

## Progress Report: Sri Lanka Clinical Trials Registry

---

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): 09 April 2015. Global – 04 April 2013

Progression: 6 months                       1 year                       2 years                       3 years

At completion

---

### 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 amendment was notified via protocol amendment sheet dated 02 Nov 2015.

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

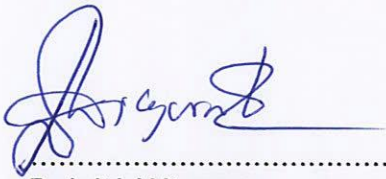
### 3. Trial output

Summary of Interim/Final data (if available):

Completion of an interim analysis of its Phase 3 trial (CHABLIS-SCI) of blisibimod 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-SCI study, evaluating the SRI-6 response at the 24 week time point

Presentations of results at scientific meetings: No presentations of results have occurred during the reporting period.

Publications: No publications relevant to blisibimod have been published during the reporting period.



Date: 16.02.2017

.....  
Dr Lalith Wijyaratne  
Consultant Rheumatologist  
National Hospital of Sri Lanka

**Dr. LALITH S. WIJAYARATNE**  
MBBS, MD, FRCP (Lond)  
CONS. PHYSICIAN IN CHARGE  
DEPARTMENT OF RHEUMATOLOGY &  
MEDICAL REHABILITATION (G)  
THE NATIONAL HOSPITAL, COLOMBO