Bimekizumab 3-year safety and tolerability in moderate to severe plaque psoriasis: Long-term pooled analysis from five phase 3/3b trials

**Synopsis**
- Since psoriasis is a chronic disease, assessment of long-term safety of treatments is essential to inform decision-making for clinicians while managing risks for patients.
- Data pooled over 2 years have previously shown that bimekizumab (BKZ), a humanized monoclonal IgG1 antibody that selectively inhibits interleukin (IL)-17F in addition to IL-23, is well tolerated in the treatment of moderate to severe plaque psoriasis.

**Objective**
To evaluate 3-year safety data for BKZ in patients with moderate to severe plaque psoriasis from five phase 3/3b clinical trials.

**Methods**
- Data were pooled from the BE SURE, BE VIVID, and BE READY phase 3 trials, their open-label extension (OLE) BE BRIGHT, and the BE RADIANT phase 3b trial.
- Included patients received BKZ 320 mg every 4 weeks (Q4W) or every 8 weeks (Q8W).
- Treatment-emergent adverse events (TEAEs) were coded using MedDRA v3.0 and are reported over 3 years using exposure-adjusted incidence rates (EAIRs) per 100 patient-years (PY) for all patients who received at least 1 BKZ dose (BKZ Total).
- Data are also separately reported for Years 1 (Week 0–52), 2 (Week 52–104), and 3 (Week 104–156) of BKZ exposure.

**Results**
- BKZ demonstrated a favorable safety profile over 3 years of treatment, with no new safety signals identified; rates of TEAEs did not increase with longer duration of BKZ exposure.

**Conclusions**
Over 3 years of treatment, BKZ demonstrated a favorable safety profile, with no new safety signals observed. EAIRs of TEAEs did not increase with longer exposure to BKZ.

**Table 1**

<table>
<thead>
<tr>
<th>Year</th>
<th>TEAEs of interest</th>
<th>EAIR/100 PY (95% CI)</th>
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<tbody>
<tr>
<td>Year 1</td>
<td>Any TEAE</td>
<td>227.7 (94.8, 397.0)</td>
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<tr>
<td>Year 2</td>
<td>Serious TEAEs</td>
<td>0.5 (0.1, 2.3)</td>
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<tr>
<td>Year 3</td>
<td>TEAEs leading to discontinuation</td>
<td>0.2 (0.0, 1.0)</td>
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**Figure 1**
Included trials

**Figure 2**
Overall TEAEs, serious TEAEs, and TEAEs leading to discontinuation by year

**Figure 3**
TEAEs of interest by year

**Figure 4**
Fungal infections by year

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