EVALUATION OF USE OF BELIMUMAB IN CLINICAL PRACTICE SETTINGS
PATIENT CASE RECORD FORM – PHASE II, 18 - 24 MONTH PATIENT FOLLOW-UP

NOTE: Important Definition of Study Treatment Period

Please provide patient information only for the period between month 18 and month 24 post belimumab therapy initiation. Based on data previously submitted in Phase I, the post-belimumab therapy initiation follow-up time period of months 18 to 24 for this patient is: **FROM:** __________ **TO:** __________

MD OFFICE ID #: __________ (MDA ASSIGNED) **PATIENT ID #:** __________

PATIENT GENDER: ___ **PATIENT ETHNICITY:** __________ **BELIMUMAB START DATE:** __________

Did this patient experience any adverse event(s) related to belimumab between __________ and __________?

☐2 No ☐1 Yes ➔ **If Yes, please provide a description of the adverse experience(s) including the date of the event, belimumab dose at the time of event, and if the event was resolved / unresolved. If the patient died, please include cause of death and all relative details.**

Adverse Event 1:____

____

Date of event #1: M_____ D_____ Y_____

Belimumab dose at the time of the event: _________

Was this adverse event resolved? Yes ☐1 No ☐2

Did this patient die? No ☐2 Yes ☐1 ➔ Continue below

If this patient died, what was the cause of death: ____

If this patient died, what was the date of death: M_____ D_____ Y_____

Adverse Event 2:____

____

Date of event #2: M_____ D_____ Y_____

Belimumab dose at the time of the event: _________

Was this adverse event resolved? Yes ☐1 No ☐2

Did this patient die? No ☐2 Yes ☐1 ➔ Continue below

If this patient died, what was the cause of death: ____

If this patient died, what was the date of death: M_____ D_____ Y_____

NOTE: Any serious adverse events related to the treatment of SLE should be reported to the FDA via the MedWatch system on the FDA website

SECTION I: PATIENT PROFILE

1. Current weight: _______ ☐$_1$ lbs ☐$_2$ kg

SECTION II: CURRENT BELIMUMAB THERAPY

2. Is this patient still on belimumab therapy?

☐$_1$ Yes **Skip to Q3**

☐$_2$ No ➔ Date of discontinuation: _____ / _____ / _______ ➔ **Answer below:**

If belimumab therapy ended, specify reasons for ending therapy [“x” all that apply]:

☐$_1$ Disease progression
☐$_4$ Patient request
☐$_2$ Medication not effective
☐$_5$ Loss of insurance or reimbursement
☐$_3$ Lack of compliance
☐$_6$ Lost to follow-up or death
☐$_x$ Adverse Event **(SPECIFY)**: _______________________________________
☐$_x$ Other **(SPECIFY)**: __________________________

3. Specify the **LAST or MOST RECENT DOSE** of belimumab (**at 24 months post-initiation or at time of discontinuation)**: ________ mg/kg

4. Any CHANGES to the belimumab dose between __________ and __________ **or date of discontinuation**?

☐$_2$ No ➔ **Skip to Q5**

☐$_1$ Yes ➔ **# of dose changes?** _____ ➔ **Please indicate the date, dose, and reason for each dose change below:**

Date: 1st : ___/ ___/____ ➔ **New Dose:** _______mg/kg Reason (**SPECIFY**): ______________________________

Date: 2nd: ___/ ___/____ ➔ **New Dose:** _______mg/kg Reason (**SPECIFY**): ______________________________

Date: 3rd : ___/ ___/____ ➔ **New Dose:** _______mg/kg Reason (**SPECIFY**): ______________________________

5. What is your overall clinical assessment of disease severity of this patient at the end of month 18 (as of __________) post belimumab therapy initiation? **(“X” one only)**

☐$_1$ **Mild** ☐$_2$ **Moderate** ☐$_3$ **Severe** ☐$_0$ **Not documented**

SECTION III: SLE CLINICAL MANIFESTATIONS, SEVERITY, AND IMPROVEMENT ASSESSMENT BETWEEN MONTHS 18 AND 24 POST BELIMUMAB THERAPY INITIATION

6. Complete table below based on the period of 18-24 months following the start of belimumab therapy on: ___________.
PLEASE NOTE: This section pertains only to the 6-month period **between** ___________ and ___________; **NOT** from initiation to current.

