Efficacy of Belimumab Across Multiple Organ Domains in Systemic Lupus Erythematosus: Results of a Large Integrated Analysis

**Background**
- Systemic lupus erythematosus (SLE) affects multiple organs, most commonly those of the musculoskeletal, mucocutaneous, cutaneous, and renal systems.
- Belimumab, an anti-lymphocyte stimulator antibody, has demonstrated efficacy in Phase 3 trials, improving renal outcomes in active nephritis, and reduced organ damage progression.
- Belimumab is approved for the treatment of active SLE andsolid patients with active lupus nephritis.

**Objective**
This pooled analysis evaluated the effects of belimumab on SLE disease activity in different organs.

**Methods**
- This was a pooled analysis of 5 Phase III, randomized, placebo-controlled belimumab clinical trials (BLISS-52, BLISS-76, BLISS-NEA, BLISS-SC, and EMBRACE).

**Results**

**Baseline characteristics**
- The proportion of female patients (94%) and the mean age (37 ± 12 years) were similar between both treatment groups (Figure 2).

**Figure 2:** Patient demographics and baseline characteristics

<table>
<thead>
<tr>
<th>Variable</th>
<th>Belimumab</th>
<th>Placebo</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>37.1 (12.6)</td>
<td>37.2 (12.7)</td>
<td>0.98</td>
</tr>
<tr>
<td>Female (%)</td>
<td>94.2%</td>
<td>93.8%</td>
<td>0.78</td>
</tr>
<tr>
<td>Disease duration (years)</td>
<td>6.5 (3.8)</td>
<td>6.6 (4.0)</td>
<td>0.88</td>
</tr>
</tbody>
</table>

**Changes in organ involvement by SELENA-SLEDAI (Figure 4)**
- Significantly more patients receiving belimumab demonstrated an improvement in musculoskeletal, mucocutaneous, cutaneous, cardiovascular, and renal domains at Week 52 versus placebo.
- Improvements were numerically greater between belimumab and placebo patients by Week 12.
- No significant improvements were observed between patients receiving belimumab versus placebo in any hematologic, orthopedic, neurological, and general domains.

**Figure 3:** Proportion of patients improving by SELENA-SLEDAI in each organ domain by weeks

**Conclusions**
- Belimumab demonstrated significant improvements in the commonly observed mucocutaneous and musculoskeletal organ involvement, as well as in musculoskeletal, cardiovascular, and renal domains. Improvements were observed at Week 52, and were subsequently maintained until Week 52.

**Disclosures**
- JTW has received grant/research support from AbbVie, Bristol Myers Squibb, and GSK, and has worked as a paid consultant for AbbVie, Merck, Alexion, Argenx, and Pfizer.
- BD has received honoraria for lecture, consulting, and having served on advisory boards for Biogen, GSK, Janssen, Mitsubishi, Novartis, Pfizer, Sanofi, and UCB.
- PR has received grant/research support from AbbVie, Genentech, GSK, Hoffmann-La Roche, Janssen, Pfizer, and Sanofi.
- KI has received research support from AbbVie, Bristol Myers Squibb, GSK, Janssen, Novartis, Pfizer, and Sanofi. MM has received grant/research support from Pﬁzer and has been a paid speaker for AbbVie, Bristol Myers Squibb, GSK, Janssen, Novartis, Pfizer, and Sanofi. BB has been a paid speaker for AbbVie, BMS, Biogen, GSK, and UCB.
- The study sponsor has also provided funding to the study site.

**Figure 1:** Study design

**Figure 3:** Proportion of patients responding by BLAIR index in each organ domain by weeks

**Figure 5:** Changes in organ involvement by BELAG index (Figure 5)
- Significantly more patients receiving belimumab versus placebo had improvements in musculoskeletal, mucocutaneous, and vasculitis domains at Week 52.
- An observable difference between belimumab and placebo patients typically occurred before Week 24.
- No significant improvements were observed between patients receiving belimumab versus placebo in any hematologic, orthopedic, neurological, and general domains.

**Figure 6:** Conclusions
- Belimumab demonstrated significant improvements in the commonly observed mucocutaneous and musculoskeletal organ involvement, as well as in musculoskeletal, cardiovascular, and renal domains. Improvements were observed at Week 52, and were subsequently maintained until Week 52.

**The results of this pooled analysis support the efficacy of belimumab across the most common organ manifestations in SLE.**

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**References**
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