event ☐
Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:	

** Is there a reasonable possibility that the AE was caused by study treatment?*

END OF STUDY *O.ENDST_1*

Date of end of study*: <DSSTDTC> ⌊⌊ day ⌊⌊⌊ month ⌊⌊⌊⌊ year

Main reason for stopping study (tick one box only): <DSTERM>

- Completed follow-up period . . . . . ❑
- Adverse event** . . . . . ❑
- Death*** . . . . . ❑
- Poor compliance to protocol . . . . . ❑
- Subject lost to follow-up . . . . . ❑
- Other reason . . . . . ❑

If other reason, specify: <DSTERM> _____

_____

- Subject request . . . . . ❑

This box should be checked only if the subject withdraw his consent and none of the above reasons are present especially adverse event.

Specify : <DSTERM> _____

* ***Date of last contact in case of patient lost to follow-up.***

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

*** ***In case of death, complete the Death form.***

"I, the undersigned, certify that I have carefully examined all entries on the CRF for this subject. To the best of my knowledge, all information is correct."

Investigator signature: _____ Date: ⌊⌊ day ⌊⌊⌊ month ⌊⌊⌊⌊ year

CONCOMITANT MEDICATION *O.MED_9*

☐ NONE

Tick the box if no medication(s) has been taken concomitantly with study drug.

	MEDICATION	START DATE Day Month Year	END DATE Day Month Year
1.		☐ Ongoing	☐ Ongoing
2.		☐ Ongoing	☐ Ongoing
3.		☐ Ongoing	☐ Ongoing
4.		☐ Ongoing	☐ Ongoing
5.		☐ Ongoing	☐ Ongoing
6.		☐ Ongoing	☐ Ongoing
7.		☐ Ongoing	☐ Ongoing
8.		☐ Ongoing	☐ Ongoing
9.		☐ Ongoing	☐ Ongoing
10.		☐ Ongoing	☐ Ongoing

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CONCOMITANT MEDICATION *O.MED_9*

	MEDICATION	START DATE Day Month Year	END DATE Day Month Year
1.		❑ Ongoing	❑ Ongoing
2.		❑ Ongoing	❑ Ongoing
3.		❑ Ongoing	❑ Ongoing
4.		❑ Ongoing	❑ Ongoing
5.		❑ Ongoing	❑ Ongoing
6.		❑ Ongoing	❑ Ongoing
7.		❑ Ongoing	❑ Ongoing
8.		❑ Ongoing	❑ Ongoing
9.		❑ Ongoing	❑ Ongoing
10.		❑ Ongoing	❑ Ongoing

CONCOMITANT MEDICATION *O.MED_9*

	MEDICATION	START DATE Day Month Year	END DATE Day Month Year
1.		❑ Ongoing	❑ Ongoing
2.		❑ Ongoing	❑ Ongoing
3.		❑ Ongoing	❑ Ongoing
4.		❑ Ongoing	❑ Ongoing
5.		❑ Ongoing	❑ Ongoing
6.		❑ Ongoing	❑ Ongoing
7.		❑ Ongoing	❑ Ongoing
8.		❑ Ongoing	❑ Ongoing
9.		❑ Ongoing	❑ Ongoing
10.		❑ Ongoing	❑ Ongoing

ADDITIONAL HEMATOLOGY

LABH_1

Date of sampling: __ __ day __ __ __ month __ __ __ __ year

TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
WBC		10^9/L	
RBC		10^6/mm^3	
Neutrophils		10^9/L	
Eosinophils		10^9/L	
Basophils		10^9/L	
Monocytes		10^9/L	
Lymphocytes		10^9/L	
Platelets		10^9/L	
Hemoglobin		g/dL	

ADDITIONAL HEMATOLOGY

LABH_1

Date of sampling: __ __ day __ __ __ month __ __ __ __ year

TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
WBC		10^9/L	
RBC		10^6/mm^3	
Neutrophils		10^9/L	
Eosinophils		10^9/L	
Basophils		10^9/L	
Monocytes		10^9/L	
Lymphocytes		10^9/L	
Platelets		10^9/L	
Hemoglobin		g/dL	

ADDITIONAL HEMATOLOGY

LABH_1

Date of sampling: ☐☐ ☐☐☐ ☐☐☐☐
day month year

TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
WBC		10^9/L	
RBC		10^6/mm^3	
Neutrophils		10^9/L	
Eosinophils		10^9/L	
Basophils		10^9/L	
Monocytes		10^9/L	
Lymphocytes		10^9/L	
Platelets		10^9/L	
Hemoglobin		g/dL	