CLINICAL ASSESSMENT BETWEEN MONTH 18 AND MONTH 24 POST BELIMUMAB THERAPY INITIATION			
SLE Clinical Manifestations at Start of month 18 *(Use # Codes In Legend Sheet. Use one row for each clinical manifestation)*	**Severity of Clinical Manifestation at start of month 18** *("X" one only for each)*	**% Improvement in Individual Clinical Manifestations from months 18 to 24** (or date of belimumab discontinuation) *("X" one only for each manifestation)*	**OVERALL CLINICAL RESPONSE to belimumab: during months 18 to 24** (or to belimumab discontinuation)
Code #: ________	☐$_1$ Mild ☐$_2$ Moderate ☐$_3$ Severe	☐$_1$ Worse ☐$_2$ No Improvement ☐$_3$ <20% ☐$_4$ 20-49% ☐$_5$ 50-79% ☐$_6$ ≥80%	**Clinician impression of overall clinical manifestations observed:** **("X" one only)**
Code #: ________	☐$_1$ Mild ☐$_2$ Moderate ☐$_3$ Severe	☐$_1$ Worse ☐$_2$ No Improvement ☐$_3$ <20% ☐$_4$ 20-49% ☐$_5$ 50-79% ☐$_6$ ≥80%	☐$_1$ Deteriorated
Code #: ________	☐$_1$ Mild ☐$_2$ Moderate ☐$_3$ Severe	☐$_1$ Worse ☐$_2$ No Improvement ☐$_3$ <20% ☐$_4$ 20-49% ☐$_5$ 50-79% ☐$_6$ ≥80%	☐$_2$ No Improvement
Code #: ________	☐$_1$ Mild ☐$_2$ Moderate ☐$_3$ Severe	☐$_1$ Worse ☐$_2$ No Improvement ☐$_3$ <20% ☐$_4$ 20-49% ☐$_5$ 50-79% ☐$_6$ ≥80%	☐$_3$ <20% Improvement
Code #: ________	☐$_1$ Mild ☐$_2$ Moderate ☐$_3$ Severe	☐$_1$ Worse ☐$_2$ No Improvement ☐$_3$ <20% ☐$_4$ 20-49% ☐$_5$ 50-79% ☐$_6$ ≥80%	☐$_4$ 20-49% Improvement
Code #: ________	☐$_1$ Mild ☐$_2$ Moderate ☐$_3$ Severe	☐$_1$ Worse ☐$_2$ No Improvement ☐$_3$ <20% ☐$_4$ 20-49% ☐$_5$ 50-79% ☐$_6$ ≥80%	☐$_5$ 50-79% Improvement
Other (SPECIFY): ___________	☐$_1$ Mild ☐$_2$ Moderate ☐$_3$ Severe	☐$_1$ Worse ☐$_2$ No Improvement ☐$_3$ <20% ☐$_4$ 20-49% ☐$_5$ 50-79% ☐$_6$ ≥80%	☐$_6$ ≥80% Improvement

SECTION IV: SLE DISEASE ACTIVITY ASSESSMENT BETWEEN MONTHS 18 AND 24 POST BELIMUMAB THERAPY INITIATION

7. Did you use any of the disease activity assessment tools listed below for this patient to be able to provide assessments at end of month 24 (as of __________, or date of belimumab discontinuation) post belimumab therapy initiation? **("X" one only)**

☐$_1$ Yes ➔ **Complete table below** ☐$_2$ No ➔ **Skip to Q8**

Q7b. Assessment at the end of month 24 post belimumab initiation (or at date of belimumab discontinuation)		
	YES, tool used *("X" box below)*	**Score**
Physician Global Assessment Scale ➔ **Specify range of scale used: ___ to ___**	☐$_1$ ➔	________
Patient Global Assessment Scale ➔ **Specify range of scale used: ___ to ___**	☐$_2$ ➔	________
SELENA-SLEDAI *(Systemic Lupus Erythematosus Disease Activity Index SELENA Modification)* / SLEDAI)	☐$_3$ ➔	________
BILAG *(British Isles Lupus Assessment Group Index)*	☐$_4$ ➔	________
SLAM *(Systemic Lupus Activity Measure)*	☐$_5$ ➔	________
ECLAM *(European Consensus Lupus Activity Measurement Index)*	☐$_6$ ➔	________
Other (SPECIFY): _____________	☐$_x$ ➔	________

