Bimekizumab efficacy and safety through two years in patients with moderate psoriasis: Analysis of pooled data from five phase 3/3b clinical trials

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Objectives
To evaluate efficacy and safety of bimekizumab (BKZ) in patients with moderate plaque psoriasis over two years using data from five phase 3/3b trials.

Introduction
- BKZ has demonstrated high levels of efficacy in patients with moderate to severe plaque psoriasis.1-4
- Here, we consider BKZ efficacy and safety in patients with moderate psoriasis.

Materials and Methods
- Moderate psoriasis was defined as body surface area (BSA) ≥10%–<30%, Plaque Severity Index (PSI) ≥12, and Investigators Global Assessment (IGA) ≥3 as baseline.
- Data were pooled from BE SURE, BE VIVID, BE READY, the first year of the BE BRIGHT open-label extension (OLE) trial, and BE ADVANTAGE (48-week double-blind period and ongoing OLE).1-4
- Patients received BKZ 320 mg every 4 weeks (Q4W) or every 8 weeks (Q8W) maintenance dosing (Figure 1).
- Efficacy outcomes are reported through two years for all BKZ treated patients.

Results
- At baseline, 301 patients with moderate psoriasis were randomised to BKZ, 269 continued to the OLEs.
- Baseline characteristics for patients with moderate psoriasis were similar to the BKZ-randomised study population with moderate to severe plaque psoriasis (except for criteria used to distinguish between moderate and moderate to severe psoriasis, Table 1).
- High levels of PASI ≥2, PASI 100, and BSA ≥1% responses were observed in BKZ-treated patients at Week 16. Similarly high response levels were reported after two years of treatment (OLE Week 48) among patients who entered the OLEs (Figure 2).
- TEAEs occurred in 90.7% of patients and were lower with BKZ Q8W vs Q4W. Serious TEAEs and TEAEs leading to discontinuation were low (Table 2).
- The most common TEAEs were nasopharyngitis, oral candidiasis, and upper respiratory tract infections (Table 2, Table 3).
- Oral candidiasis TEAEs were lower with BKZ Q8W vs Q4W.
- The majority of oral candidiasis TEAEs were mild/moderate (98.2%). Two patients with oral candidiasis discontinued BKZ.
- Similar to the overall study population,4 TEAEs of safety topics of interest were low in moderate psoriasis patients (Table 2).
- Occurrence of TEAEs and serious TEAEs generally decreased or remained comparable over time (Table 3).

Conclusions
Results demonstrate that continuously high levels of skin clearance were seen with BKZ over two years in patients with moderate psoriasis.

BKZ was well-tolerated over two years in patients with moderate psoriasis.