The Effect of Belimumab on SRI-4 Response in Multiple Subgroups of Patients With Systemic Lupus Erythematosus: Results of a Large Integrate Analysis

Poster No. POS0183

Introduction

- Belimumab is approved for the treatment of active autoantibody- positive systemic lupus erythematosus (SLE).1
- Four Phase 3 studies have consistently demonstrated greater SLE Responder Index (SRI) response rates with belimumab plus standard therapy versus placebo plus standard therapy.2-5
- This robust dataset allows for additional exploration of the onset of efficacy of belimumab and response rates in subgroups of patients with different baseline characteristics.

Objective

To perform a post hoc analysis evaluating the effect of belimumab on SRI-4 response across a large, pooled population and patient subgroups.

Methods

- This is an integrated, post hoc analysis (Belimumab Summary of Lupus Efficacy (Be-SLE) of five Phase 3, double-blind, placebo-controlled belimumab clinical studies: BLISS-52, BLISS-76, BLISS-NEA, BLISS-SC, and EMPOWER (Figure 1).1-5
- Baseline disease characteristics used for patient subgroups were defined according to baseline disease characteristics (Table 2).
- Odds ratios (ORs) and 95% confidence intervals (CIs) were calculated using a logistic regression model with covariates of treatment, study, and baseline SLEDAI-2K score (ORs) were not adjusted for multiple comparisons.
- Analyses were presented were not adjusted for multiplicity.

Results

Baseline characteristics

- In this pooled analysis, 1853 patients received belimumab and 1217 patients received placebo. Patients were stratified into 24 subgroups using subgroup identifiers (Table 1).
- A significantly greater proportion of SRI-4 responders was observed with belimumab versus placebo as early as Week 8, which continued to increase to Week 52 (Figure 2).
- A Week 52, more patients in the belimumab than placebo group had a 4-point reduction in SELENA-SLEDAI score, no worsening in PGA, and no new BILAG-10 organ domain scores (Figure 4).

Overall SRI-4 response

<table>
<thead>
<tr>
<th>Subgroup</th>
<th>Placebo</th>
<th>Belimumab</th>
</tr>
</thead>
<tbody>
<tr>
<td>Responders (%)</td>
<td>0.41</td>
<td>0.50</td>
</tr>
<tr>
<td>Relative risk</td>
<td>1.23 (1.00, 1.51)</td>
<td></td>
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</tbody>
</table>

SRI-4 response by subgroup

- Belimumab response rates were significantly higher with belimumab versus placebo in most subgroups, with the highest response rates observed in patients with SLENA-SLEDAI score ≤10, anti-dsDNA positive and low C3 and/or C4, and low C3 and/or C4 baseline (Figure 4).

Conclusions

- Patients receiving belimumab had an SRI-4 response that occurred as early as Week 8 compared with patients receiving placebo. In addition, compared with placebo, patients who received belimumab had a significantly greater SRI-4 response maintained through Week 52 compared with patients receiving placebo.
- The efficacy of belimumab was consistent across multiple patient subgroups, with higher responses rates observed in patients with SLENA-SLEDAI scores of ≤10, anti-dsDNA positive, and low C3 and/or C4 baseline.
- Significant decreases in SRI-4 responder rates were observed regardless of SLEDAI score, disease duration, glucocorticoid dose (> 7.5 mg per day), and receipt of ICS.
- The results further support the benefit of belimumab treatment of patients with SLE.

Acknowledgments

This analysis of studies BLISS-52 (GSK Study B0111072), BLISS-76 (GSK Study B0111074), BLISS-NEA (GSK Study B0111073), BLISS-SC (GSK Study B0111071), and EMPOWER (GSK Study B0111074) was funded by GSK. Medical writing support was provided by CHA (USA) DMP, in accordance with GSK. Poorna B. Arumugam, MD, has been an employee of GSK. Arumugam B. Poornav, MD, and Rahul H. Arumugam, PhD, have received research support from GSK. All authors report no conflicts of interest. All authors fulfill the criteria for authorship and have read and approved the final manuscript.

References


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