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ADDITIONAL BIOCHEMISTRY

LABB_1

Date of sampling: __ __ day __ __ __ month __ __ __ __ year

TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
Sodium		mmol/L	
Potassium		mmol/L	
SGOT (AST)		U/L	
SGPT (ALT)		U/L	
Alkaline phosphatase		U/L	
Total bilirubin		mg/dL	
BUN		mg/dL	
Creatinine		mg/dL	
Glucose		mg/dL	
Chloride		mmol/L	
Bicarbonate		mmol/L	

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ADDITIONAL BIOCHEMISTRY

LABB_1

Date of sampling: ☐☐ ☐☐☐ ☐☐☐☐
day month year

TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
Sodium		mmol/L	
Potassium		mmol/L	
SGOT (AST)		U/L	
SGPT (ALT)		U/L	
Alkaline phosphatase		U/L	
Total bilirubin		mg/dL	
BUN		mg/dL	
Creatinine		mg/dL	
Glucose		mg/dL	
Chloride		mmol/L	
Bicarbonate		mmol/L	

See Page 25

ADDITIONAL BIOCHEMISTRY

LABB_1

Date of sampling: __ __ day __ __ month __ __ __ __ year

TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
Sodium		mmol/L	
Potassium		mmol/L	
SGOT (AST)		U/L	
SGPT (ALT)		U/L	
Alkaline phosphatase		U/L	
Total bilirubin		mg/dL	
BUN		mg/dL	
Creatinine		mg/dL	
Glucose		mg/dL	
Chloride		mmol/L	
Bicarbonate		mmol/L	

REPEATED TESTOSTERONE

LABB_1

Date of sampling: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
day month year

TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
Testosterone		ng/dL	

See Page 25

REPEATED TESTOSTERONE

LABB_1

Date of sampling: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
day month year

TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
Testosterone		ng/dL	

REPEATED TESTOSTERONE

LABB_1

Date of sampling: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
day month year

TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
Testosterone		ng/dL	

REPEATED PSA

LABH_1

DATE OF SAMPLING day month year	TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
␣␣ ␣␣␣ ␣␣␣␣	PSA		ng/mL	

REPEATED PSA

LABH_1

DATE OF SAMPLING day month year	TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
␣␣ ␣␣␣ ␣␣␣␣	PSA		ng/mL	

REPEATED PSA

LABH_1

DATE OF SAMPLING day month year	TEST	VALUE (MD if not done)	UNIT	IF OTHER UNIT, SPECIFY
␣␣ ␣␣␣ ␣␣␣␣	PSA		ng/mL	

REPEATED ECG

ECG_1

- Date performed: ☐☐ ☐☐☐ ☐☐☐☐
  day month year

- **ECG:** Normal ❑ Abnormal* ❑

If abnormal, specify: _____

_____

* If clinically relevant, please report on appropriate form.

REPEATED ECG

ECG_1

- Date performed: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
  day month year

- **ECG:** Normal ❑ Abnormal* ❑

If abnormal, specify: _____

_____

* If clinically relevant, please report on appropriate form.

REPEATED ECG

ECG_1

- Date performed: ☐☐ ☐☐☐ ☐☐☐☐ (day / month / year)

- **ECG:** Normal ❑ Abnormal* ❑

If abnormal, specify: _____

_____

* If clinically relevant, please report on appropriate form.

See Page 29

REPEATED ECHOCARDIOGRAPHY *ECHOCARD_1*

- Date performed: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
  day month year

- **2D-Echocardiography:** Normal ❑ Abnormal* ❑

- Left ventricular ejection fraction (LVEF) ⌊_⌋⌊_⌋ . ⌊_⌋ %

- Lower Limit Normal of LVEF ⌊_⌋⌊_⌋ . ⌊_⌋ %

* If clinically relevant, please report on appropriate form.

REPEATED ECHOCARDIOGRAPHY *ECHOCARD_1*

- Date performed: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
  day month year

- **2D-Echocardiography:** Normal ❑ Abnormal* ❑

- Left ventricular ejection fraction (LVEF) ⌊_⌋⌊_⌋ . ⌊_⌋ %

- Lower Limit Normal of LVEF ⌊_⌋⌊_⌋ . ⌊_⌋ %

* If clinically relevant, please report on appropriate form.

REPEATED ECHOCARDIOGRAPHY *ECHOCARD_1*

- Date performed: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
  day month year

- **2D-Echocardiography:** Normal ❑ Abnormal* ❑

- Left ventricular ejection fraction (LVEF) ⌊_⌋⌊_⌋ . ⌊_⌋ %

- Lower Limit Normal of LVEF ⌊_⌋⌊_⌋ . ⌊_⌋ %

* If clinically relevant, please report on appropriate form.