8. Did you use any **other assessment tools** for this patient **at the end of month 24** (as of __________) post belimumab therapy initiation? **("X" one only)**

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☐1 Yes ➔ **Complete table below** ☐2 No ➔ **Skip to Q9**

Q8b. Assessment at the end of month 24 post belimumab initiation (or at date of belimumab discontinuation)		
	YES, tool used *("X" box below)*	**Score**
Fatigue Severity Scale➔ ***Please normalize the scale/score to a range of 0-100 and provide your assessment***	☐1 ➔	________
Other (**SPECIFY**): _____________	☐x	________

SECTION V: OTHER SLE THERAPIES PRESCRIBED/USED BETWEEN MONTHS 18 & 24 POST BELIMUMAB THERAPY INITIATION

9. Was this patient prescribed other SLE medications, other than belimumab, **between months 18 & 24 post belimumab therapy initiation**? **("X" one only)** ☐1 Yes ➔ **Complete table below** ☐2 No ➔ **Skip to Q10**

Q.9a SLE medications [CONTINUED FROM PREVIOUS TREATMENT PERIOD used between __________ and __________.			
	Dose per Administration	**Route of Administration**	**Frequency**
Medication (use Legend # codes) _____________	**Original Start Date**: Mo____ Day____ Yr____		
At the end of 24 months post belimumab initiation, or at time of med discontinuation (if <24 months) **Date of discontinuation:** Mo____ Day____ Yr____ ☐1 N/A	______ ☐1 mg ☐2 mg/kg ☐x Other: ____	☐1 Oral ☐2 IV ☐3 IM ☐x Other:______	☐1 Daily ☐2 BID ☐3 TID ☐4 Once a week ☐5 Every 2 weeks ☐6 Every 3 weeks ☐7 Every 4 weeks ☐x Other:________
Medication (use Legend # codes) _____________	**Original Start Date**: Mo____ Day____ Yr____		
At the end of 24 months post belimumab initiation, or at time of med discontinuation (if <24 months) **Date of discontinuation:** Mo____ Day____ Yr____ ☐1 N/A	______ ☐1 mg ☐2 mg/kg ☐x Other: ____	☐1 Oral ☐2 IV ☐3 IM ☐x Other:______	☐1 Daily ☐2 BID ☐3 TID ☐4 Once a week ☐5 Every 2 weeks ☐6 Every 3 weeks ☐7 Every 4 weeks ☐x Other:________
Medication (use Legend # codes) _____________	**Original Start Date**: Mo____ Day____ Yr____		
At the end of 24 months post belimumab initiation, or at time of med discontinuation (if <24 months) **Date of discontinuation:** Mo____ Day____ Yr____ ☐1 N/A	______ ☐1 mg ☐2 mg/kg ☐x Other: ____	☐1 Oral ☐2 IV ☐3 IM ☐x Other:______	☐1 Daily ☐2 BID ☐3 TID ☐4 Once a week ☐5 Every 2 weeks ☐6 Every 3 weeks ☐7 Every 4 weeks ☐x Other:________
Medication (use Legend # codes) _____________	**Original Start Date**: Mo____ Day____ Yr____		
At the end of 24 months post belimumab initiation, or at time of med discontinuation (if <24 months) **Date of discontinuation:** Mo____ Day____ Yr____ ☐1 N/A	______ ☐1 mg ☐2 mg/kg ☐x Other: ____	☐1 Oral ☐2 IV ☐3 IM ☐x Other:______	☐1 Daily ☐2 BID ☐3 TID ☐4 Once a week ☐5 Every 2 weeks ☐6 Every 3 weeks ☐7 Every 4 weeks ☐x Other:________

