Bimekizumab Improves Signs and Symptoms Including Inflammation in Patients with Active Ankylosing Spondylitis: 24-Week Efficacy & Safety from a Phase 3, Multicenter, Randomized, Placebo-Controlled Study

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Bimekizumab (BKZ), a monoclonal IgG1 antibody that selectively inhibits interleukin 17A (IL-17A) and IL-17F in addition to IL-17A, has demonstrated sustained efficacy and was well-tolerated up to 156 weeks in a phase 2 study in patients with AS.1

Background

- BKZ, a monoclonal antibody that selectively inhibits interleukin 22.9%
- Substantial reductions of hs-CRP by Week 2, and sacroiliac joints (SIJ)
- BE MOBILE 2 (NCT03928743) comprised a 16-week double-blind, placebo-controlled study in patients with active ankylosing spondylitis (AS; i.e. radiographic and/or MRI evidence of inflammation).2

Methods

- BE MOBILE 2 (NCT03928743) comprised a 24-week double-blind, PBO-controlled period followed by a 52-week, maintenance period (Figure 1).3
- Primary and secondary efficacy endpoints were assessed at Week 16, and eligible endpoints are also presented in this analysis to Week 24 (randomized set).
- Treatment-emergent adverse events (TEAEs) and serious TEAEs are reported to Week 16 for the treatment group, and at Week 24 for exposure to BKZ (SAF).2

Results

Patients

- Of 323 randomized patients (BKZ: 221; PBO: 102), 321 (99.4%) completed Week 16 and 133 (41.3%) completed treatment up to Week 24.
- Baseline characteristics were comparable between groups (Table 1).

Efficacy

- At Week 16, the primary (ASAS40) and all-ranked secondary endpoints were met, with rapid separation of BKZ from PBO as early as Week 2 (Figures 2–3).
- At Week 16, 24.2% of patients (107/442) met the ASAS20 criteria, with 37.8% (169/442) meeting ASAS40 criteria.

Safety

- No new safety signals were observed.1
- No serious infections were reported.1
- The most common TEAEs in the BKZ and PBO groups were upper respiratory tract infections, nasopharyngitis, and rhinitis.

Conclusions

- Dual inhibition of IL-17A in addition to IL-17F with BKZ in patients with active AS resulted in rapid, clinically relevant improvements of key signs and symptoms of disease and reduction of radiographic and/or MRI evidence of inflammation.
- Objective signs of inflammation, as measured by CRP and MRI, were reduced by Week 24.

References


Table 1: Baseline characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>BKZ (n=221)</th>
<th>PBO (n=102)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean (SD)</td>
<td>46.0 (11.2)</td>
<td>45.6 (11.0)</td>
<td>0.70</td>
</tr>
<tr>
<td>Sex, male, %</td>
<td>81.1</td>
<td>77.5</td>
<td>0.20</td>
</tr>
<tr>
<td>Disease activity score, mean</td>
<td>4.8 (0.7)</td>
<td>4.9 (0.7)</td>
<td>0.10</td>
</tr>
<tr>
<td>EMPA SIJ MRI score, mean</td>
<td>2.0 (1.1)</td>
<td>1.8 (1.0)</td>
<td>0.06</td>
</tr>
<tr>
<td>ASAS20 at Week 16</td>
<td>47.4%</td>
<td>22.2%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>ASAS40 at Week 16</td>
<td>37.8%</td>
<td>24.2%</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

Table 2: Safety table

<table>
<thead>
<tr>
<th>TEAE</th>
<th>BKZ (n=221)</th>
<th>PBO (n=102)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Most frequent</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Upper respiratory tract infections</td>
<td>97 (43.8)</td>
<td>78 (76.5)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Nasopharyngitis</td>
<td>75 (34.0)</td>
<td>47 (45.1)</td>
<td>0.02</td>
</tr>
<tr>
<td>Rhinitis</td>
<td>63 (28.9)</td>
<td>40 (38.8)</td>
<td>0.20</td>
</tr>
<tr>
<td>URI</td>
<td>53 (24.0)</td>
<td>40 (38.8)</td>
<td>0.01</td>
</tr>
<tr>
<td>URI</td>
<td>53 (24.0)</td>
<td>40 (38.8)</td>
<td>0.01</td>
</tr>
</tbody>
</table>

Figure 1: Study design

- Randomization to BKZ or PBO at Week 0: Double-blind, 24 weeks: Phase 3, 16 weeks: Treatment (randomized set); 52 weeks: Maintenance (non-randomized set).

Figure 2: Primary and all-ranked secondary endpoints at Week 16

- ASAS20, ASAS40, ASAS40 in TNFi-naive and TNFi-IR patients, ASAS20, ASAS40 in TNFi-naive patients, ASAS20, ASAS40 in TNFi-IR patients.

Figure 3: ASAS40 Response (NRI)

- ASAS40 response: meeting the ASAS40 criteria at Week 16 in TNFi-naive and TNFi-IR patients.

Figure 4: ASDAS states over time (as observed)

- ASDAS: Ankylosing Spondylitis Disease Activity Score.

Figure 5: Objective measures of inflammation

- CRP: C-reactive protein; MRI: magnetic resonance imaging; NRI: Normalized Response Index.