Bimekizumab efficacy and safety through three years in patients with moderate to severe plaque psoriasis: Long-term results from the BE SURE randomised controlled trial and the BE BRIGHT open-label extension

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Objective

To evaluate the long-term efficacy and safety of bimekizumab (BKZ) over three years in patients with moderate to severe plaque psoriasis who enrolled in the BE SURE phase 3 trial and entered the BE BRIGHT open-label extension (OLE).

Introduction

- In BE SURE (NCT03412747), BKZ demonstrated superior efficacy compared with adalimumab (ADA) over 24 weeks. After patients switched from ADA to BKZ at Week 24, responses improved and were maintained over two years, with no unexpected safety findings.
- Here, we consider long-term efficacy and safety over three years.

Materials and Methods

- Treatment in BE SURE was as shown in Figure 1.
- Upon completion of BE SURE, patients could enrol in the BE BRIGHT OLE (NCT03568790; Figure 1).
- Dose adjustments to BKZ 320 mg every 4 weeks (Q4W) or every 8 weeks (Q8W) could occur at Week 56 and Week 80 (OLE Week 24) based on achievement of ≥90% improvement from baseline in Psoriasis Area and Severity Index (PASI 90). All patients received BKZ Q8W from Week 104 (OLE Week 48; or next visit).
- Efficacy outcomes are reported for the intention-to-treat (ITT) population through Week 152 by initial randomisation group at BE SURE baseline.
- Data are reported using modified non-responder imputation (mNNRI), NRI, and as the observed case (OC).
- For mNNRI, patients who discontinued treatment due to lack of efficacy were considered non-responders at subsequent timepoints, multiple imputation was used for all other missing data.
- Safety data are reported for Weeks 104–152 (data cut-off 23 Oct 2021), and include treatment-emergent adverse events (TEAEs) reported using exposure-adjusted incidence rates (EAIRs). Two-year safety data have been reported previously (Weeks 0–104).
- Overview of adverse events and the most common TEAEs are reported by both initial randomisation group regardless of BKZ OLE dosing regimen, and for all patients pooled (BKZ Total).
- BKZ Total only was used for safety topics of interest.

Results

- In BE SURE, 478 patients were randomised 1:1:1 to: BKZ Q4W/Q4W (N=158), BKZ Q4W/Q8W (N=161), and ADA/BKZ Q4W (N=159) (Figure 1).
- Baseline demographics have been reported previously and were almost identical across treatment arms.
- BKZ-randomised patients maintained high levels of PASI 90 and PASI 100 responses to three years of treatment (Week 152/OLE Week 96; Figure 2).
- Among ADA-randomised patients, the rapid increases seen in PASI 90 and PASI 100 responses after the Week 24 ADA to BKZ switch were durable to Week 152, reaching similar levels to BKZ-randomised patients (Figure 2).
- These trends were also reflected in DLQI (Q1) responses over three years (Figure 2).
- The most common TEAEs across BKZ-treated patients were coronary infection, oral candidiasis, and nasopharyngitis (Table 2). Rates of safety topics of interest were low (Table 3).
- Two coronary infections were reported as serious; only one was confirmed by testing.

Conclusions

Clinical and health-related quality of life responses observed during the first two years of treatment were sustained to three years of treatment, regardless of BKZ maintenance dose frequency prior to the third year.

Additionally, responses were sustained in the third year, regardless of all patients switching to BKZ every 8 weeks.

Increases in responses after the ADA to BKZ switch were also sustained to Week 152.

BKZ was well-tolerated over three years, with no unexpected safety findings.