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

Objectives

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), including those who received continuous BKZ every 8 weeks (Q8W) during the maintenance period and the OLE.

Introduction

- Loss of response to biologics over time is commonly observed in plaque psoriasis. It is therefore important to understand long-term efficacy of new therapies.
- BE BRIGHT (NCT03598790) is an ongoing, multicentre, OLE study assessing long-term safety, tolerability, and efficacy of BKZ in patients with moderate to severe plaque psoriasis who completed one of three phase 3 head studies.
- Data reported previously indicated that response to BKZ treatment is maintained over two years.

Materials and Methods

- All patients who completed one of the BE SURE (NCT03424247), BE VIVID (NCT03517013), and BE READY (NCT03401992) phase 3 studies were eligible to enrol 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 100 responders, maintenance of body surface area (BSA) ≤1% among Week 16 BSA ≤1% responders, and maintenance of PASI 100 (%) improvement from baseline in PASI and Dermatology Life Quality Index (DLQI) of ≥70% among Week 16 PASI 100 responders are reported through Year 3 (OLE Week 96).

Results

- 989 patients were randomised to BKZ Q4W at baseline in the phase 3 studies. 894 Week 16 PASI 100 responders, 517 BSA ≤1% responders, and 513 Week 16 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 achieved PASI 100, BSA ≤1%, and PASI 100 respectively, at Week 16 maintained their response at Year 3 (OLE Week 96) (Figure 2, Table 2).

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/Q8W.

Table 1 Baseline characteristics

<table>
<thead>
<tr>
<th>Year 0</th>
<th>Year 1</th>
<th>Year 2</th>
<th>Year 3</th>
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<tbody>
<tr>
<td>PASI 90% responders</td>
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<tr>
<td>86.0%</td>
<td>84.4%</td>
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<td>BSA ≤1% responders</td>
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<td>BSA ≤1% responders</td>
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<tr>
<td>87.8%</td>
<td>94.6%</td>
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<td>Generalized Pruritus</td>
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Table 2 Summary of efficacy outcomes (NRI and OC)

- PASI 100: 100% improvement from baseline in PASI.
- BSA ≤1%: BSA ≤1% of body surface area.
- DLQI: Dermatology Quality of Life Index.

Prevalence of PASI 100 responders and BSA ≤1% responders in the open-label extension over years.

Figure 1 Study design (included patients)

Figure 2 Maintenance of efficacy in patients with a Week 16 response who entered the OLE (mNRI)