Maintenance of bimekizumab efficacy through 2 years in patients with moderate to severe plaque psoriasis: Pooled results from five phase 3/3b trials

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Objectives

To evaluate the long-term maintenance of Psoriasis Area and Severity Index (PASI) ≤90 and PASI=0 responses with bimekizumab (BKZ), using the largest available two-year data pool, in patients with moderate to severe plaque psoriasis.

Introduction

• Long-term treatment efficacy is an important consideration in chronic diseases such as psoriasis.
• BKZ has demonstrated high levels of skin clearance for the treatment of moderate to severe plaque psoriasis in phase 3/3b clinical trials.1,2

Methods

• Data were pooled from the BE SURE, BE VIVID and BE READY phase 3 trials, the BE BRIGHT open-label extension (OLE), and BE RADIANT 48-week double-blinded phase 3b trial and ongoing OLE.3
• Patients included in these analyses were randomized at baseline to BKZ 320 mg every four weeks (Q4W) to Week 16, followed by BKZ Q4W or every eight weeks (Q8W) maintenance dosing for the remainder of the double-blind period of the trials (Figure 1).
• Upon OLE entry, patients received BKZ 320 mg Q4W or Q8W based on PASI (Psoriasis Area and Severity Index) response at the end of the feeder studies (Figure 1).
• We report the proportion of patients achieving PASI ≤2 and PASI=0 through two years of treatment (OLE Week 48) among BKZ-randomized Week 16 PASI ≤2 and PASI=0 responders, who remained on the same BKZ maintenance dose upon entering the relevant OLE (Q4W/Q4W or Q4W/Q4W/Q4W/Q4W).
• Missing data were imputed using non-responder imputation (NRI), modified NRI (mNRI), and observed case (OC).
• For mNRI, patients who discontinued treatment due to lack of efficacy were considered non-responders; multiple imputation was used for all other missing data.

Results

• Baseline characteristics of Week 16 PASI ≤2 and PASI=0 responders who entered BE BRIGHT or the BE RADIANT OLE are reported in Table 1.
• At Week 16, 87.1% of the 1,362 patients randomized to BKZ 320 mg Q4W at baseline of the feeder studies achieved PASI ≤2 (mNRI; Figure 2A) and 83.8% achieved PASI=0 (mNRI; Figure 2B).
• Among Week 16 PASI ≤2 responders who entered the OLEs, 98.3% of the 349 patients on Q4W/Q4W/Q4W and 95.1% of the 449 patients on Q4W/Q4W/Q4W maintained PASI ≤2 through two years (OLE Week 48; mNRI; Figure 2A).
• Of the Week 16 PASI=0 responders who entered the OLEs, 83.8% of the 267 patients on Q4W/Q4W/Q4W and 85.2% of the 316 patients on Q4W/Q4W/Q4W maintained PASI=0 through two years (OLE Week 48; mNRI; Figure 2B).

Conclusions

A high proportion of patients who achieved complete or near-complete skin clearance at Week 16 maintained their response through two years, regardless of BKZ maintenance dosing regimen (Q4W/Q4W/Q4W or Q4W/Q4W/Q4W).