Efficacy and Safety of 108 Weeks Bimekizumab Treatment in Patients with Psoriatic Arthritis: Interim Results from a Phase 2 Open-Label Extension Study

Iain B. McInnes,1 Joseph F. Merola,2 Philip J. Mease,3 Laura C. Coates,4 Paulatsya Joshi,5 Jason Coarse,6 Barbara Ink,7 Christopher T. Ritchlin8

RheumNow Live 2021 | Forth Worth, TX | March 20–21, 2021

Objective
To report 2-year interim results from a phase 2 dose-ranging study and open-label extension (OLE) of bimekizumab (BKZ) in patients with psoriatic arthritis (PsA).

Background
PsA is a chronic, systemic immune-mediated inflammatory disease that occurs in as many as 20% of patients with psoriasis.1 A meta-analysis of data for patients with PsA, only 35% achieved minimal disease activity (MDA) with currently available therapies.2 BKZ, a monoclonal antibody that selectively neutralizes both interleukin-17A and interleukin-17F, has shown clinical improvements in joint and skin outcomes over 48 weeks in patients with active PsA.3 Interim efficacy and safety outcomes of BKZ treatment were assessed over 120 weeks (Figure 1).4

Methods
Study Design and Patients
• BKZ was administered in a phase 2b dose-ranging study (NCT03347110) and ongoing OLE (NCT03347110).5
• Eligible patients were aged ≥18 years with diagnosis of active PsA symptoms for ≥6 months duration, and before entering the OLE completed 48 weeks of BKZ treatment in the dose-ranging period (n = 206).6

Study Assessments
• Efficacy measurements from baseline are reported to allow subsequent analysis (108 weeks of therapy).

Study Results
• Baseline characteristics were comparable across treatment arms (Table 1).7

Conclusions
BKZ shows long-term efficacy for joint and skin manifestations of PsA with ≤50% patients achieving high thresholds of disease control (ACR70, BSA ≤3%, NRI) after 108 weeks’ treatment. BKZ was well-tolerated, reflecting previous studies.8

Table 1
Demographics and baseline characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Placebo (n=32)</th>
<th>BKZ 16 mg (n=32)</th>
<th>BKZ 160 mg LD (n=32)</th>
<th>BKZ 160 mg Q4W (n=32)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years, mean (SD)</td>
<td>53.8 (14.3)</td>
<td>53.8 (14.3)</td>
<td>53.8 (14.3)</td>
<td>53.8 (14.3)</td>
</tr>
<tr>
<td>Gender, female (%)</td>
<td>62.5</td>
<td>62.5</td>
<td>62.5</td>
<td>62.5</td>
</tr>
<tr>
<td>BMI, kg/m², mean (SD)</td>
<td>28.1 (4.9)</td>
<td>28.1 (4.9)</td>
<td>28.1 (4.9)</td>
<td>28.1 (4.9)</td>
</tr>
<tr>
<td>Psoriasis duration, years</td>
<td>9.1 (6.4)</td>
<td>9.1 (6.4)</td>
<td>9.1 (6.4)</td>
<td>9.1 (6.4)</td>
</tr>
<tr>
<td>Psoriasis BSA &lt;3%, n (%)</td>
<td>33 (102)</td>
<td>33 (102)</td>
<td>33 (102)</td>
<td>33 (102)</td>
</tr>
<tr>
<td>Psoriasis BSA &lt;10%, n (%)</td>
<td>17 (53)</td>
<td>17 (53)</td>
<td>17 (53)</td>
<td>17 (53)</td>
</tr>
</tbody>
</table>

Table 2
Safety at Week 108

<table>
<thead>
<tr>
<th>TEAEs</th>
<th>Placebo (n=32)</th>
<th>BKZ 16 mg (n=32)</th>
<th>BKZ 160 mg LD (n=32)</th>
<th>BKZ 160 mg Q4W (n=32)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any TEAEs</td>
<td>196 (60.6)</td>
<td>196 (60.6)</td>
<td>196 (60.6)</td>
<td>196 (60.6)</td>
</tr>
<tr>
<td>Serious TEAEs</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Serious TEAEs leading to death</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Any AE leading to discontinuation</td>
<td>22 (68.8)</td>
<td>22 (68.8)</td>
<td>22 (68.8)</td>
<td>22 (68.8)</td>
</tr>
<tr>
<td>Serious AE</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Serious AE leading to death</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

References

Author Contributions:
Iain B. McInnes,1 Joseph F. Merola,2 Philip J. Mease,3 Laura C. Coates,4 Paulatsya Joshi,5 Jason Coarse,6 Barbara Ink,7 Christopher T. Ritchlin8

© 2021 Lippincott Williams & Wilkins. Unauthorized reproduction of this article is prohibited.