RADIONUCLIDE VENTRICULOGRAPHY

MUGA_1

- Date performed: ☐☐ ☐☐ ☐☐☐☐ (day / month / year)

- **Radionuclide Ventriculography:** Normal ❑ Abnormal* ❑

- Left ventricular ejection fraction (LVEF) ☐☐ . ☐ %

- Lower Limit Normal of LVEF ☐☐ . ☐ %

* If clinically relevant, please report on the Adverse Event form.

See Page 29

RADIONUCLIDE VENTRICULOGRAPHY

MUGA_1

- Date performed: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
  day month year

- **Radionuclide Ventriculography:** Normal ❑ Abnormal* ❑

- Left ventricular ejection fraction (LVEF) ⌊_⌋⌊_⌋ . ⌊_⌋ %

- Lower Limit Normal of LVEF ⌊_⌋⌊_⌋ . ⌊_⌋ %

* If clinically relevant, please report on the Adverse Event form.

RADIONUCLIDE VENTRICULOGRAPHY

MUGA_1

- Date performed: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
  day month year

- **Radionuclide Ventriculography:** Normal ❑ Abnormal* ❑

- Left ventricular ejection fraction (LVEF) ⌊_⌋⌊_⌋ . ⌊_⌋ %

- Lower Limit Normal of LVEF ⌊_⌋⌊_⌋ . ⌊_⌋ %

* If clinically relevant, please report on the Adverse Event form.

PAIN INTENSITY ASSESSMENT

PAINVAS1

Date (Day Month Year)	PPI	Analgesic Score
1. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
2. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
3. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
4. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
5. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
6. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
7. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣

PAIN INTENSITY ASSESSMENT

PAINVAS1

Date (Day Month Year)	PPI	Analgesic Score
1. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
2. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
3. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
4. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
5. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
6. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
7. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣

PAIN INTENSITY ASSESSMENT

PAINVAS1

Date (Day Month Year)	PPI	Analgesic Score
1. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
2. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
3. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
4. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
5. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
6. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣
7. ␣␣ ␣␣␣ ␣␣␣␣	␣	␣␣␣ . ␣␣

*** Location:**

01	Skin	12	Liver	22	Mediastinum
02	Muscle/Soft Tissue	13	Stomach	23	Uterus
03	Bone	14	Pancreas	24	Abdomen
04	Bone Marrow	15	Kidneys	25	Gastrointestinal Tract
05	Peripheral Blood Stream	16	Ovaries	26	Pelvis
06	Brain/CNS	16.01	Fallopian Tubes	27	Peritoneum
07	Head/Neck	17	Bladder	28	Testis
08	Esophagus	18	Prostate	29	Thorax
09	Breast	19	Cervix	29.01	Pleura
10	Lungs	20.10	Colon	30	Other
11.01	Regional Lymph Nodes	20.20	Rectum		
11.02	Distant Lymph Nodes	21	Adrenal		

**** Method of Measurement Codes:**

1 - CT Scan	3 - MRI	5 - Scintigraphy
2 - Spiral CT	4 - PET	7 - Ultrasound
8 - X-Ray	10 - Physical Exam	99 - Other

*****Response of Non-Target Codes:**

CR - Complete Response	IR/SD - Incomplete Response/Stable Disease	PD - Progressive Disease
NL - New Lesion	NE - Not Evaluable	

See Page 55

TUMOR MEASUREMENTS

O.ASSESS_3

❑ NOT DONE

LESION NUMBER	LOCATION SITE*	DATE OF ASSESSMENT Day Month Year	METHOD OF MEASUREMENT**	MEASUREMENT OF TARGET LESION: longest diameter	RESPONSE OF NON-TARGET LESIONS***
1	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋
2	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋
3	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋
4	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋
5	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋
6	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋
7	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋
8	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋
9	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋
10	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋
11	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋
12	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋
13	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋
14	⌊_⌋⌊_⌋.⌊_⌋⌊_⌋	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ ❑ Not Done	⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mm	⌊_⌋⌊_⌋

TUMOR MEASUREMENTS

O.ASSESS_3

❑ NOT DONE

LESION NUMBER	LOCATION SITE*	DATE OF ASSESSMENT Day Month Year	METHOD OF MEASUREMENT**	MEASUREMENT OF TARGET LESION: longest diameter	RESPONSE OF NON-TARGET LESIONS***
1	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
2	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
3	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
4	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
5	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
6	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
7	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
8	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
9	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
10	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
11	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
12	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
13	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
14	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣

See Page 55

TUMOR MEASUREMENTS

O.ASSESS_3

❑ NOT DONE

LESION NUMBER	LOCATION SITE*	DATE OF ASSESSMENT Day Month Year	METHOD OF MEASUREMENT**	MEASUREMENT OF TARGET LESION: longest diameter	RESPONSE OF NON-TARGET LESIONS***
1	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
2	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
3	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
4	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
5	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
6	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
7	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
8	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
9	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
10	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
11	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
12	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
13	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣
14	␣␣.␣␣	␣␣ ␣␣␣ ␣␣␣␣ ❑ Not Done	␣␣	␣␣␣ mm	␣␣