Q.9b SLE medications [NEWLY STARTED] between __________ and __________.			
	Dose per Administration	Route of Administration	Frequency
Medication (use Legend # codes) ____________	**Original Start Date**: Mo____ Day____ Yr____		
At the time of medication start	______ ☐1 mg ☐2 mg/kg ☐x Other: ____	☐1 Oral ☐2 IV ☐3 IM ☐x Other:_____	☐1 Daily ☐2 BID ☐3 TID ☐4 Once a week ☐5 Every 2 weeks ☐6 Every 3 weeks ☐7 Every 4 weeks ☐x Other:_______
At the end of 24 months post belimumab initiation, or at time of med discontinuation (if <24 months) **Date of discontinuation:** Mo____ Day____ Yr____ ☐1 N/A	______ ☐1 mg ☐2 mg/kg ☐x Other: ____	☐1 Oral ☐2 IV ☐3 IM ☐x Other:_____	☐1 Daily ☐2 BID ☐3 TID ☐4 Once a week ☐5 Every 2 weeks ☐6 Every 3 weeks ☐7 Every 4 weeks ☐x Other:_______
Medication (use Legend # codes) ____________	**Original Start Date**: Mo____ Day____ Yr____		
At the time of medication start	______ ☐1 mg ☐2 mg/kg ☐x Other: ____	☐1 Oral ☐2 IV ☐3 IM ☐x Other:_____	☐1 Daily ☐2 BID ☐3 TID ☐4 Once a week ☐5 Every 2 weeks ☐6 Every 3 weeks ☐7 Every 4 weeks ☐x Other:_______
At the end of 24 months post belimumab initiation, or at time of med discontinuation (if <24 months) **Date of discontinuation:** Mo____ Day____ Yr____ ☐1 N/A	______ ☐1 mg ☐2 mg/kg ☐x Other: ____	☐1 Oral ☐2 IV ☐3 IM ☐x Other:_____	☐1 Daily ☐2 BID ☐3 TID ☐4 Once a week ☐5 Every 2 weeks ☐6 Every 3 weeks ☐7 Every 4 weeks ☐x Other:_______
Medication (use Legend # codes) ____________	**Original Start Date**: Mo____ Day____ Yr____		
At the time of medication start	______ ☐1 mg ☐2 mg/kg ☐x Other: ____	☐1 Oral ☐2 IV ☐3 IM ☐x Other:_____	☐1 Daily ☐2 BID ☐3 TID ☐4 Once a week ☐5 Every 2 weeks ☐6 Every 3 weeks ☐7 Every 4 weeks ☐x Other:_______
At the end of 24 months post belimumab initiation, or at time of med discontinuation (if <24 months) **Date of discontinuation:** Mo____ Day____ Yr____ ☐1 N/A	______ ☐1 mg ☐2 mg/kg ☐x Other: ____	☐1 Oral ☐2 IV ☐3 IM ☐x Other:_____	☐1 Daily ☐2 BID ☐3 TID ☐4 Once a week ☐5 Every 2 weeks ☐6 Every 3 weeks ☐7 Every 4 weeks ☐x Other:_______

SECTION VI: SLE-RELATED RESOURCE UTILIZATION

10. How many scheduled and unscheduled SLE-related office visits did this patient have between __________ and __________ or the date of belimumab discontinuation? **(Record below)**

SLE – RELATED PATIENT VISITS TO YOUR OFFICE	**Between months 18 & 24** (or date of belimumab discontinuation) **post belimumab therapy initiation** (ENTER '0' IF NONE DOCUMENTED)
# of **Scheduled** SLE-related visits to your office:	# of visits: ____
# of **Unscheduled SLE-related** visits to your office:	# of visits: ____

11. Between __________ and __________ (or the date of belimumab discontinuation), which other physician specialties, if any, did this patient see for SLE-related reasons? **Complete the number of visits for each specialty seen in table below.**

SPECIALISTS VISITED FOR SLE-RELATED REASONS ["X" all that apply]	**Between months 18 & 24** (or date of belimumab discontinuation) **post belimumab therapy initiation** (ENTER '0' IF NONE DOCUMENTED)
☐1 Another Rheumatologist	# of visits: ____
☐2 Allergist	# of visits: ____
☐3 Cardiologist	# of visits: ____
☐4 Dermatologist	# of visits: ____
☐5 Gastroenterologist	# of visits: ____
☐6 Internist	# of visits: ____
☐7 Nephrologist	# of visits: ____
☐8 Neurologist	# of visits: ____
☐9 Ophthalmologist	# of visits: ____
☐10 Psychologist	# of visits: ____
☐11 Radiologist	# of visits: ____
☐x Other (Please Specify): _______________	# of visits: ____

12. Has this patient had at least one Emergency Room (ER) visit related to SLE between __________ and __________ or the date of belimumab discontinuation?

