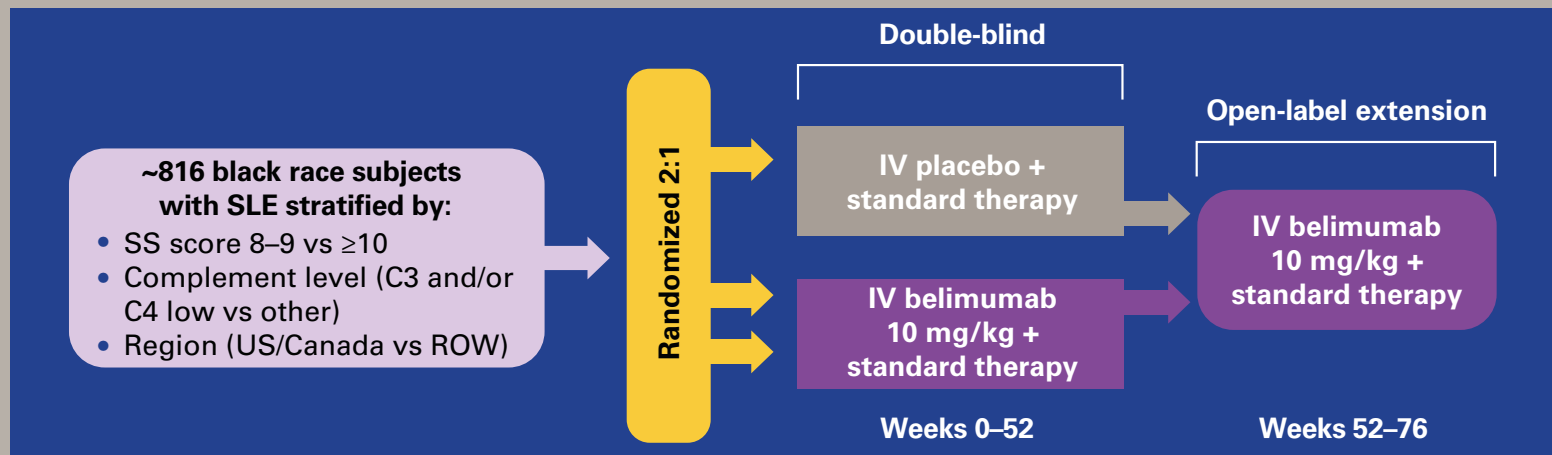


# EMBRACE (Efficacy of Belimumab in Lupus Subjects of Black Race)

A Phase 3/4, Multicenter, Randomized, Double-Blind, Placebo-Controlled, 52-Week Study to Evaluate the Efficacy and Safety of Belimumab in Adult Subjects of Black Race With Systemic Lupus Erythematosus



The only large-scale, Phase 3/4 randomized and controlled intervention trial focused solely on African-American/Black lupus patients

## Study design

- 52-week double-blind trial with a 24-week open-label extension randomized 2 (10 mg/kg IV belimumab + standard therapy): 1 (IV placebo + standard therapy)

## Key inclusion criteria

- Self-identify as black (US Census definition; origins from any black racial groups of Africa), including mixed race
- SELENA SLEDAI  $\geq 8$  at screening
- Unequivocally positive autoantibody test
- Stable SLE medications for 30 days prior to first belimumab infusion
- Subjects will be dosed on Day 0, 14, 28, and then every 28 days through 48 weeks with final evaluation for the double-blind phase at Week 52

## Primary efficacy endpoint

- SLE Responder Index at 52 weeks

## Major secondary efficacy endpoints

- Time to first severe flare
- Percent of subjects whose average prednisone dose has been reduced by  $\geq 25\%$  from baseline to  $\leq 7.5$  mg/day during Weeks 40 through 52 in subjects receiving  $>7.5$  mg/day at baseline

For more information on this trial please go to: <http://www.clinicaltrials.gov/ct2/show/NCT01632241>

For information about participating as a clinical site or referring a potential patient, please call: 1-855-WE-EMBRACE