<PETEST>

SYMPTOMATIC DETERIORATION

O.SYMPTO_1

Was there symptomatic deterioration? Yes ❑ No ❑ <PEORRES>

<PEDTC>

If yes, date: ⌊_⌊_⌋ ⌊_⌊_⌋ ⌊_⌊_⌊_⌊_⌋ (day / month / year)

NOT SUBMITTED

PHARMACOKINETIC - BLOOD SAMPLING (SCHEDULE 1) *PK_1*

☐ NOT APPLICABLE

SAMPLE ID	THEORETICAL TIME	SAMPLE DATE day month year	SAMPLE TIME 24 hour clock
P00	Prior to Infusion of XRP6528	__ __ __ __ __ __ __ __	__ __ : __ __
P01	30 minutes before end of infusion	__ __ __ __ __ __ __ __	__ __ : __ __
P02	5 minutes post end of Infusion	__ __ __ __ __ __ __ __	__ __ : __ __
P03	1 hour post end of infusion	__ __ __ __ __ __ __ __	__ __ : __ __
P04	6-10 hours post end of infusion	__ __ __ __ __ __ __ __	__ __ : __ __
P05	24-72 hours post end of infusion	__ __ __ __ __ __ __ __	__ __ : __ __

PHARMACOKINETIC - BLOOD SAMPLING (SCHEDULE 2) *PK_1*

☐ NOT APPLICABLE

SAMPLE ID	THEORETICAL TIME	SAMPLE DATE day month year	SAMPLE TIME 24 hour clock
P00	Prior to Infusion of XRP6528	__ __ __ __ __ __ __ __	__ __ : __ __
P01	10 minutes before end of infusion	__ __ __ __ __ __ __ __	__ __ : __ __
P02	10 minutes post end of Infusion	__ __ __ __ __ __ __ __	__ __ : __ __
P03	2 hours post end of infusion	__ __ __ __ __ __ __ __	__ __ : __ __
P04	8-12 hours post end of infusion	__ __ __ __ __ __ __ __	__ __ : __ __
P05	72-168 hours post end of infusion	__ __ __ __ __ __ __ __	__ __ : __ __

NOT SUBMITTED

PHARMACOKINETIC - BLOOD SAMPLING (SCHEDULE 1) *PK_1*

☐ NOT APPLICABLE

SAMPLE ID	THEORETICAL TIME	SAMPLE DATE day month year	SAMPLE TIME 24 hour clock
P00	Prior to Infusion of XRP6528	__ __ __ __ __ __ __ __	__ __ : __ __
P01	30 minutes before end of infusion	__ __ __ __ __ __ __ __	__ __ : __ __
P02	5 minutes post end of Infusion	__ __ __ __ __ __ __ __	__ __ : __ __
P03	1 hour post end of infusion	__ __ __ __ __ __ __ __	__ __ : __ __
P04	6-10 hours post end of infusion	__ __ __ __ __ __ __ __	__ __ : __ __
P05	24-168 hours post end of infusion	__ __ __ __ __ __ __ __	__ __ : __ __

PHARMACOKINETIC - BLOOD SAMPLING (SCHEDULE 2) *PK_1*

☐ NOT APPLICABLE

SAMPLE ID	THEORETICAL TIME	SAMPLE DATE day month year	SAMPLE TIME 24 hour clock
P00	Prior to Infusion of XRP6528	__ __ __ __ __ __ __ __	__ __ : __ __
P01	10 minutes before end of infusion	__ __ __ __ __ __ __ __	__ __ : __ __
P02	10 minutes post end of Infusion	__ __ __ __ __ __ __ __	__ __ : __ __
P03	2 hours post end of infusion	__ __ __ __ __ __ __ __	__ __ : __ __
P04	8-12 hours post end of infusion	__ __ __ __ __ __ __ __	__ __ : __ __
P05	24-168 hours post end of infusion	__ __ __ __ __ __ __ __	__ __ : __ __

NOT SUBMITTED

PHARMACOKINETIC - BLOOD SAMPLING (SCHEDULE 3) *PK_1*

☐ NOT APPLICABLE

SAMPLE ID	THEORETICAL TIME	SAMPLE DATE day month year	SAMPLE TIME 24 hour clock
P00	Prior to Infusion of XRP6528	__ __ __ __ __ __ __ __	__ __ : __ __
P01	30 minutes before end of infusion	__ __ __ __ __ __ __ __	__ __ : __ __
P02	20 minutes post end of Infusion	__ __ __ __ __ __ __ __	__ __ : __ __
P03	3 hours post end of infusion	__ __ __ __ __ __ __ __	__ __ : __ __
P04	10-14 hours post end of infusion	__ __ __ __ __ __ __ __	__ __ : __ __
P05	24-72 hours post end of infusion	__ __ __ __ __ __ __ __	__ __ : __ __

