Efficacy and Safety of Bimekizumab in Patients with Moderate to Severe Plaque Psoriasis: Results from BE READY, a 56-Week Phase 3, Randomized, Double-Blinded, Placebo-Controlled Study with Randomized Withdrawal

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Objectives

To compare the efficacy and safety of bimekizumab with placebo over 56 weeks in patients with plaque psoriasis, and evaluate the effect of randomized treatment withdrawal, compared with continued treatment, in week 16 responders.

Background

Bimekizumab is a monoclonal IgG2 antibody that has been rationally designed to selectively inhibit IL-17A in addition to IL-17F. Both of these interleukins are implicated in the immunopathogenesis of plaque psoriasis (PsO).1 Bimekizumab led to substantial clinical improvements in patients with moderate to severe PsO in the phase 2, ABLE study (NCT02525005, NCT02525122), with no unexpected safety findings.2

Methods

Adult patients with moderate to severe PsO were enrolled in the pivotal phase 3 BE READY study (NCT03402701), which incorporated a 6-week randomized, double-blind, placebo-controlled period followed by a 40-week randomized withdrawal period (Figure 1).

- The co-primary endpoints were PASI 90 and IGA 0/1 at Week 16.
- Other endpoints included PASI 90 and IGA 0/1 at Week 12, PASI 75 and IGA 0/1 at Week 4.
- All endpoints were based on the change from baseline in PASI and IGA, respectively.

Results

BE READY met both of its co-primary endpoints at Week 16, with significantly higher PASI 90 and IGA 0/1 responder rates in placebo treatment, in Week 16 responders.

Conclusions

High levels of skin clearance were observed with bimekizumab at one dose and at Week 16, compared with placebo. Clinical response were durable through 56 weeks, regardless of bimekizumab dosing schedule. Bimekizumab was well-tolerated and the safety profile was consistent with previous studies.

Synopsis

Objective

To compare the efficacy and safety of bimekizumab with placebo in patients with moderate to severe plaque psoriasis.

Methods

Patients were randomized 4:1 to receive bimekizumab every 4 weeks or placebo for an initial 16 weeks of treatment.

Efficacy

- Co-primary endpoints of PASI 90 and IGA 0/1 at Week 16 were achieved by 90.8% and 95.4% of bimekizumab-treated patients, respectively.
- Treatment effect was maintained at Week 56 (primary endpoint), with 84.0% and 82.1% of patients achieving PASI 90 and IGA 0/1, respectively.

Safety

- Overall, bimekizumab was well-tolerated; discontinuation due to TEAEs was low, and there were no deaths in the study.

Table 1: Baseline characteristics

<table>
<thead>
<tr>
<th>Group</th>
<th>Age (years), mean ± SD</th>
<th>Sex (M:F)</th>
<th>Body mass index, mean ± SD</th>
<th>Disease severity</th>
<th>Active disease area (cm²), mean ± SD</th>
<th>Prior biologic exposure</th>
<th>Number of prior biologic agents</th>
<th>Prior biologic exposure within 6 months</th>
<th>Prior biologic exposure within 12 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Placebo</td>
<td>43.5 ± 13.1</td>
<td>1:1</td>
<td>25.9 ± 4.1</td>
<td>27.9%</td>
<td>3.8 ± 1.9</td>
<td>30%</td>
<td>1.0 ± 0.0</td>
<td>0.0 ± 0.0</td>
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<tr>
<td>Bimekizumab</td>
<td>44.5 ± 12.9</td>
<td>1:1</td>
<td>25.6 ± 4.2</td>
<td>27.9%</td>
<td>3.8 ± 1.9</td>
<td>30%</td>
<td>1.0 ± 0.0</td>
<td>0.0 ± 0.0</td>
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Table 2: Safety

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<thead>
<tr>
<th>Group</th>
<th>Treatment emergent adverse events (TEAEs) in &gt;5% of patients</th>
<th>Discontinuation due to TEAEs</th>
<th>Serious TEAEs</th>
<th>Adjudicated serious infection (SIB)</th>
<th>Adjudicated severe infection (SIB)</th>
<th>MACE</th>
<th>Non-fatal myocardial infarction</th>
<th>Inflammatory arthritis</th>
<th>Necrotizing fasciitis</th>
<th>Serious skin infection</th>
<th>Adjudicated serious sepsis (SSS)</th>
<th>Adjudicated severe sepsis (SSS)</th>
<th>Severe bacterial infection</th>
<th>Serious bacterial infection</th>
<th>Severe viral infection</th>
<th>Non-fatal stroke</th>
<th>Non-fatal MI</th>
<th>Malignant neoplasm</th>
<th>Myocardial infarction (MI)</th>
<th>MACE 0 0 0 0 0</th>
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<tbody>
<tr>
<td>Placebo</td>
<td>2 (2.3) 6 (1.7) 4 (3.8) 3 (3.0) 5 (4.7)</td>
<td>0.0 ± 0.0</td>
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<td>Bimekizumab 320 mg Q8W</td>
<td>2 (2.3) 6 (1.7) 4 (3.8) 3 (3.0) 5 (4.7)</td>
<td>0.0 ± 0.0</td>
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<td>0.0 ± 0.0</td>
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<tr>
<td>Bimekizumab 320 mg Q4W</td>
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<td>0.0 ± 0.0</td>
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References: