SJD Institutional Review Board Title: Pregnancy Report Form Code: SJDIRB Form 15.1

Version: 01

Section 1.To be filled up by the Principal Investigator.

- 1. Documents relevant to the Pregnancy should be submitted together with this form.
- 2. Pregnancy on a clinical trial must be recorded and reported to the Sponsor.
- 3. It is desirable to follow up the pregnancy but consent must be obtained.
- 4. The forms are complementary to reduce duplication. This should follow the Notification form
- 5. Follow-ups to be completed at the end of the pregnancy and 6 months post birth (if applicable)

SJDIRB Reference Code							Date of Subm	ission	DD N	lonth	YYYY
Protocol Code							SJREB Co	de			
Protocol Title											
Principal Investig											
Sponsor/CRO							<u> </u>				0.4
Approval Date	e			th YYYY			Start Date D		D Month YYYY		
The newticines tie	famal	Participant Informa							YES		NO
		and has become pregnant while ta									
		ose female partner has become pregnant while he is on a trial sent been given to follow up the pregnancy?									
PATIENT INFORITIES TO STATE TO STATE THE PATIENT OF	MATION nts are a informa the fathe	I - In Pre llocated tion. In tl r's patie	gnancy an alph ne case nt initial	Report For a-numeric s where the s/number s	orms, the prince identifier, the patient should be	the a	nt is always the mo appropriate field ('le e female partner o	Patient Ir an enrol By using	itials/Nu led male the tick	mber' e patie) should ent (drug
O Mother	o Fath	er	Patie	ent Initial	s/Numbe	er:		Moth	er initi	als:	
MATERNAL HISTORY											
Mother's Birth	day	DD Month YYYY		Mother	Mother's Height & Weight		cm			kg	
Last Menses		DD	DD Month YYYY		Expe	Expected Delivery Date			DD Month YYYY		
Date of Pregnancy	y Test	DD	DD Month YYYY Date of F			Pos	sitive Blood Test DD Month YYYY			/ Y	
name/active sub	the pag ther rele stance),	e can be vant dru daily do	reprint gs inclu se, rout	ed with the ding the Ir e of admin	e mention nternational istration,	'Sup al No batch		dded mai e (INN - p inistratio	nually. In preferred n dates	nforma d) (or t should	ation on rade
Drug Name											
Daily dose/s & ro administration Batch number	on										
Treatment start	date										
Treatment stop	date										
Drug taken by		○ Father ○ Mother				○ Father ○ Mother			○ Father ○ Mother		
		1			PONSE		THE PREGNAN				
Drug Maintair	ned	(Drug N	lame)		(Dr	rug Name)		(Drug N	lame))
Drug Reduce: Nev	w Dose				1			1			





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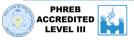
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Started on	ı YYYY	DD Month YYYY		DI	D Month YYYY			
Drug permanently	(Drug Na		(Drug Name 8	withdrawa	al (Drug	Name & withdrawal		
withdrawn	withdrawa	al date)	date			date)		
Drug interrupted (From	DD Month	YYYY to	DD Month	YYYY to	DD	DD Month YYYY to		
& To)	DD Month		DD Month	n YYYY	DI	DD Month YYYY		
PREGNANCY OUTCOME								
Carried Term	O Yes O No	Week of delivery	DD Month YYYY		Date of delivery	DD Month YYYY		
If YES was the delivery	Normal	○ Force	eps/Ventouse		O Cae	○ Caesarean		
If NO was the delivery	Spontaneo	ous O The	erapeutic	Terminati	on Date	DD Month YYYY		
Was t	oorn?	O YES			O NO			
Were there any congenital abnormalities at birth? YES NO						○ NO		
If with congenital abno birth, please record								
CHILD OUTCOME AT 6 MONTHS								
Has a Birt	O YES			O NO				
Record the details of the	birth defect							
ADDITIONAL INFORMATION								

THIS REPORT MUST BE SIGNED AND DATED BY THE INVESTIGATOR

- 1. Fill in the form and email an electronic copy to:
- 2. Print two copies of the completed form, sign and date
- 3. Send one signed copy to SJDIRB
- 4. Put one signed copy in your Trial Master File in the Pharmacovigilance section
- 5. Receipt will be acknowledged by email

Signature Date Name of Primary Investigator





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Section 2: FOR SJDIRB USE ONLY (To be filled by the Primary Reviewer)								
Decision Points Recommendation								
 Recommend further action Request additional information Continued Monitoring Withdrawal from the Study Specialized Consultations Long-Term Follow-up Pending (if substantial clarifications are necessary prior to reaching a decision 	 Close monitoring of the pregnancy through regular ultrasounds and prenatal tests. In some cases, it may be recommended that the participant withdraw from the study to minimize potential risks to the fetus. Referral to specialists, such as maternal-fetal medicine specialists or geneticists, for further evaluation and counseling. Continued monitoring of the child's development after birth to assess for any long-term effects of the investigational drug. 							
Primary Reviewer		Signature		Date				
SJDIRB Final Action								
Final Decis O Recommend further act		Recor	<u>nmendation/Com</u>	ments				
 Recommend further act Request additional infor Continued Monitoring Withdrawal from the Stu Specialized Consultation Long-Term Follow-up Pending (if substantial concessary prior to reaching 		(e.g. Proceed with the recommendation of the reviewer or full board meeting last)						
SJDIRB Officer Na				Signature	Date			
Board/Panel Secretary								
Chair/Panel Lead								



