

## Progress Report: Sri Lanka Clinical Trials Registry

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SLCTR registration number: SLCTR/2015/002

Scientific title of trial: A Randomized, Double-Blind, Placebo-Controlled Phase 3 Study to Evaluate the Efficacy and Safety of Blisibimod Administration in Subjects With Systemic Lupus Erythematosus

Date of commencement (enrolment of first participant): 9 April 2015

Global – 4<sup>th</sup> April 2013

Progression: 6 months       1 year      2 years      3 years  
At completion

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### 1. Baseline data

Date of commencement:

Global commencement date – 4<sup>th</sup> April 2013

Study commencement date in Sri Lanka – 9 April 2015

Any changes to the trial design/ methodology/ protocol after commencement: Yes. Protocol change sheet has been submitted separately.

Any changes to trial outcomes after commencement: Yes, SRI-8 to SRI-6

### 2. Current status

Recruitment status: recruitment suspended

Number assessed for eligibility:

Globally- 588

In Sri Lanka - 02

Number recruited and randomized:

Globally - 442

In Sri Lanka -01

Number allocated to each intervention/arm: Study is blinded so this information cannot be provided.

Losses/exclusions after randomization:

Globally – 82

In Sri Lanka – 0

### 3. Trial output

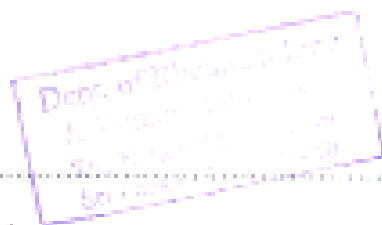
Summary of Interim/Final data (if available):

Completion of an interim analysis of its Phase 3 trial (CHABLIS-SC1) of belimumab in patients with Systemic Lupus Erythematosus took place in February 2015. The outcome was that the study should continue to completion as planned. An independent statistician conducted the interim futility analysis for the CHABLIS-SC1 study, evaluating the SRI-6 response at the 24 week time point.

Presentations of results at scientific meetings: N/A

Publications: No publications for Chablis-SC1 study. Final data not available yet, planned for Q3 2016.

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(for WP)



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