EudraCT Number 2015-003487-36 Sponsor Reference – 6867

Participant ID: _____

Pregnancy Reporting Form

Please complete the form and submit to NCTU
Do not sent identifiable data or source documents with this report
Guidance is given in *italics*

1. Pregnant Participant *(to be completed following notification of pregnancy)*				
Type of exposure:	Study participant			
Type of Report:	Initial	Follow-up		
Investigational Medicinal Product Information (IMP allocated/taken prior to pregnancy reported)				
Drug	**Route/Dose/ Schedule**	**Date of first dose** (DD/MM/YYYY)	**Ongoing**	**Date of last dose** (DD/MM/YYYY)
Has the participant swapped IMP due to pregnancy? ……Yes…….No (if yes, give details of IMP swapped to below)				
Drug	**Route/Dose/ Schedule**	**Date of first dose** (DD/MM/YYYY)	**Ongoing**	**Date of last dose** (DD/MM/YYYY)
Has the participant withdrawn from the trial due to pregnancy? ……Yes…….No (if yes, please give date of withdrawal) ……../……../…… (DD/MM/YYYY)				
Pregnancy Information				
Start date of last menstrual period:				
Estimated date of conception:				
Expected date of delivery:				
Obstetric History				
Number of previous pregnancies:	*(not including current pregnancy)*	Unknown		
Number of terminations of pregnancy. *(spontaneous or elective)*		Number of deliveries:		
Any children born with defects:	Yes No	*If yes, please specify:*		
2. Pregnancy Outcome – Live Birth *(only to be completed following completion of pregnancy)*				
If this is a twin or multiple birth, please complete a separate pregnancy form for each infant This information is for infant _____ of _____				
Birth Date: (DD/MM/YYYY)	Gender: M F	Apgar score (0-10):_____ (at 5 minutes)		
Infant weight: _____ kg lbs	Infant length: _____ cm ins	Gestational week at birth: _____		
Method of delivery:	Vaginal delivery Caesarean section - please give indication:			
Infant normal?	If "No", is this considered related to the study drug?			

Yes No	Yes No N/A
If considered related to study drug, please provide reason:	
Abnormal foetal diagnostic tests during pregnancy?	Yes No If "Yes", please give dates and test results:
Congenital anomalies?	Yes No If "Yes", please describe:
Newborn complications?	Yes No If "Yes", please describe:

3. Pregnancy Outcome - Foetal Demise *(only to be completed following completion of pregnancy)*

Cause:	Elective Termination Spontaneous Abortion Stillbirth Date:
Products of conception examined?	Yes No Unknown
If Yes, any congenital abnormalities found?	Yes No Unknown If "Yes", please describe:

4. Concomitant Medications *(required only if pregnancy outcome is abnormal)*

List all known therapies taken prior to and during pregnancy

Name of Drug	Daily Dose	Route	Start date DD/MM/YYYY	Ongoing	Stop Date DD/MM/YYYY	Indication

5. Relevant Medical History *(required only if pregnancy outcome is abnormal)*

Include information on familial disorders, known risk factors or conditions that may affect pregnancy outcome.

6. REPORTER DETAILS	
Name	
Role	
Site name & contact details	

TO BE COMPLETED BY NCTU		
Date of receipt of Report		
Confirmation of receipt sent	☐ Yes	☐ No
Date sent		

Is this an SAE	☐ Yes	☐ No