ZENTIVA

POMALIDOMIDE ZENTIVA PREGNANCY REPORTING FORM

Pregnancy reports must be sent **IMMEDIATELY** to: PV-iceland@zentiva.com

THIS PART TO BE COMPLETED BY ZENTIVA

A. AER REGISTRATION

1. INITIAL RECEIVED DATE: ☐☐ / ☐☐ / ☐☐☐☐ (Day / Month / Year)	**2.** REPORT TYPE - INITIAL	**3.** LOCAL REFERENCE ID:	**4.** TRACKWISE ID (if applicable):
5. GLOBAL SAFETY DATABASE ID:	**6.** OTHER REFERENCE ID (if applicable):	**7.** CLASSIFICATION: ☐ Spontaneous ☐ Study ☐ **Pregnancy** ☐ Internet or digital media ☐ Other:	**8.** PRIMARY SOURCE COUNTRY:

PARTS TO BE COMPLETED BY REPORTER

B. REPORTER´S DETAILS

9. REPORTER TYPE

☐ Physician ☐ Physician assistant ☐ Dentist ☐ Pharmacist ☐ Nurse ☐ Other Health Care Professional (HCP): _____

Other: _____

10. REPORTER INITIALS (first, last)	**11.** DOES THE REPORT INCLUDE A MEDICAL INQUIRY? ☐ YES ☐ NO If YES – this automatically triggers question 12. To be YES.

C. FOLLOW-UP CONSENT

12. HAS THE REPORTER GIVEN HIS/HER CONSENT TO BE CONTACTED (for the future follow-up to initial case)? ☐ YES ☐ NO ☐ Not specified)[1]	**13.** MAY ZENTIVA CONTACT PATIENT´S PHYSICIAN?[2] ☐ YES ☐ NO ☐ Not specified)[1]	**14.** PHYSICIAN NAME AND CONTACT DETAILS (e-mail address, phone, address)

[1] If information is not specified in the received report; [2] If NO, questions 14 is not filled

D. PATIENT´S AND PREGNANT FEMALE DETAILS

15. PATIENT INITIALS (first, last)	**16**. AGE	**17**. PATIENT´S GENDER: ☐ Female ☐ Male
18. PREGNANT FEMALE INITIALS (first, last)	**19.** PREGNANT FEMALE AGE	

E. PREGNANCY EVENT DETAILS

20. ☐ Pregnancy of Patient

21. ☐ Pregnancy of Patient's Partner

22. ☐ Exposure of a Pregnant Female

23. COUNTRY OF PREGNANCY CASE REPORTING

24. Pregnancy Initially Diagnosed By:
☐ Home Urine Test
☐ Office Urine Test
☐ Serum Test

25. Date of Pregnancy Test (DD-MON-YEAR):

26. Last Menstrual Period (DD-MON-YEAR):

27. Female is Currently: ☐ weeks pregnant OR ☐ No longer Pregnant ☐ Unknown

28. Female has Elected to:

☐ Carry Pregnancy to Term. Expected Date of Delivery (DD-MON-YEAR):

☐ Terminate Pregnancy Date Performed or Pending (DD-MON-YEAR):

F. MEDICATION USED PRIOR TO AND DURING PREGNANCY						
29. BRAND NAME (including INN, strength, pharmaceutical form, batch number and LOT)	**30.** INDICATION FOR USE	**31.** ROUTE OF ADMINISTRATION	**32.** DAILY DOSE	**33.** THERAPY DATES (from/to -first to last dose)	**34.** THERAPY DURATION	**35.** ACTION TAKEN WITH DRUG
						☐ Treatment ongoing ☐ Treatment discontinued on: _____ ☐ Treatment discontinued on: _____ and reintroduced on: _____ ☐ Unknown
						☐ Treatment ongoing ☐ Treatment discontinued on: _____ ☐ Treatment discontinued on: _____ and reintroduced on: _____ ☐ Unknown
						☐ Treatment ongoing ☐ Treatment discontinued on: _____ ☐ Treatment discontinued on: _____ and reintroduced on: _____ ☐ Unknown
						☐ Treatment ongoing ☐ Treatment discontinued on: _____ ☐ Treatment discontinued on: _____ and

						reintroduced on: ☐ Unknown
						☐ Treatment ongoing ☐ Treatment discontinued on: ☐ Treatment discontinued on: and reintroduced on: ☐ Unknown

G. OTHER RELEVANT PATIENT HISTORY (e.g. diagnostics, allergies, risk factors, personal or family medical history if relevant for the adverse event described in this form, pregnancy with last month of period, etc)	
36. FROM/TO DATE	**37.** DESCRIPTION

H. LABORATORY DATA			
38. TEST DATE	**39.** TEST NAME	**40.** RESULTS	**41**. NOTES

THIS PART TO BE COMPLETED BY ZENTIVA	
THIS REPORTING FORM WAS FILLED BY :	
Name: _	
Contact: _	**Department:** _ _ _ _ _ _ _ _ _ _ _
Company name: _	**Date:** _ _ _ _ / _ _ _ _ _ _ / _ _ _ _