OPTIMAL Pregnancy Form 15 (A)

Patient Initials: [ ] - [ ] [ ] Date of Birth: [d][d] - [m][m] - [y][y][y][y] Trial Number: [0] [ ] [ ] - [0] [ ] [ ]

OPTIMAL (A study of Thalidomide, Bendamustine, and Dexamethasone (BTD) vs Bortezomib, Bendamustine, and Dexamethasone (BBD) in patients with renal failure defined as a GFR below 30 mls/ min. Eudract: 2012-003947-31)

Product Exposure During Pregnancy Collection Form A

A. EXPOSURE TO THE STUDY DRUGS			
Exposure: Maternal: ☐ Paternal: ☐			
Trial No.:			
Study medication/products(s): ☐ Bendamustine; ☐ Bortezomib; ☐ Thalidomide; ☐ Dexamethasone			
Date of Birth (dd/mm/yyyy):			
B. MATERNAL INFORMATION			
Initials:			
Date of birth (dd/mm/yyyy):	Age at time of exposure:		Weight in Kg:
Height in cm:	Occupation:		Ethnic origin:
Were there any relevant maternal risk factors in the home/work environment (such as chemical exposure, x-rays, history of miscarriages, etc.)?	No ☐	Yes ☐	If yes, please describe:

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Patient Initials: [ ] - [ ][ ] Date of Birth: [d][d] - [m][m] - [y][y][y][y] Trial Number: [0][ ][ ] - [0][ ][ ]

C. PRESENT PREGNANCY

1. Date of mother's last menstrual period (dd/mm/yyyy):

2. Pregnancy confirmed on (dd/mm/yyyy): ☐ Beta Hcg ☐ Urine Test

3. Date of mother's first prenatal exam (dd/mm/yyyy):

4. Expected date of delivery (dd/mm/yyyy):

5. Is the mother experiencing any medical disorder/problems during this pregnancy? ☐ No ☐ Yes — If yes, describe:

6. Is the mother continuing with the study drugs? ☐ No ☐ Yes ☐ N/A ☐ Unknown

Please specify:

a. Were product(s) taken correctly at the time of gestation? ☐ Yes ☐ No
If no, please explain:

7. List all medications mother used since date of last menstrual period (include study drugs and concomitant drugs, prescription, over-the-counter, vitamins, and herbal preparations - list below).

Medication (preferably generic name)	Route	Formulation	Dosing regimen			Start date dd/mm/yyyy	End Date dd/mm/yyyy/ Or Ongoing	Exposure time in gestational weeks	Indication
			Amount	Unit	Freq.				
IMPs									
Bendamustine									Trial Medications
Bortezomib									
Thalidomide									
Other Medications:									
Dexamethasone:									Trial Medication

8. Was an ultrasound performed? ☐ No ☐ Yes

If yes, provide date and results of each ultrasound (dd/mm/yyyy):

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9. Were any other investigations/diagnostics performed, such as amniocentesis, blood test, urine test, etc? ☐ No ☐ Yes	If yes, provide date (dd/mm/yyyy), test performed, results of each test performed.			
10. What is the clinical condition of the foetus(es)?	Unknown ☐	Normal ☐	Abnormal ☐	If abnormal, describe:

11. What is the status of the current pregnancy?

☐ Continuing

☐ Spontaneous abortion Date of abortion: (dd/mm/yyyy):

☐ Elective abortion Date of procedure: (dd/mm/yyyy):

D. MATERNAL HISTORY

1. Describe pertinent medical/obstetrical history (include but not limited to endocrine disorders, medical disorders or recent infections requiring treatment, infertility or use of fertility methods):

2. **Substance History**	**No**	**Yes**	**Select all that apply**
Alcohol	☐	☐	Units of alcohol per day:
Tobacco	☐	☐	Cigarettes per day:
Recreational drugs:	☐	☐	Type of drug and frequency:

3. Is there any family history of congenital anomalies, significant obstetrical outcomes or hereditary disorders?	No	Yes	If yes, describe:
	☐	☐	

E. PREVIOUS PREGNANCIES

1. Has mother been pregnant before? No ☐ Yes ☐	Gravida (include present pregnancy)	Para	Abortions: Induced: Spontaneous: Gestational age: _____weeks _____days
	No. of normal outcomes:	No. of abnormal outcomes:	No. of unknown outcomes:

2. Describe any abnormal outcomes (include spontaneous abortion, ectopics, congenital anomalies, hereditary disorders, stillbirths or intrauterine death, etc):

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Date of Birth: d d - m m - y y y y

Trial Number: 0 [ ] [ ] - 0 [ ] [ ]

3. In case of a previous abnormal pregnancy outcome, list all known medications used during the pregnancy:

F. PATERNAL HISTORY

Substance History	No	Yes	Select all that apply:
Alcohol	☐	☐	Drinks per day:
Tobacco	☐	☐	Cigarettes per day:
Recreational drugs:	☐	☐	Type of drug and frequency:

G. PRINCIPAL INVESTIGATOR DETAILS

Name:

