Belimumab is a human monoclonal antibody that binds to and blocks the biological actions of BAFF, a B-cell activating factor that plays an important role in the pathogenesis of systemic lupus erythematosus (SLE) in an adenosine A2a receptor-independent mechanism.

At Week 52, the geometric mean (95% CI) belimumab trough concentration was 9.0 (5.00, 15.00) μg/mL in the belimumab group versus 1.0 (1.00, 1.00) μg/mL in the placebo group. A logistic regression model was used to estimate the odds of achieving ≥50% improvement in SELENA-SLEDAI score from baseline at Week 52. The results showed that belimumab treatment was associated with a significant improvement in disease activity compared to placebo.

**Objective**

The primary objective of this study was to evaluate the efficacy and safety of intravenous belimumab in pediatric patients with cSLE, aged 5–17 years, who were not responsive to standard-of-care therapy.

**Methods**

Study design and participants

- The study design was a double-blind, placebo-controlled trial (Figure 1).
- Eligible participants were children aged 5–17 years with active cSLE disease according to SELENA-SLEDAI.
- Approximately 200 patients were enrolled across 42 sites in North America and Europe.
- The study consisted of three parts: Part A (treatment), Part B (blinded follow-up), and Part C (safety follow-up).

**Results**

**Patient disposition and baseline characteristics**

- A total of 40 patients were randomized to the placebo (n=20) and belimumab (n=20) groups.
- Baseline demographic and disease characteristics were similar between the two groups (Table 1).

**Pharmacokinetics**

- Observed belimumab concentrations were consistent with those observed in Phase 3 trials in younger patients.
- Younger patients had slightly lower exposures than older patients.

**Efficacy**

- The primary endpoint was the proportion of patients achieving ≥50% improvement in SELENA-SLEDAI score from baseline at Week 52.
- In addition, responder results for the three core SRI4 endpoints were analyzed.
- Patients in the belimumab group showed a greater response compared to placebo (Table 2).

**Safety**

- No new safety concerns were identified.
- The most common adverse events were upper respiratory infections and headache.

**Conclusions**

- At Week 52, compared to placebo, numerically higher proportions of patients receiving belimumab achieved SRI4 and vomitUCG responder status.
- Patients in the belimumab group had a lower risk of experiencing a severe flare compared with placebo.
- Belimumab was well tolerated and no new safety concerns were identified.

**References**


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**Disclosures**

- No conflicts of interest were declared by any of the authors.

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