Bimekizumab safety in patients with moderate to severe plaque psoriasis: Analysis of pooled data from up to three years of treatment in phase 2 and 3 clinical trials

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Objective

To report long-term safety data, pooled to include three years of treatment, in patients with moderate to severe plaque psoriasis treated with bimekizumab (BKZ) across four phase 2 and four phase 3 clinical trials.

Introduction

- BKZ is a monoclonal immunoglobulin G1 antibody which selectively inhibits interleukin (IL)-17A in addition to IL-17A and is used in the treatment of psoriasis.
- Baseline demographics were similar between BKZ dose groups.
- Here, the first three-year safety data for BKZ in patients with psoriasis are presented.
- Data pooled over two years have indicated that BKZ is generally well-tolerated.
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Materials and Methods

- Long-term safety data were evaluated for all patients who received ≥1 dose of BKZ in four phase 3 trials (BE SURE, BE VIVID, BE READY, and their ongoing open-label extension BE BRIGHT). Data cut-off: 23 Oct 2021) and four phase 2 trials (BE ABL, BE ALE, BE ALL, P50106, and P50108).
- Safety data were also evaluated separately for patients receiving BKZ dose 320 mg every 4 weeks (Q4W) or every 8 weeks (Q8W). Q8W dosing was only used in maintenance treatment in phase 3 trials, however, most patients were receiving BKZ Q8W by Year 3.
- Treatment-emergent adverse events (TEAEs) were coded using MedDRA v10.0. Data are presented cumulatively as exposure-adjusted incidence rates (EAIRs), defined as the incidence of new cases per 100 patient-years (PY).

Results

- Baseline demographics were similar between BKZ dose groups (Table 1).
- Safety data observed over three years of BKZ treatment were consistent with those observed over two years.1,2 EAIRs did not increase with longer BKZ exposure, and were generally lower in Q8W vs Q4W-treated patients (Figure 1, Table 2).
- The three most common TEAEs in the phase 2/3 trials with BKZ were nasopharyngitis, oral candidiasis, and upper respiratory tract infection, consistent with previous reports (Table 2).3
- Eighteen deaths occurred; all were deemed unrelated to BKZ except one (relationship unknown) at the time of the data cut-off.
- One serious adverse event occurred during any treatment period (Table 2).4
- The rates of inflammatory bowel disease, adjudicated major adverse cardiac events, malignancies, adjudicated suicidal ideation and behaviour, and neutropenia remained low, and were comparable to two-year data (Table 2).5
- There were no cases of active tuberculosis.
- Rates of oral candidiasis decreased with longer duration of bimekizumab exposure (Figure 1C, Table 2). No serious oral candidiasis events occurred; the vast majority were mild or moderate (99.4%).
- Over three years of BKZ treatment, 79.9% of patients experienced no oral candidiasis events. Of those who did experience such events, most had either one (9.8%) or two (5.1%) occurrences.

Conclusions

BKZ was well-tolerated over three years of treatment; no safety signals were identified. EAIRs of TEAEs did not increase compared with data from two years of treatment.

References