Address:

Phone number:

Email:

Fax Number:

Person completing report (please note you must be on the delegation log)

Name:

Signature:

Date of Signing:

Designation:

Contact Telephone:

Email:

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OPTIMAL Pregnancy Form 15 (B)

Patient Initials: ☐ - ☐☐ Date of Birth: dd-mm-yyyy Trial Number: 0☐☐-0☐☐

OPTIMAL (A study of Thalidomide, Bendamustine, and Dexamethasone (BTD) vs Bortezomib, Bendamustine, and Dexamethasone (BBD) in patients with renal failure defined as a GFR below 30 mls/ min, Eudract: 2012-003947-31)

Product Exposure During Pregnancy Collection Form B

Exposure to the study drugs: ☐ Maternal ☐ Paternal

Trial No.:

Subject Initials:

Site:

Study medication/product(s): ☐ Bendamustine; ☐ Bortezomib; ☐ Thalidomide; ☐ Dexamethasone

Date of Birth (dd/mm/yyyy):

A. MOTHER'S INFORMATION

Initials:

Date of birth (dd/mm/yyyy): Age: **(Please complete even if information was already provided in Form A)**

B. COURSE AND OUTCOME OF PREGNANCY

1. Did the mother experience any medical problems during the course of this pregnancy?	**No** ☐ **Yes** ☐	If yes, describe:

2. List all medications the mother has used since last menses, until day of delivery? (include study drugs and concomitant drugs, prescription, over-the counter, vitamins and herbal preparations , but exclude medication used during labour and delivery)

Medication (preferably generic name)	Route	Formulation	Dosing regimen			Start date dd/mm/yyyy	End Date dd/mm/yyyy/ Or Ongoing	Exposure time in gestational weeks	Indication
			Amount	Unit	Freq.				
IMPs									
Bendamustine									Trial Medications
Bortezomib									
Thalidomide									
Other Medications:									
Dexamethasone:									Trial Medication

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3. Did the mother receive any **medication during labour and delivery**? (include anaesthesia, analgesia, labour induction meds)

Medication (preferably generic name)	Route	Formulation	Dosing regimen			Start date dd/mm/yyyy	End date dd/mm/yyyy or ongoing	Indication
			Amt	Unit	Freq			

4. Specify the outcome of pregnancy and complete the rest of the form as applicable:

a) Interrupted pregnancy No ☐ Yes ☐	☐ Spontaneous Abortion	(dd/mm/yyyy):
	☐ Elective Abortion	
	☐ Intrauterine Death (≥20 Gestational Wks)	Interruption date (dd/mm/yyyy): Gestational age: Weeks Days

Specify suspected cause for intrauterine death or spontaneous abortion (autopsy report if done):

Describe the developmental status of the foetus (include anomalies):

b) Uninterrupted pregnancy:	Delivery date (dd/mm/yyyy):
	Gestational age: Weeks Days
What was the method of delivery?	☐ Spontaneous ☐ Forceps ☐ Vacuum Extraction ☐ Caesarean Section ☐ Other, Specify:

C. CHARACTERISTICS OF THE BABY

1. General appearance: ☐ Mature ☐ Premature ☐ Postmature

2. Sex: ☐ Male ☐ Female Weight: kg g Length: cm Head circumference: cm

Apgar score: 1min: 5min: 10min:

Clinical condition of the baby: ☐ Normal newborn

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OPTIMAL Pregnancy Form 15 (B)

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3. Clinical condition of the baby:

☐ Normal newborn; ☐ Congenital anomaly; ☐ Neonatal problem; ☐ Neonatal death; ☐ Stillbirth.

(go to Q.6) ←

Describe the probable cause for the abnormal outcome:

Date of death if applicable (dd/mm/yyyy):

4. Was any relationship suspected between the abnormal pregnancy outcome and the use of the study drug(s)?

	Causality-Could this have been caused by study drug?	**Expectedness**-If related, was this expected?
Thalidomide	☐ Related; ☐ Unrelated.	☐ Expected; ☐ Unexpected.
Bendamustine	☐ Related; ☐ Unrelated.	☐ Expected; ☐ Unexpected.
Bortezomib	☐ Related; ☐ Unrelated.	☐ Expected; ☐ Unexpected.
Dexamethasone	☐ Related; ☐ Unrelated.	☐ Expected; ☐ Unexpected.

5. Was any relationship suspected between the abnormal pregnancy outcome and the use of **CONCOMITANT** medications? ☐ No ☐ Yes (if yes, describe)

Describe:

	No	**Yes**	
6. Was the baby's hospitalisation prolonged?	☐	☐	If yes, describe
7. Did the baby receive any medical therapy different from normal newborn care?	☐	☐	If yes, describe
8. Is the baby being breastfed?	☐	☐	

D. PRINCIPAL INVESTIGATOR DETAILS

Name:

Address:

Phone Number: | Fax Number: | Email:

Person completing report: *(please note your name must be on the delegation log)*

Name: | Signature: | Date:

Designation (according to delegation log):

Phone Number: | Email:

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