PHARMACOKINETIC - BLOOD SAMPLING (SCHEDULE 4) *PK_1*

☐ NOT APPLICABLE

SAMPLE ID	THEORETICAL TIME	SAMPLE DATE day month year	SAMPLE TIME 24 hour clock
P00	Prior to Infusion of XRP6528	__ __ __ __ __ __ __ __	__ __ : __ __
P01	10 minutes before end of infusion	__ __ __ __ __ __ __ __	__ __ : __ __
P02	30 minutes post end of Infusion	__ __ __ __ __ __ __ __	__ __ : __ __
P03	4 hours post end of infusion	__ __ __ __ __ __ __ __	__ __ : __ __
P04	12-24 hours post end of infusion	__ __ __ __ __ __ __ __	__ __ : __ __
P05	72-168 hours post end of infusion	__ __ __ __ __ __ __ __	__ __ : __ __

NOT SUBMITTED

PHARMACOKINETIC - BLOOD SAMPLING (SCHEDULE 3) *PK_1*

☐ NOT APPLICABLE

SAMPLE ID	THEORETICAL TIME	SAMPLE DATE day month year	SAMPLE TIME 24 hour clock
P00	Prior to Infusion of XRP6528	__ __ __ __ __ __ __ __	__ __ : __ __
P01	30 minutes before end of infusion	__ __ __ __ __ __ __ __	__ __ : __ __
P02	20 minutes post end of Infusion	__ __ __ __ __ __ __ __	__ __ : __ __
P03	3 hours post end of infusion	__ __ __ __ __ __ __ __	__ __ : __ __
P04	10-20 hours post end of infusion	__ __ __ __ __ __ __ __	__ __ : __ __
P05	24-168 hours post end of infusion	__ __ __ __ __ __ __ __	__ __ : __ __

PHARMACOKINETIC - BLOOD SAMPLING (SCHEDULE 4) *PK_1*

☐ NOT APPLICABLE

SAMPLE ID	THEORETICAL TIME	SAMPLE DATE day month year	SAMPLE TIME 24 hour clock
P00	Prior to Infusion of XRP6528	__ __ __ __ __ __ __ __	__ __ : __ __
P01	10 minutes before end of infusion	__ __ __ __ __ __ __ __	__ __ : __ __
P02	30 minutes post end of Infusion	__ __ __ __ __ __ __ __	__ __ : __ __
P03	4 hours post end of infusion	__ __ __ __ __ __ __ __	__ __ : __ __
P04	10-22 hours post end of infusion	__ __ __ __ __ __ __ __	__ __ : __ __
P05	24-168 hours post end of infusion	__ __ __ __ __ __ __ __	__ __ : __ __

OTHER PROCEDURES <PRCAT>

O.PROCEDUR_1

	PROCEDURE	DATE PERFORMED Day Month Year	REASON
1.	<PRTRT>	<PRDTC>	<SUPPPR.QNAM= PROTHCM>
2.			
3.			
4.			
5.			
6.			
7.			
8.			
9.			
10.			

See Page 511

OTHER PROCEDURES

O.PROCEDUR_1

	PROCEDURE	DATE PERFORMED Day Month Year	REASON
1.		__ __ __ __ __ __ __ __	
2.		__ __ __ __ __ __ __ __	
3.		__ __ __ __ __ __ __ __	
4.		__ __ __ __ __ __ __ __	
5.		__ __ __ __ __ __ __ __	
6.		__ __ __ __ __ __ __ __	
7.		__ __ __ __ __ __ __ __	
8.		__ __ __ __ __ __ __ __	
9.		__ __ __ __ __ __ __ __	
10.		__ __ __ __ __ __ __ __	

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OTHER PROCEDURES

O.PROCEDUR_1

	PROCEDURE	DATE PERFORMED Day Month Year	REASON
1.		|__|__| |__|__|__| |__|__|__|__|	
2.		|__|__| |__|__|__| |__|__|__|__|	
3.		|__|__| |__|__|__| |__|__|__|__|	
4.		|__|__| |__|__|__| |__|__|__|__|	
5.		|__|__| |__|__|__| |__|__|__|__|	
6.		|__|__| |__|__|__| |__|__|__|__|	
7.		|__|__| |__|__|__| |__|__|__|__|	
8.		|__|__| |__|__|__| |__|__|__|__|	
9.		|__|__| |__|__|__| |__|__|__|__|	
10.		|__|__| |__|__|__| |__|__|__|__|	

