Pregnancy Reporting Form (Antepartum Information)

Please complete this form to report a pregnancy in:
- a female patient treated with pomalidomide or
- a female partner of a male patient treated with pomalidomide.

Please email immediately to BMS at safety_netherlands@bms.com. As part of BMS's Safety Monitoring System, we may require further information on reported pregnancies. BMS may therefore be in contact with you for further information in due course and would value your cooperation to ensure we are able to obtain all relevant information.

PATIENT IDENTIFIER: *(FOR STUDIES, MUST INCLUDE PROTOCOL, SITE & SUBJECT NUMBERS)*	CASE # (BMS ONLY)	LOCAL COUNTRY NUMBER: (BMS ONLY)

BMS RECEIPT DATE (BMS USE ONLY)		WWPS RECEIPT DATE (BMS USE ONLY)	

REPORT TYPE:	☐ SPONTANEOUS OR ☐ STUDY	COUNTRY*	
	☐ INITIAL REPORT OR ☐ FOLLOW-UP REPORT	*If UK, was Country of Incidence, Specify if Northern Ireland below? Yes ☐ No ☐	

EVENT: PREGNANCY

EXPOSURE TYPE: ☐ MATERNAL DRUG EXPOSURE OR ☐ PATERNAL DRUG EXPOSURE

FOR PATERNAL DRUG EXPOSURE ONLY: WAS PREGNANT PARTNER INFORMED CONSENT FORM SIGNED? ☐ NO ☐ YES

IF NO, DID THE MALE SUBJECT PROVIDE ALL OF THE PREGNANCY SURVEILLANCE INFORMATION BELOW? ☐ NO ☐ YES

REPORT TYPE: ☐ PROSPECTIVE REPORT OR ☐ RETROSPECTIVE REPORT

WERE THERE ANY ADDITIONAL MATERNAL/PATERNAL ADVERSE EVENTS? ☐ NO ☐ YES

IF YES, REPORT THE ADVERSE EVENTS APPROPRIATELY (FOR STUDIES, REFER TO STUDY-SPECIFIC INSTRUCTIONS)

MATERNAL INFORMATION	AGE AT	HEIGHT:	WEIGHT:	RACE:
DATE OF BIRTH:	CONCEPTION:			☐ WHITE ☐ BLACK ☐ ASIAN
		☐ inches	☐ lb	☐ AMERICAN INDIAN OR ALASKAN NATIVE
		☐ cm	☐ kg	☐ NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER
				☐ Aboriginal ☐ Torres Strait Islander
				☐ OTHER RACE:

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NUMBER OF PREGNANCIES INCLUDING THIS ONE		NUMBER OF BIRTHS		NUMBER OF LIVING CHILDREN	

ONSET DATE LAST MENSTRUAL PERIOD (LMP):		APPROXIMATE DATE OF CONCEPTION:		DATE PREGNANCY WAS CONFIRMED:	
		ESTIMATED DATE OF DELIVERY:		TEST METHOD: ☐ SERUM ☐ URINE	

ESTIMATED GESTATIONAL AGE WHEN PREGNANCY DIAGNOSED:		WEEKS	DETERMINED BY: ☐ FETAL ULTRASOUND ☐ DATE FROM LMP

CONTRACEPTION AT TIME OF CONCEPTION: ☐ NO ☐ YES ☐ UNKNOWN (IF YES, SPECIFY)

RELEVANT MATERNAL MEDICAL HISTORY/RISK FACTORS	DATE OF ONSET	IF APPLICABLE SPECIFY PERTINENT DETAILS

PATERNAL INFORMATION: AGE YEARS DATE OF BIRTH:

