Bimekizumab in patients with moderate to severe plaque psoriasis by bodyweight: Pooled results from phase 3 trials

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Objective
To evaluate the effect of bodyweight on response to bimekizumab (BKZ) when dosed 320 mg every 4 weeks (Q4W) or every 8 weeks (Q8W) during maintenance treatment, following an initial 16 weeks of treatment with 320 mg Q4W.

Introduction
- Increased bodyweight may affect response to biologic treatments in patients with moderate to severe plaque psoriasis.
- Here, we report the efficacy and safety of BKZ dosing regimens over 48 weeks using data from four phase 3b trials in patients with moderate to severe plaque psoriasis categorized by bodyweight at baseline.

Materials and Methods
- Data were pooled from three BKZ in plaque psoriasis phase 3b trials: BE SURE (NCT03432747), BE VIVID (NCT03370130) and BE RADIANT (NCT03356844). For safety analyses, and efficacy analyses over the initial 16-week period, the phase 3 randomized withdrawal trial BE READY (NCT03410992) was also included.
- Analyses included patients who were randomized to BKZ 320 mg Q4W for 16 weeks. At Week 16, patients could either continue on BKZ 320 mg Q4W (Q4W/Q4W) or switch to BKZ 320 mg Q8W (Q4W/Q8W) for maintenance treatment to Week 48.
- Patients were categorized by baseline bodyweight: bodyweight <120 kg and ≥120 kg were stratified as a potential weight threshold above which efficacy may differ between dosing regimens based on PK-PD modeling.
- Missing efficacy data were imputed as non-response (NRI).
- Safety analyses were conducted during the maintenance period (Weeks 16–48) by maintenance dosing regimen (Q4W versus Q8W).
- Treatment-emergent adverse events (TEAEs) were coded using MedDRA v10.2.

Results
- Baseline characteristics for patients categorized by bodyweight are presented in Table 1.
- In 1,246 patients included in the efficacy analyses to Week 16, had bodyweight <120 kg: 520 kg.
- At Week 16, PASI 100 and IGA 0 response for all patients randomized to BKZ 320 mg Q4W were higher in patients <120 kg p<0.001 (Table 2).
- In 517 (517) patients included in the maintenance efficacy analyses, had bodyweight ≥120 kg: 250 kg.
- For patients <120 kg, Week 16 PASI 100, PASI 50, PASI 90 and IGA 0 response rates were markedly higher in patients <120 kg vs ≥120 kg (Table 2).
- For patients ≥120 kg, greater increase in the proportions of patients achieving PASI 100 and IGA 0 were observed in those receiving BKZ 320 mg Q4W vs BKZ 320 mg Q8W between Week 16 and Week 48.

Conclusions
- At Week 16, a greater proportion of patients <120 kg achieved PASI 100 vs those ≥120 kg. At Week 48, higher PASI 100 responses were observed in patients ≥120 kg receiving BKZ 320 mg Q4W vs Q8W, supporting use of Q4W maintenance dosing in patients ≥120 kg who do not achieve complete skin clearance at Week 16.

Table 1 Baseline characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Bodyweight &lt;120 kg (N=1,246)</th>
<th>Bodyweight ≥120 kg (N=43)</th>
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<tbody>
<tr>
<td>Mean age (years)</td>
<td>47.6 ± 11.9</td>
<td>45.7 ± 11.9</td>
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<tr>
<td>Mean bodyweight (kg)</td>
<td>69.2 ± 19.7</td>
<td>100.0 ± 10.8</td>
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<tr>
<td>Mean DLQI total score</td>
<td>15.2 ± 6.0</td>
<td>21.9 ± 7.9</td>
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<tr>
<td>Mean Disease severity score</td>
<td>3.0 ± 0.8</td>
<td>3.0 ± 0.7</td>
</tr>
<tr>
<td>Mean Disease duration (years)</td>
<td>12.9 ± 11.8</td>
<td>11.2 ± 10.0</td>
</tr>
<tr>
<td>Mean BSA (%)</td>
<td>7.4 ± 9.0</td>
<td>12.6 ± 10.0</td>
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Table 2 Efficacy outcomes by baseline bodyweight category

<table>
<thead>
<tr>
<th>Week</th>
<th>PASI 100 (%)</th>
<th>IGA 0 (%)</th>
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<tbody>
<tr>
<td>Week 16</td>
<td>51.4</td>
<td>25.0</td>
</tr>
<tr>
<td>Week 48</td>
<td>77.1</td>
<td>58.6</td>
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</table>

Figure 1 Cumulative EARs for TEAEs over three years in the phase 2 and 3 trials

Figure 2 PASI 100 responses through Weeks 16–48 by baseline bodyweight category (NRI)

Figure 3 PASI 100 responses through Weeks 16–48 in Week 16 PASI 100 non-responder patients ≥120 kg (NRI)

References:
3. BSA: body surface area.
4. IL: interleukin.
5. TNF: tumor necrosis factor.
6. MACE: major adverse cardiovascular events.

Previously presented at G2C 2021

Appendix: Additional information and tables are available in the full manuscript.