See Page 62

ADVERSE EVENT FORM

O.1_AE_1

1. ADVERSE EVENT DIAGNOSIS	AE form no: 99-01 AE ref. no: ___-___	AE form no: 99-02 AE ref. no: ___-___
2. STATUS OF AE 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: ___ ___ ___ (day / month / year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑	1 ❑ Date of start: ___ ___ ___ (day / month / year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑
3. GRADE (1 - 4)	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. ACTION TAKEN WITH STUDY TREATMENT	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. OUTCOME 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: ___ ___ ___ (day / month / year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: ___ ___ ___ (day / month / year) 6 ❑	1 ❑ / 4 ❑ Date: ___ ___ ___ (day / month / year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: ___ ___ ___ (day / month / year) 6 ❑
8. SERIOUSNESS CRITERIA **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ IF YES: - Date event became serious: ___ ___ ___ (day / month / year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ IF YES: - Date event became serious: ___ ___ ___ (day / month / year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:		Monitoring representative's name, date of receipt:

** Is there a reasonable possibility that the AE was caused by study treatment?*

See Page 62

ADVERSE EVENT FORM

O.1_AE_1

1. **ADVERSE EVENT DIAGNOSIS**	AE form no: ␣␣-␣␣ AE ref. no: ␣␣-␣␣	AE form no: ␣␣-␣␣ AE ref. no: ␣␣-␣␣
2. **STATUS OF AE** 1= New 2= Ongoing from previous period without change 3= Ongoing with change	1 ❑ Date of start: ␣␣ ␣␣ ␣␣␣␣ (day / month / year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑ If grade changes, date of change: ␣␣ ␣␣ ␣␣␣␣ (day / month / year)	1 ❑ Date of start: ␣␣ ␣␣ ␣␣␣␣ (day / month / year) 2 ❑ *(do not complete the remaining items in the column)* 3 ❑ If grade changes, date of change: ␣␣ ␣␣ ␣␣␣␣ (day / month / year)
3. **GRADE (1 - 4)**	1 ❑ 2 ❑ 3 ❑ 4 ❑	1 ❑ 2 ❑ 3 ❑ 4 ❑
4. RELATIONSHIP TO STUDY TREATMENT*	Yes ❑ No ❑	Yes ❑ No ❑
5. **ACTION TAKEN WITH STUDY TREATMENT**	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑	0= None / 1= Permanently discontinued / 2= Delayed 3= Dose reduced / 4= Delayed and reduced / 5= Interrupted 0 ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑
6. CORRECTIVE TREATMENT/THERAPY	Yes ❑ No ❑	Yes ❑ No ❑
7. **OUTCOME** 1= Recovered 4= Recovered with sequelae 2= Recovering 3= Not recovered 5= Fatal *(complete the death report form)* 6= Unknown	1 ❑ / 4 ❑ Date: ␣␣ ␣␣ ␣␣␣␣ (day / month / year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: ␣␣ ␣␣ ␣␣␣␣ (day / month / year) 6 ❑	1 ❑ / 4 ❑ Date: ␣␣ ␣␣ ␣␣␣␣ (day / month / year) Specify sequelae: _____ 2 ❑ 3 ❑ 5 ❑ Date of death: ␣␣ ␣␣ ␣␣␣␣ (day / month / year) 6 ❑
8. **SERIOUSNESS CRITERIA** **IF YES, COMPLETE THIS SECTION AND THE SAE COMPLEMENTARY FORM**	Yes ❑ No ❑ ➲ **IF YES** - Date event became serious: ␣␣ ␣␣ ␣␣␣␣ (day / month / year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑	Yes ❑ No ❑ ➲ **IF YES** - Date event became serious: ␣␣ ␣␣ ␣␣␣␣ (day / month / year) - Tick below all criteria that apply: Resulting in death ❑ Life-threatening ❑ Requiring/prolonging hospitalization ❑ Persistent/significant disability/incapacity ❑ Congenital anomaly/birth defect ❑ Other medically important event ❑
Investigator's name, date of report and signature:		Monitoring representative's name, date of receipt:

** Is there a reasonable possibility that the AE was caused by study treatment?*

NOT SUBMITTED

SAE COMPLEMENTARY FORM 1/2 *O.SAEC_1*

AE FORM NO.: ☐☐-☐☐

1. DEMOGRAPHIC INFORMATION

Date of birth: ☐☐ (day) ☐☐☐ (month) ☐☐☐☐ (year)

or Age: ☐☐

Sex: male ☑ female ☐

Race:
Caucasian ☐ Black ☐
Asian, Oriental ☐ Other ☐
*If other, specify:*_____

Height: ☐☐☐ cm Weight: ☐☐☐ . ☐ kg

2. DETAILED DESCRIPTION OF THE SERIOUS ADVERSE EVENT
(including complementary investigations)

3. DATE OF START OF EVENT: ☐☐ (day) ☐☐☐ (month) ☐☐☐☐ (year)

4. STUDY TREATMENT

First administration of study treatment: ☐☐ (day) ☐☐☐ (month) ☐☐☐☐ (year)