RELEVANT PATERNAL MEDICAL HISTORY/RISK FACTORS	DATE OF ONSET	IF APPLICABLE SPECIFY PERTINENT DETAILS

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MEDICATION NAME AND INDICATION	PREGNANCY RELATED TO MEDICATION?*	DOSE AND UNITS	FREQ	ROUTE **	PERIOD(S) OF DRUG EXPOSURE ***	ONCOLOGY DRUGS ONLY	START AND STOP DATES
1. INDICATION ☐ MATERNAL OR ☐ PATERNAL ☐ NON-STUDY OR ☐ STUDY	☐ NOT RELATED ☐ RELATED					CYCLE #: CUMULATIVE DOSE WITH UNITS	OR ☐ ONGOING
2. INDICATION ☐ MATERNAL OR ☐ PATERNAL ☐ NON-STUDY OR ☐ STUDY	☐ NOT RELATED ☐ RELATED					CYCLE #: CUMULATIVE DOSE WITH UNITS	OR ☐ ONGOING
3. INDICATION ☐ MATERNAL OR ☐ PATERNAL ☐ NON-STUDY OR ☐ STUDY	☐ NOT RELATED ☐ RELATED					CYCLE #: CUMULATIVE DOSE WITH UNITS	OR ☐ ONGOING
4. INDICATION ☐ MATERNAL OR ☐ PATERNAL ☐ NON-STUDY OR ☐ STUDY	☐ NOT RELATED ☐ RELATED					CYCLE #: CUMULATIVE DOSE WITH UNITS	OR ☐ ONGOING
5.						CYCLE #:	

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INDICATION ☐ MATERNAL OR ☐ PATERNAL ☐ NON-STUDY OR ☐ STUDY	☐ NOT RELATED ☐ RELATED					CUMULATIVE DOSE WITH UNITS	OR ☐ ONGOING
6. INDICATION ☐ MATERNAL OR ☐ PATERNAL ☐ NON-STUDY OR ☐ STUDY	☐ NOT RELATED ☐ RELATED					CYCLE #: CUMULATIVE DOSE WITH UNITS	OR ☐ ONGOING
7. INDICATION ☐ MATERNAL OR ☐ PATERNAL ☐ NON-STUDY OR ☐ STUDY	☐ NOT RELATED ☐ RELATED					CYCLE #: CUMULATIVE DOSE WITH UNITS	OR ☐ ONGOING

* MANDATORY FOR ALL STUDIES

**ROUTE:

1 = ORAL 2 = INTRAVENOUS 3 = SUBCUTANEOUS 4 = OTHER

***PERIOD(S) OF DRUG EXPOSURE: (INCLUDE ALL THAT APPLY)

0 = PRIOR TO CONCEPTION 1 = 1ST TRIMESTER 2 = 2ND TRIMESTER

3 = 3RD TRIMESTER 4 = LABOR & DELIVERY 5 = UNKNOWN

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PRENATAL DIAGNOSTIC TESTING	BASE-LINE	DATE	TEST RESULTS UNITS	NORMAL RANGE	
				LOW	HIGH
	☐				
	☐				
	☐				
	☐				
	☐				
	☐				
	☐				

DESCRIBE RESULTS IN DETAIL, IF APPLICABLE:

REPORTER INFORMATION: ☐ BMS STUDY INVESTIGATOR ☐ NON-BMS STUDY SPONSOR ☐ OTHER*

*QUALIFICATION: (COMPLETE ONLY IF "OTHER" IS CHECKED)

☐ PHYSICIAN ☐ PHARMACIST ☐ NURSE/NURSE PRACTITIONER ☐ OTHER HEALTH PROFESSIONAL

☐ CONSUMER ☐ ATTORNEY ☐ OTHER NON-HEALTH PROFESSIONAL

PERSON COMPLETING THE FORM (IF DIFFERENT FROM INVESTIGATOR/SPONSOR) : DATE:

PRINTED NAME

SIGNATURE

INSTITUTION/ORGANIZATION:

STREET ADDRESS:

CITY:

STATE/PROVINCE:

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POST CODE:		COUNTRY:		PHONE NUMBER:	
Email address					
INVESTIGATOR/SPONSOR/OTHER:					
	LAST NAME				
	FIRST NAME		MIDDLE INITIAL		
SIGNATURE:		DATE:			