

Orphan SA Pharmaceuticals (Pty) Ltd.
Phone: +27 11 467 8868 Fax: +27 11 467 8868

ADVERSE EVENT REPORTING FORM
BDP-GVHD-06

Type of Report: Initial Follow-Up Patient Initials: _____

A. TREATING PHYSICIAN/REPORTER INFORMATION

TREATING PHYSICIAN INFORMATION		
Name	Title	<input type="checkbox"/> Physician <input type="checkbox"/> Other
City/State/Province		Country
Institute Name	Address:	Telephone #
Fax #	Email:	Mobile # (if available)

REPORTER INFORMATION (IF DIFFERENT THAN ABOVE TREATING PHYSICIAN INFORMATION)		
Name	Title	<input type="checkbox"/> Physician <input type="checkbox"/> Nurse <input type="checkbox"/> Pharmacist <input type="checkbox"/> Other
City/State/Province		Country
Institute Name	Address:	Telephone #
Fax #	Email:	Mobile # (if available)

- **CONFIDENTIAL** -

Company Code No:	Received date:
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B. ADVERSE EVENT INFORMATION

Adverse Event _____

Serious* Non-serious**

*Check serious if any of the responses to questions 1 – 8 below is yes. If the event is serious, please also complete sections C, D, E and F and sign page 4 of the form.

**Check non-serious if all of the responses to question 1-8 below is no. If the event is non-serious please finish completing section B and sign page 4 of the form. There is no need to complete sections C, D, E and F.

1. Fatal? YES NO -----/-----/----- (Date of death)
(If yes, Autopsy Performed?) YES NO

2. Life threatening? YES NO

3. Caused Persistent/ Significant Disability? YES NO

4. Prolongs existing hospitalization? YES NO

5. Requires NEW (inpatient) hospitalization? YES NO

6. Required medical/surgical intervention to prevent permanent/significant impairment/damage? YES NO

7. Congenital Anomaly/Birth Defect? YES NO

8. Other medically important condition? YES NO

Onset Date _____

Does the patient have a history of this type of event prior to initiating orBec treatment? YES NO
(Comment) _____

Severity	Relationship	Action Taken	Outcome
Mild <input type="checkbox"/>	Not Related <input type="checkbox"/>	None <input type="checkbox"/>	Recovered <input type="checkbox"/> (Date: _____)
Moderate <input type="checkbox"/>	Remote <input type="checkbox"/>	Rx Therapy <input type="checkbox"/>	Improved <input type="checkbox"/>
Severe <input type="checkbox"/>	Possible <input type="checkbox"/>	Prolonged Hosp. <input type="checkbox"/>	Unchanged <input type="checkbox"/>
	Probable <input type="checkbox"/>	Interrupt Tx <input type="checkbox"/>	Worsened <input type="checkbox"/>
	Highly Probable <input type="checkbox"/>	Discontinue Tx <input type="checkbox"/>	Died <input type="checkbox"/> (Date: _____)
			Permanent Sequelae <input type="checkbox"/> <i>Please provide more detail in narrative description of event</i>

C. ORBEC TREATMENT INFORMATION

The patient STARTED treatment on _____ at _____ AM PM

orBec treatment discontinued? YES NO If yes, treatment STOPPED on _____ at _____ AM PM

LOT NUMBER(S): _____

EXPIRY/RETEST DATE: _____

Fax the initial report to Orphan SA Pharmaceuticals (Pty) Ltd within 24 hours of contact.