	Last Administration Before SAE (day / month / year)	Last dosage Before SAE	Action taken*	New Dosage (dose reduced)
XRP6258	☐☐ / ☐☐☐ / ☐☐☐☐	☐☐☐ mg/m²/cycle	☐	☐☐☐ mg/m²/cycle
Mitoxantrone	☐☐ / ☐☐☐ / ☐☐☐☐	☐☐☐ mg/m²/cycle	☐	☐☐☐ mg/m²/cycle
Prednisone	☐☐ / ☐☐☐ / ☐☐☐☐	☐☐☐ mg	☐	☐☐☐ mg

* 0 = None 1 = Permanently discontinued 2 = Delayed 3 = Dose reduced 4 = Delayed/reduced 5 = Interrupted

5. IN CASE OF HOSPITALIZATION hospital report to be sent

Date of admission: ☐☐ (day) ☐☐☐ (month) ☐☐☐☐ (year)

6. IN CASE OF DEATH Autopsy report: Yes ☐ *(copy to be sent)* No ☐

SAE COMPLEMENTARY FORM 2/2 *O.SAEC_1.1*

7. CORRECTIVE TREATMENT/THERAPY

(Relevant CRF page can be faxed)

8. PREVIOUS AND CONCOMITANT MEDICATIONS:

(Relevant CRF page can be faxed)

9. RELEVANT MEDICAL HISTORY AND CONCOMITANT DISEASES:

(Relevant CRF page can be faxed)

10. STATUS OF THE DISEASE

Is this SAE related to progression of the cancer? Yes ❑ No ❑ Unknown ❑

If Yes: Local ❑ Lymph nodes ❑ Peritoneum ❑ Brain ❑

Liver ❑ Bone ❑ Lung ❑

Other ❑ _____

SAE FOLLOW-UP FORM *O.SAEF_1*

PROVIDE THE SPONSOR BY FAX WITH ALL ADDITIONAL INFORMATION INCLUDING AE FORM IF UPDATED

AE FORM NO.: ☐☐-☐☐

1. SERIOUS ADVERSE EVENT (diagnosis):

2. DATE OF THE EVALUATION: ☐☐ ☐☐☐ ☐☐☐☐ (day / month / year)

3. NEW RELEVANT INFORMATION ADDED TO INITIAL REPORT(S):

Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:

NOT SUBMITTED

SAE COMPLEMENTARY FORM 1/2 *O.SAEC_1*

AE FORM NO.: ⌊_⌋⌊_⌋-⌊_⌋⌊_⌋

1. DEMOGRAPHIC INFORMATION

Date of birth: ⌊_⌋⌊_⌋ (day) ⌊_⌋⌊_⌋⌊_⌋ (month) ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ (year)

or Age: ⌊_⌋⌊_⌋

Sex: male ☑ female ☐

Race:
Caucasian ☐ Black ☐
Asian, Oriental ☐ Other ☐
*If other, specify:*_____

Height: ⌊_⌋⌊_⌋⌊_⌋ cm Weight: ⌊_⌋⌊_⌋⌊_⌋ . ⌊_⌋ kg

2. DETAILED DESCRIPTION OF THE SERIOUS ADVERSE EVENT
(including complementary investigations)

3. DATE OF START OF EVENT: ⌊_⌋⌊_⌋ (day) ⌊_⌋⌊_⌋⌊_⌋ (month) ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ (year)

4. STUDY TREATMENT

First administration of study treatment: ⌊_⌋⌊_⌋ (day) ⌊_⌋⌊_⌋⌊_⌋ (month) ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ (year)

	Last Administration Before SAE (day / month / year)	Last dosage Before SAE	Action taken*	New Dosage (dose reduced)
XRP6258	⌊_⌋⌊_⌋ / ⌊_⌋⌊_⌋⌊_⌋ / ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mg/m²/cycle	⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mg/m²/cycle
Mitoxantrone	⌊_⌋⌊_⌋ / ⌊_⌋⌊_⌋⌊_⌋ / ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mg/m²/cycle	⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mg/m²/cycle
Prednisone	⌊_⌋⌊_⌋ / ⌊_⌋⌊_⌋⌊_⌋ / ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mg	⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mg

* 0 = None 1 = Permanently discontinued 2 = Delayed 3 = Dose reduced 4 = Delayed/reduced 5 = Interrupted

5. IN CASE OF HOSPITALIZATION hospital report to be sent

Date of admission: ⌊_⌋⌊_⌋ (day) ⌊_⌋⌊_⌋⌊_⌋ (month) ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ (year)

