Bimekizumab maintenance of response through three years in patients with moderate to severe plaque psoriasis who responded at Week 16: Results from the BE BRIGHT open-label extension trial

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Objective

To evaluate maintenance of response over three years among patients with moderate to severe plaque psoriasis who had an initial efficacy response after 16 weeks’ bimekizumab (BKZ) treatment and entered the BE BRIGHT open-label extension (OLE) trial, including those who received continuous BKZ every 8 weeks (QBW) dosing in the maintenance period and the OLE.

Methods

• All patients who completed one of the BE SURE (NCT03412747), BE VIVID (NCT03370133), and BE READY (NCT03340992) phase 3 studies were eligible to enroll in BE BRIGHT and were assigned to treatment as shown in Figure 1.

• Here, maintenance of Psoriasis Area and Severity Index (PASI) ≤2 among Week 16 PASI ≤2 responders, maintenance of body surface area (BSA) ≤1% among Week 16 BSA ≤1% responders, and maintenance of PASI 100 (100% improvement from baseline in PASI) and Dermatology Life Quality Index (DLQI) ≤0 among Week 16 PASI 100 responders are reported through Year 3 (OLE Week 96).

• Data are presented for all BKZ-treated patients (BKZ Total) who entered the OLE, and in the subset of patients who received BKZ 320 mg every 4 weeks (Q4W) through Week 16 followed by continuous BKZ 320 mg QBW (Q4W/QBW).

• Data are reported using modified non-responder imputation (mNRI) and, as observed case (OC).

• For mNRI, patients who discontinued due to lack of efficacy were considered non-responders at subsequent timepoints; multiple imputation was used for all other missing data.

Results

• 989 patients were randomised to BKZ Q4W at baseline in the feeder studies; 694 Week 16 PASI ≤2 responders; 597 BSA ≤1% responders, and 503 PASI 100 responders entered the OLE. Baseline characteristics are presented in Table 1.

• 94.2%, 90.8%, and 82.0% of BKZ-treated patients who completed one of three phase 3 feeder studies who entered the OLE, and in the subset of patients who entered the OLE and who achieved an initial response at Week 16.

Conclusions

Among Week 16 responders, efficacy and health-related quality of life response rates were maintained through to three years' BKZ treatment, including among those who received BKZ 320 mg Q4W/QBW.

Table 1

Baseline characteristics

<table>
<thead>
<tr>
<th>Week 16 PASI ≤2 Response</th>
<th>Week 16 BSA ≤1% Response</th>
<th>Week 16 PASI 100 Response</th>
</tr>
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<tbody>
<tr>
<td>NRI: N=989</td>
<td>OC: n/N (%)</td>
<td>NRI: N=989</td>
</tr>
<tr>
<td>PASI 0/1</td>
<td>n (%)</td>
<td>503/530 (95.2)</td>
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Table 2

Summary of efficacy outcomes (mNRI and OC)

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The ORN, PASI, PASI 0/1, and DLQI have been included here, due to the lack of common visits at which DLQI was recorded.

Table 3

Comparison of Week 16 PASI ≤2 responders and Week 16 BSA ≤1% responders

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Figure 1

Study design (included patients)

- Week 16 PASI ≤2 responders (N=989)
- Week 16 BSA ≤1% responders (N=597)
- Week 16 PASI 100 responders (N=503)

Figure 2

Maintenance of efficacy in patients with a Week 16 response who entered the OLE (mNRI)

- Maintenance of PASI ≤2 (NRI and OC)
- Maintenance of BSA ≤1% (NRI and OC)
- Maintenance of PASI 100 (NRI and OC)

Figure 3

DLQI 0/1 in Week 16 PASI 100 responders

- DLQI 0/1 in Week 16 PASI 100 responders who entered the OLE (mNRI and OC)
- DLQI 0/1 in Week 16 PASI 100 responders who entered the OLE (mNRI and OC)
- DLQI 0/1 in Week 16 PASI 100 responders who entered the OLE (mNRI and OC)

Figure 4

Maintenance of PASI 100 and DLQI 0/1 in Week 16 responders who entered the OLE (mNRI and OC)

- Maintenance of PASI 100 and DLQI 0/1 in Week 16 responders who entered the OLE (mNRI and OC)
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