

BLISS-SC (Belimumab International SLE Study – Subcutaneous)

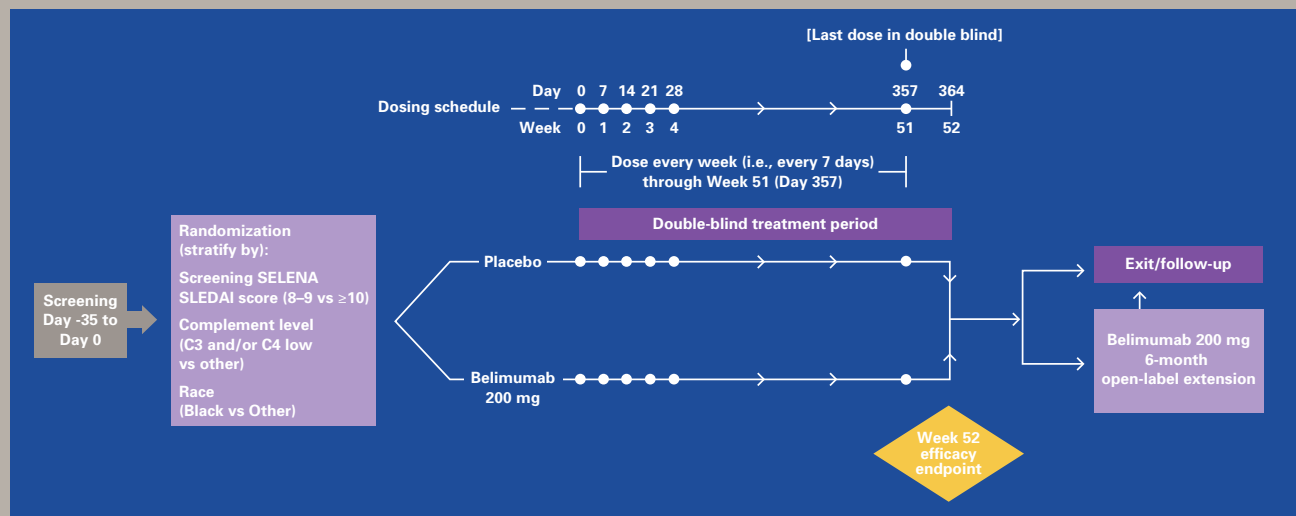
A Phase 3, Multicenter, Randomized, Double-Blind, Placebo-Controlled, 52-Week Study to Evaluate the Efficacy and Safety of Belimumab (HGS1006) Administered Subcutaneously to Subjects With Systemic Lupus Erythematosus (SLE)

BLISS-SC is a Phase 3, multicenter, international, randomized, double-blind, placebo-controlled study to evaluate the efficacy, safety, and tolerability of belimumab administered subcutaneously (SC) to adult subjects with active SLE.

A total of 816 subjects will be randomly assigned in a 2:1 ratio to a 52-week treatment period with belimumab or placebo.

All subjects will continue the stable standard therapy they were receiving during the screening period.

Subjects who successfully complete the 52-week double-blind phase may enter into a 6-month open-label extension phase of this study.



Primary efficacy endpoints

- The primary efficacy endpoint is the SLE Responder Index response rate at Week 52, defined as:
 - ≥4 point reduction from baseline in SELENA SLEDAI score
 - No worsening (increase of <0.30 points from baseline) in Physician's Global Disease Assessment
 - No new BILAG A organ domain score or two new BILAG B organ domain scores compared with baseline

Key inclusion criteria

- Adult subjects ≥18 years of age
- Clinical diagnosis of SLE
- SELENA SLEDAI score ≥8 at screening
- Auto-antibody positive
- On a stable SLE treatment regimen

Key exclusion criteria

- Treated with an investigational biological agent in past year
- Severe active lupus kidney disease
- Severe active central nervous system lupus
- Required management of acute or chronic infections within 60 days
- Unable or unwilling to administer study agent by SC injection and has no other reliable resource to administer the injection

For information about referring a potential patient, please use the following contacts:

North America: Robert.Weldon@quintiles.com **Latin America:** Brian.Stout@quintiles.com **Western Europe:** Estelle.Guy@quintiles.com **Eastern Europe:** Miquel.Ruda@quintiles.com **Asia Pacific:** Sanjay.Akhani@quintiles.com **Japan:** Hiroki.Fujii@quintiles.com