Bimekizumab provides rapid and sustained improvements in QoL that correlate with clinical outcomes in patients with moderate-to-severe plaque psoriasis: 60-week results from a randomized, double-blinded, Phase 2b extension study

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Synopsis

- Bimekizumab, a monoclonal IgG1 antibody that potently and selectively binds, neutralizes both IL-17A and IL-17F, provided rapid, substantial and sustainable clinical improvements in patients with moderate-to-severe plaque psoriasis in the 12-week BE ABLE 1 (NCT0295006) and the 48-week BE ABLE 2 extension (NCT03010527) studies, with no unexpected safety findings.
- The disease burden of psoriasis extends beyond physical manifestations and can have a profound negative impact on quality of life (QoL).
- A substantial proportion of patients with moderate to severe psoriasis experience impaired QoL, including negative effects on emotional well-being and ability to perform everyday activities.
- Approximately 50% of patients with moderate-to-severe psoriasis have a Dermatology Life Quality Index (DLQI) score >0, indicating a very large effect on patient QoL.

Objective

- In this post-hoc QoL analysis, we evaluated the effect of bimekizumab on health-related QoL (HRQoL) in patients with moderate-to-severe psoriasis and correlation with clinical response over the 60-week treatment period.

Methods

- In BE ABLE 1, patients were randomized to placebo or bimekizumab 64 mg, 160 mg, 160 mg with a 320 mg loading dose (LD), 320 mg or 480 mg.
- In BE ABLE 1 responders (≥90% reduction in Psoriasis Area and Severity Index [PASI90]) at Week 12 randomized to placebo or bimekizumab every 4 weeks (Q4W) 64 mg, 160 mg, 160 mg or 320 mg (320 mg LD), continued the same treatment to Week 60 (Figure 1).
- Patients completed the DLQI questionnaire throughout the treatment period.
- A DLQI score of 0/1 indicated no impact of psoriasis on disease-specific HRQoL.
- To evaluate a possible correlation between clinical response and HRQoL, patients achieving DLQI of 0/1 were grouped by absolute PASI (0, 0–2, 2–5, 5) at Weeks 12 and 60.
- Non-responder imputation (NRI) and observed data are presented.

Results

- Patient demographics and baseline disease characteristics were balanced across treatment groups (Table 1).

Table 1. Demographics and baseline disease characteristics

<table>
<thead>
<tr>
<th>Treatment</th>
<th>N</th>
<th>Age, year, mean (SD)</th>
<th>Sex, male, n (%)</th>
<th>Weight, kg, mean (SD)</th>
<th>Race, Caucasian, n (%)</th>
<th>Prior systemic therapy, n (%)</th>
<th>Prior non-biologic systemic therapy</th>
<th>Prior biologic therapy</th>
<th>Prior anti-TNF therapy, n (%)</th>
<th>Disease duration, years, median (range)</th>
<th>PASI, median (IQR)</th>
<th>IGA score, n (%)</th>
<th>DLQI 0/1 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bimekizumab 64 mg</td>
<td>15</td>
<td>44.5 (14.7)</td>
<td>9 (60.0)</td>
<td>85.2 (16.8)</td>
<td>13 (86.7)</td>
<td>6 (40.0)</td>
<td>6 (40.0)</td>
<td>2 (13.3)</td>
<td>4 (26.7)</td>
<td>13.9 (6.0–34.4)</td>
<td>17.1 (4.5)</td>
<td>17 (3.3)</td>
<td>117 (78.0)</td>
</tr>
<tr>
<td>Bimekizumab 160 mg</td>
<td>111</td>
<td>44.5 (12.8)</td>
<td>71 (64.0)</td>
<td>88.4 (19.1)</td>
<td>13 (9.1)</td>
<td>6 (54.5)</td>
<td>6 (36.3)</td>
<td>2 (17.3)</td>
<td>6 (54.5)</td>
<td>15.0 (5.0–58.7)</td>
<td>15.0 (5.0–58.7)</td>
<td>13 (11.7)</td>
<td>121 (88.0)</td>
</tr>
<tr>
<td>Bimekizumab 320 mg</td>
<td>91</td>
<td>43.6 (14.7)</td>
<td>60 (66.0)</td>
<td>90.3 (23.5)</td>
<td>13 (14.3)</td>
<td>6 (66.7)</td>
<td>7 (77.8)</td>
<td>6 (66.7)</td>
<td>2 (22.2)</td>
<td>15.0 (5.0–58.7)</td>
<td>15.0 (5.0–58.7)</td>
<td>12 (13.3)</td>
<td>112 (90.0)</td>
</tr>
<tr>
<td>All patients</td>
<td>217</td>
<td>44.1 (13.7)</td>
<td>119 (54.8)</td>
<td>89.0 (20.9)</td>
<td>13 (9.1)</td>
<td>6 (28.0)</td>
<td>7 (33.3)</td>
<td>6 (28.0)</td>
<td>2 (9.3)</td>
<td>15.0 (5.0–58.7)</td>
<td>15.0 (5.0–58.7)</td>
<td>13 (6.0)</td>
<td>117 (54.3)</td>
</tr>
</tbody>
</table>

- Substantial proportions of patients achieved PASI90 at Week 12, which was maintained to Week 60 (Figure 2).
- In BE ABLE 1 PASI90 responders, bimekizumab provided rapid improvements in QoL (achieving DLQI of 0 or 1) at Week 8 (Figure 3).
  - The majority achieved DLQI 0 or 1 by Week 12.
  - DLQI responses were maintained to Week 60 (75–93%).
- In PASI90 non-responders, rapid improvements in QoL were observed and maintained in patients re-assigned from placebo to bimekizumab 160 mg, with 84% of patients achieving DLQI of 0/1 at Week 12.
- Across the other bimekizumab dose groups, DLQI of 0/1 was achieved by 50–71% of non-responders at Week 60.
- In the pooled bimekizumab group, patients with an absolute PASI of 0 were most frequently associated with higher QoL, with 79% and 95% achieving DLQI of 0/1 at Weeks 12 and 60, respectively (Figure 4).

Conclusions

- Bimekizumab treatment resulted in rapid, substantial and sustained improvements in QoL in patients with moderate-to-severe psoriasis.
  - The majority of BE ABLE 1 responders achieved DLQI of 0 or 1 by Week 12 and maintained responses up to Week 60.
  - Improvements in QoL was associated with clinical response.
- Patients with an absolute PASI of 0 were most frequently associated with high QoL, with 79% and 95% achieving DLQI of 0 or 1 at Weeks 12 and 60, respectively.

References

4. Myers Squibb, Celgene, Dow Pharma, Eli Lilly, Galderma, Janssen, Merck (MSD), Merck
5. Takeda, UCB Pharma. CEM Griffiths reports advisory board honoraria from AbbVie, Almir
6. CEM Griffiths reports advisory board honoraria from AbbVie, Almir
7. Myers Squibb, Celgene, Dow Pharma, Eli Lilly, Galderma, Janssen, Merck (MSD), Merck
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Figure 1. BE ABLE 1 and BE ABLE 2 study design

Figure 2. Phase 2 BE ABLE study: Substantial proportions of patients achieved PASI90 at Week 12, which was maintained to Week 60 (NRI)

Figure 3. DLQI scores in PAS90 responders: Bimekizumab provided rapid improvements in QoL that were sustained to Week 60 (NRI)

Figure 4. Percentage of patients achieving DLQI of 0 or 1 by absolute PASI at Weeks 12 and 60 (pooled: observed)

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