GlaxoSmithKline | HUMAN GENOME SCIENCES

Protocol: BEL114256/HGS1006-C1101

BENLYSTA™ (belimumab) Pregnancy Registry

Obstetrical Pregnancy Outcome Form

(to be completed at or immediately after pregnancy outcome)

CONFIDENTIAL

Registry ID _____

Fax or Mail to: *Benlysta* Pregnancy Registry using the contact information provided below

1.0 MATERNAL INFORMATION

1.1 Date of Outcome ☐☐ ☐☐☐ ☐☐☐☐

DD MMM YYYY

1.2 Pregnancy Type

☐ **Singleton**
☐ **Twin** (*Complete separate Outcome Forms)*
☐ **Triplet** (*Complete separate Outcome Forms)*
☐ **Other** *(Specify)*_____

If multiple births, please photocopy page 2 and complete it for each infant or pregnancy outcome

2.0 PRENATAL IMAGING AND ANEUPLOIDY SCREENING/TESTING

Was prenatal test performed? ☐ Yes ☐ No ☐ Unknown
If Yes, please complete the table below with all prenatal tests performed If No or Unknown, proceed to Section 3.0

Prenatal Test Name (e.g. Ultrasound, Amniocentesis, MSAFP, Quad Screen, CVS)	Test Date (DD/MMM/YYYY)	Fetal Abnormality Noted? Y = Yes N = No P = Result Pending U = Unknown	If Fetal Abnormality was Noted Please Describe
1			
2			
3			
4			
5			

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3.0 PREGNANCY INFORMATION

3.1 Outcome

- ☐ Live Birth
- ☐ Neonatal Death
- ☐ Stillbirth *(≥20 weeks gestation)*
- ☐ Spontaneous Miscarriage *(<20 weeks gestation)*
- ☐ Elective Termination
- ☐ Ectopic Pregnancy
- ☐ Molar Pregnancy

(Complete 3.2 to 3.5 for Live Birth Outcome only; If not Live Birth Outcome, move to 3.6)

3.2 Baby # _____ **3.3 Gender** ☐ Male ☐ Female ☐ Ambiguous Gender

3.4 Birth Weight _____ **g** _____ **lbs/oz Length** _____ ☐in ☐cm **Head Circumference** _____ ☐in ☐cm

3.5 Route of Delivery ☐ Vaginal ☐ Cesarean

3.6 If pregnancy resulted in Neonatal Death, Stillbirth, Spontaneous Miscarriage, or Elective Termination was birth defect noted?

☐ Yes ☐ No **If yes, please complete section 6.0 BIRTH DEFECTS**

3.7 If Neonatal Death, Stillbirth, Spontaneous Miscarriage, Elective Termination, Ectopic, or Molar Pregnancy, please provide any contributing factors:

☐ Unknown

_____

_____

3.8 If not a live birth, is there reasonable possibility this outcome was attributable to belimumab? ☐ Yes ☐ No

4.0 INFORMATION ON BREASTFEEDING (For Live Birth Outcome only; Please move to 5.0 if the responses to 4.1 and 4.2 are No)

4.1 Is the infant currently breastfed? ☐ Yes ☐ No ☐ Unknown

4.2 Was the infant ever breastfed? ☐ Yes ☐ No ☐ Unknown

If yes, Stop Date DD MMM YYYY

5.0 INFANT INFECTIONS or FEVER OF UNKNOWN ORIGIN

5.1 Has the infant experienced a fever of unknown origin, a fever of known infectious etiology or an infection requiring treatment?

☐ Yes ☐ No ☐ Unknown

5.2 Has the infant experienced a serious infection? (i.e., Resulted in death, life threatening, required inpatient hospitalization, prolonged hospitalization, resulted in significant disability or incapacity, or considered medically important)

☐ Yes ☐ No ☐ Unknown

***If Yes to one or both questions above, please complete the Infant Infections/Fever of Unknown Origin Log**

6.0 BIRTH DEFECTS

6.1 Were there any birth defects noted? ☐ Yes (If Yes, list birth defects below) ☐ No (If No, move to 7.0) ☐ Unknown (If Unknown, move to 7.0)

Birth Defect *(List one birth defect per line)*	Reasonable Possibility Defect attributable to belimumab?	List factors that may have contributed to this defect: *(family history, maternal age, obesity, alcohol consumption during pregnancy, etc)*	Birth defect noted prior to or after birth?
1	☐ Yes ☐ No		☐ Prior to birth ☐ After birth *(specify date)* DD MMM YYYY
2	☐ Yes ☐ No		☐ Prior to birth ☐ After birth *(specify date)* DD MMM YYYY
3	☐ Yes ☐ No		☐ Prior to birth ☐ After birth *(specify date)* DD MMM YYYY

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7.0 BELIMUMAB AUTOANTIBODY AND COMPLEMENT RESULTS LOG (Please update the Belimumab Autoantibody and Complement Results Log for patients with SLE only) ☐ Updated ☐ N/A, patient does not have SLE

8.0 BELIMUMAB OTHER LABORATORY RESULTS (Please update the Belimumab Other Laboratory Results Log for patients with SLE only) ☐ Updated ☐ N/A, patient does not have SLE

9.0 CONCURRENT MEDICAL CONDITIONS WITHIN THE 6 MONTHS PRIOR TO AND/OR DURING PREGNANCY LOG (Please update the Concurrent Medical Conditions within the 6 Months Prior to and/or During Pregnancy Log) ☐ Updated

10.0 EXPOSURES PRIOR TO AND/OR DURING PREGNANCY LOG (Please update the Exposures Prior to and/or During Pregnancy Log) ☐ Updated

11.0 REPORTER INFORMATION

☐ Same reporter as Obstetrical Initial Data Form

☐ Same reporter as Obstetrical Follow-up at the End of 2nd Trimester Form

(If either box is checked, Reporter Signature and Date are the only fields that require completing below)

11.1 Health Care Provider (HCP) *(check one type)*

☐ Obstetric or Maternal Fetal Medicine HCP

☐ Belimumab Prescriber

11.2 ☐ Pregnant Patient

11.3 ☐ Retrospective Patient Report

Name _____

Address _____

_____

Alternate Contact _____

Reporter's Signature _____

Specialty _____

Phone _____

Fax _____

Email _____

Date ☐☐ ☐☐☐ ☐☐☐☐ (DD MMM YYYY)

Office Use Only

☐ Phone RCC Associate Initials _____

☐ This check indicates that all blank fields represent data that is not available