6. IN CASE OF DEATH Autopsy report: Yes ☐ *(copy to be sent)* No ☐

NOT SUBMITTED

SAE COMPLEMENTARY FORM 2/2 *O.SAEC_1.1*

7. CORRECTIVE TREATMENT/THERAPY

(Relevant CRF page can be faxed)

8. PREVIOUS AND CONCOMITANT MEDICATIONS:

(Relevant CRF page can be faxed)

9. RELEVANT MEDICAL HISTORY AND CONCOMITANT DISEASES:

(Relevant CRF page can be faxed)

10. STATUS OF THE DISEASE

Is this SAE related to progression of the cancer? Yes ❑ No ❑ Unknown ❑

If Yes: Local ❑ Lymph nodes ❑ Peritoneum ❑ Brain ❑

Liver ❑ Bone ❑ Lung ❑

Other ❑ _____

SAE FOLLOW-UP FORM *O.SAEF_1*

PROVIDE THE SPONSOR BY FAX WITH ALL ADDITIONAL INFORMATION INCLUDING AE FORM IF UPDATED

AE FORM NO.: ⌊_⌋⌊_⌋-⌊_⌋⌊_⌋

1. SERIOUS ADVERSE EVENT (diagnosis):

2. DATE OF THE EVALUATION: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
day month year

3. NEW RELEVANT INFORMATION ADDED TO INITIAL REPORT(S):

Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:

NOT SUBMITTED

SAE COMPLEMENTARY FORM 1/2 *O.SAEC_1*

AE FORM NO.: ⌊_⌋⌊_⌋-⌊_⌋⌊_⌋

1. DEMOGRAPHIC INFORMATION

Date of birth: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ (day / month / year)

or Age: ⌊_⌋⌊_⌋

Sex: male ☑ female ☐

Race:
Caucasian ☐ Black ☐
Asian, Oriental ☐ Other ☐
*If other, specify:*_____

Height: ⌊_⌋⌊_⌋⌊_⌋ cm Weight: ⌊_⌋⌊_⌋⌊_⌋ . ⌊_⌋ kg

2. DETAILED DESCRIPTION OF THE SERIOUS ADVERSE EVENT
(including complementary investigations)

3. DATE OF START OF EVENT: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ (day / month / year)

4. STUDY TREATMENT

First administration of study treatment: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ (day / month / year)

	Last Administration Before SAE (day / month / year)	Last dosage Before SAE	Action taken*	New Dosage (dose reduced)
XRP6258	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mg/m²/cycle	⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mg/m²/cycle
Mitoxantrone	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mg/m²/cycle	⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mg/m²/cycle
Prednisone	⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mg	⌊_⌋	⌊_⌋⌊_⌋⌊_⌋ mg

* 0 = None 1 = Permanently discontinued 2 = Delayed 3 = Dose reduced 4 = Delayed/reduced 5 = Interrupted

5. IN CASE OF HOSPITALIZATION hospital report to be sent

Date of admission: ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ (day / month / year)

6. IN CASE OF DEATH Autopsy report: Yes ☐ *(copy to be sent)* No ☐

NOT SUBMITTED

SAE COMPLEMENTARY FORM 2/2 *O.SAEC_1.1*

7. CORRECTIVE TREATMENT/THERAPY

(Relevant CRF page can be faxed)

8. PREVIOUS AND CONCOMITANT MEDICATIONS:

(Relevant CRF page can be faxed)

9. RELEVANT MEDICAL HISTORY AND CONCOMITANT DISEASES:

(Relevant CRF page can be faxed)

10. STATUS OF THE DISEASE

Is this SAE related to progression of the cancer? Yes ❑ No ❑ Unknown ❑

If Yes: Local ❑ Lymph nodes ❑ Peritoneum ❑ Brain ❑

Liver ❑ Bone ❑ Lung ❑

Other ❑ _____

NOT SUBMITTED

SAE FOLLOW-UP FORM *O.SAEF_1*

PROVIDE THE SPONSOR BY FAX WITH ALL ADDITIONAL INFORMATION INCLUDING AE FORM IF UPDATED

AE FORM NO.: |_|_|-|_|_|

1. SERIOUS ADVERSE EVENT (diagnosis):

2. DATE OF THE EVALUATION: |_|_| |_|_|_| |_|_|_|_| (day / month / year)

3. NEW RELEVANT INFORMATION ADDED TO INITIAL REPORT(S):

Investigator's name, date of report and signature:	Monitoring representative's name, date of receipt:

DEATH

O.DEATH_1

Date of death: <DSSTDTC> ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋
day month year

Reason for death (tick "✓" one box only): <DSTERM>

- ❑ Progression
- ❑ Adverse event
- ❑ Other *Specify:* <DSTERM>