("X" one only) ☐1 Yes ➔ **Complete table below** ☐2 No ➔ **Skip to Q13**

Q18b	**Between months 18 & 24** (or date of belimumab discontinuation) **post belimumab therapy initiation** (ENTER '0' IF NONE DOCUMENTED)
ER visits related to SLE	# of ER visits: ____

13. Has this patient had at least one SLE-related hospitalization between __________ and __________ or the date of belimumab discontinuation? **("X" one only)** ☐1 Yes ➔ **Complete table below** ☐2 No ➔ **Skip to Q14**

Q13b	**Hospitalization # 1**	**Hospitalization # 2**	**Hospitalization # 3**	**Hospitalization # 4**
Admission date	Mo____ Day____ Yr____	Mo____ Day____ Yr____	Mo____ Day____ Yr____	Mo____ Day____ Yr____
ICD-9 Code	____________	____________	____________	____________
Related to belimumab?	☐1 Yes ☐2 No	☐1 Yes ☐2 No	☐1 Yes ☐2 No	☐1 Yes ☐2 No
# Hospital days	# ______	# ______	# ______	# ______
Admitted to ICU	☐1 Yes➔# of days:____ ☐2 No	☐1 Yes➔# of days:____ ☐2 No	☐1 Yes➔# of days:____ ☐2 No	☐1 Yes➔# of days:____ ☐2 No

14. Did this patient receive any SLE-related ancillary care between __________ and __________ or the date of belimumab discontinuation? **("X" one only)**

☐1 Yes ➔ **Complete table below** ☐2 No ➔ **Skip to Q15**

Q14b SLE-RELATED ANCILLARY CARE	**Between months 18 & 24** (or date of belimumab discontinuation) **post belimumab therapy initiation**
Physical therapy	☐1 Yes ☐2 No ☐0 Don't know
Occupational therapy	☐1 Yes ☐2 No ☐0 Don't know
Home health care services	☐1 Yes ☐2 No ☐0 Don't know
Other (Specify): ____________	☐1 Yes ☐2 No ☐0 Don't know

15. Did this patient's primary or secondary medical or prescription drug insurance coverage change between months 18 and 24 post belimumab initiation? **If yes**, please indicate the patient's major medical insurance (**Column A)** and prescription drug insurance coverage **(Column B)** in the table below, **at the end of month 24** (as of __________) **post belimumab initiation,** or at the date of belimumab discontinuation. **("X" one only)**

☐1 Yes ➔ **Complete table below** ☐2 No ➔ **Please complete the remaining Patient CRFs.**

INSURANCE COVERAGE CHANGE between __________ and __________	**Column A: Medical Insurance Coverage**		**Column B: Drug Insurance Coverage**	
	Primary	**Secondary**	**Primary**	**Secondary**
Medicare (including office injection)	☐1	☐1	☐1	☐1
Medicaid	☐2	☐2	☐2	☐2
State Funded Program	☐3	☐3	☐3	☐3
Traditional Fee For Service/Indemnity Insurance	☐4	☐4	☐4	☐4
HMO	☐5	☐5	☐5	☐5
PPO	☐6	☐6	☐6	☐6
Self Pay	☐7	☐7	☐7	☐7
Indigent / No Pay	☐8	☐8	☐8	☐8
VA	☐9	☐9	☐9	☐9
None	☐0	☐0	☐0	☐0
Don't Know / Not documented	☐98	☐98	☐98	☐98

END OF THIS PATIENT CRF. PLEASE COMPLETE THE REMAINING PATIENT CRFS.

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