ADVERSE EVENT REPORT FORM

Version effective 01Jun2020

Sobi ref no:

SOBIAE **Please complete the following sections, including as much info as possible.**

1. Patient details

Patient's Initials (F-M-L): _____ ☐ Male ☐ Female Age (at onset of event): _____ Date of Birth (dd/Mmm/yyyy): _____

Weight: _____ ☐ kg ☐ lbs Height: _____ ☐ cm ☐ in Pregnant: ☐ Yes ☐ No

2. Primary Suspect Drug (If more than one, add additional page)	**Indication**	**Dose, Units** (at AE start)	**Frequency**	**Route**	**Start Date** dd/Mmm/yyyy	**Stop Date** dd/Mmm/yyyy

Batch number (LOT): _____ ☐ Unknown

Expiry date (dd/Mmm/yyyy): _____ ☐ Unknown

Serialisation number (GTIN/SN number): _____ ☐ Unknown

Was a product defect suspected? ☐ Yes ☐ No

3. Adverse Event(s) (AEs) or Special Situation(s) Special Situations include exposure during pregnancy (male or female) and exposure from breastfeeding, Lack of efficacy, Medication Errors, Overdose, Abuse, Misuse, Occupational exposure, Suspected transmission of an infectious agent		**Start Date** dd/Mmm/yyyy	**Stop Date or Duration** dd/Mmm/yyyy	**Serious**		**Outcome** (see below and choose numbers)
AE no. 1				☐ Yes	☐ No	
AE no. 2				☐ Yes	☐ No	
AE no. 3				☐ Yes	☐ No	
AE no. 4				☐ Yes	☐ No	

If any SERIOUS adverse event, select seriousness criteria (more than one can be chosen)

☐ Patient died	☐ Resulted in persistent or significant disability/incapacity
☐ Life threatening	
☐ Required inpatient hospitalization	☐ Congenital anomaly/birth defect
☐ Required prolonged hospitalization	☐ Other medically important condition

Outcome (add applicable numbers for each AE above):

Recovered/Resolved = 1 Recovered with sequel = 4

Recovering/Resolving = 2 Fatal = 5

Not recovered/Not resolved = 3 Unknown = 6

If the Patient died

Specify cause of death: _____ Date of death (dd/Mmm/yyyy): _____ Autopsy performed? ☐ Yes ☐ No

If yes, please attach report

4. Actions taken with Suspect Drug due to the Adverse Event(s) or Special Situation(s) described

a) Was the Suspect Drug discontinued? ☐ Yes, permanently ☐ Yes, temporarily ☐ No ☐ Unknown

b) Was the dose changed? ☐ Yes, increased ☐ Yes, decreased ☐ No ☐ Unknown

If Suspect Drug was discontinued or dose changed:

c) Did any AE improve *(see table above for AE number)*? ☐ Yes, AE number: _____ ☐ No ☐ Unknown

If Suspect Drug was stopped:

d) Was the suspect drug re-introduced? ☐ Yes ☐ No ☐ Unknown

If yes:

e) Did any AE reappear *(see table above for AE number)?* ☐ Yes, AE number: _____ ☐ No ☐ Unknown

5. Possible causes for the event

If the reporter of the event is a **healthcare professional (HCP)**:

a) Was the Sobi drug suspected to have caused the event? ☐ Yes ☐ No

b) Please provide any other factors that may have contributed to the event?

6. Laboratory tests and investigations

Were any relevant laboratory tests or investigations performed? ☐ Yes ☐ No

If yes, please provide a copy of the report or provide dated details of the results in section 7. Please include units and reference values for any laboratory test.

The information and personal data provided on this form will be recorded and processed electronically by Swedish Orphan Biovitrum AB (publ). The information provided will be used for the purpose of drug safety surveillance.

Please return to: Drug Safety Swedish Orphan Biovitrum, SE-112 76 Stockholm, Sweden
FAX: +46 8 697 32 30 Phone: +46 8 697 20 00 (switchboard) e-mail: adverseevent@sobi.com

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7. Event details

Please provide any further relevant information about the Adverse Event(s) or Special Situation(s), including results of related investigations and interventions

8. Medical History and concurrent disease(s) (e.g. other relevant medical conditions, allergies and past drug reactions)

Condition	Onset Date (dd/Mmm/yyyy)	Status
		☐ Past ☐ Present
		☐ Past ☐ Present
		☐ Past ☐ Present
		☐ Past ☐ Present
		☐ Past ☐ Present

9. Concomitant Drug(s) Exclude drugs for treatment of the AE(s)	Indication	Dose, Unit(s)	Frequency	Route	Start Date dd/Mmm/yyyy	Stop Date dd/Mmm/yyyy

10. Reporter contact details

Reporter's Qualification	☐ Physician ☐ Nurse ☐ Pharmacist ☐ Other HCP (specify):		☐ Non HCP (specify):	
Reporter's name:		Reporter's hospital (if applicable):		
Address:				
Email:	Phone:		Fax:	Country:

11. Prescriber contact details

Prescriber's name:	Prescriber's hospital (if applicable):	
Address:		
Email:	Phone:	Fax:

Case reported to Regulatory Authority by patient/reporter? ☐ Yes ☐ No ☐ Unknown

Does the reporter agree to be contacted for follow-up? ☐ Yes ☐ No

If the reporter of the information is a **patient or consumer**: Does the reporter allow Sobi to contact the responsible physician for follow-up?
☐ Yes ☐ No *If yes, please provide contact details:*

12. Person completing this form (if not the same as reporter or prescriber)

Name:	Title:		Organization/Company:
E-mail:	Phone:	Fax:	Internal ref. no for this case:

13. Date of awareness – to be completed by Sobi personnel and person working on behalf of Sobi

Date you first received the information provided in this report (dd/Mmm/yyyy):

Signature: **Date (dd/Mmm/yyyy):**

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