

Bimekizumab Remission and High Disease Control Over 4 years in Patients with Psoriasis Achieving Complete Skin Clearance at Week 16: Results from Four Phase 3 Trials

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Objective

To assess whether bimekizumab (BKZ)-treated patients who achieve complete skin clearance after 16 weeks maintain remission of psoriasis or high disease control over 4 years.

Introduction

- With the emergence of newer biologics, achieving and maintaining completely clear skin in the long term is now an achievable goal for patients living with psoriasis.¹ Therefore, new concepts surrounding remission in psoriasis are increasingly being explored.²
- Given the loss of disease control often seen over time with biologics,³ it is important to evaluate whether high efficacy levels with biologics such as BKZ are continuously maintained in the long term.
- Here, we report the proportions of patients continuously maintaining high efficacy levels at every visit over 4 years, allowing for up to 4 visits with lower, yet still favorable, responses (referred to here using exploratory definitions of remission and high disease control).

Methods

- Data were pooled from the BE SURE, BE VIVID, and BE READY phase 3 trials, and their open-label extension (OLE) BE BRIGHT (Figure 1).⁴⁻⁷
- Included patients received BKZ 320 mg every 4 weeks (Q4W) to Week 16, then BKZ Q4W or every 8 weeks (Q8W) into the OLE; all patients received BKZ Q8W from Week 100/104 (OLE Week 48) or the next scheduled visit.
- Data are reported for patients regardless of dosing regimen (BKZ Total), and for the subset who received BKZ Q4W to Week 16 then Q8W continuously into the OLE (Q4W/Q8W; the approved dosing regimen for the majority of patients with psoriasis).⁸
- Proportions of patients achieving remission or high disease control are explored among patients who achieved a Psoriasis Area and Severity Index (PASI) score of 0 (PASI 0) at Week 16. We assess maintenance of high efficacy levels at every subsequent study visit from Week 16–Year 4 (Week 196/200; 29/30 further visits [study-dependent]), and allowing for up to 1/2/3/4 visits (representing up to 1 visit per year on average) with lower, yet still favorable, responses.
- The following outcomes are reported among patients who achieved PASI 0 at Week 16:
 - Percentages who maintained PASI 0 at every study visit, and allowing for up to 1/2/3/4 visits with PASI >0–≤2 (remission);
 - Percentages who maintained PASI ≤2 or Body Surface Area (BSA) ≤1% at every study visit, and allowing for up to 1/2/3/4 visits with PASI >2–≤5 or BSA >1%–≤3%, respectively (high disease control; thresholds were chosen based on target outcomes defined in treatment guidelines).^{9,10}
- Patients who discontinued treatment due to lack of efficacy or treatment-related adverse events were considered non-responders at subsequent timepoints; last observation carried forward (LOCF) was used for other missing data (modified non-responder imputation [mNRI]-LOCF).

Results

- Overall, 503 BKZ-randomized patients who achieved PASI 0 at Week 16 received continuous BKZ and entered the OLE (Q4W/Q8W: N=147).
- Among these Week 16 PASI 0 responders:
 - PASI 0 was maintained by 48.9% at every visit from Week 16–Year 4; 59.8%/65.0%/68.6%/72.0% maintained PASI 0 at every visit except up to 1/2/3/4 visits with PASI >0–≤2 (Figure 2A);
 - PASI ≤2 was maintained by 81.3% at every visit to Year 4; 87.9%/90.1%/91.5%/91.8% maintained PASI ≤2 at every visit except up to 1/2/3/4 visits with PASI >2–≤5 (Figure 2B);
 - BSA ≤1% was maintained by 69.4% at every visit to Year 4; 77.5%/80.3%/81.1%/81.7% maintained BSA ≤1% at every visit except up to 1/2/3/4 visits with BSA >1%–≤3% (Figure 2C);
 - Similar results were observed in the BKZ Q4W/Q8W group (Figure 2A–C).
- Baseline characteristics were generally similar across the overall groups and the groups who maintained remission (Table 1).

Conclusions

High percentages of patients who achieved PASI 0 (complete skin clearance) at Week 16 with bimekizumab maintained remission or high disease control through 4 years.

Summary

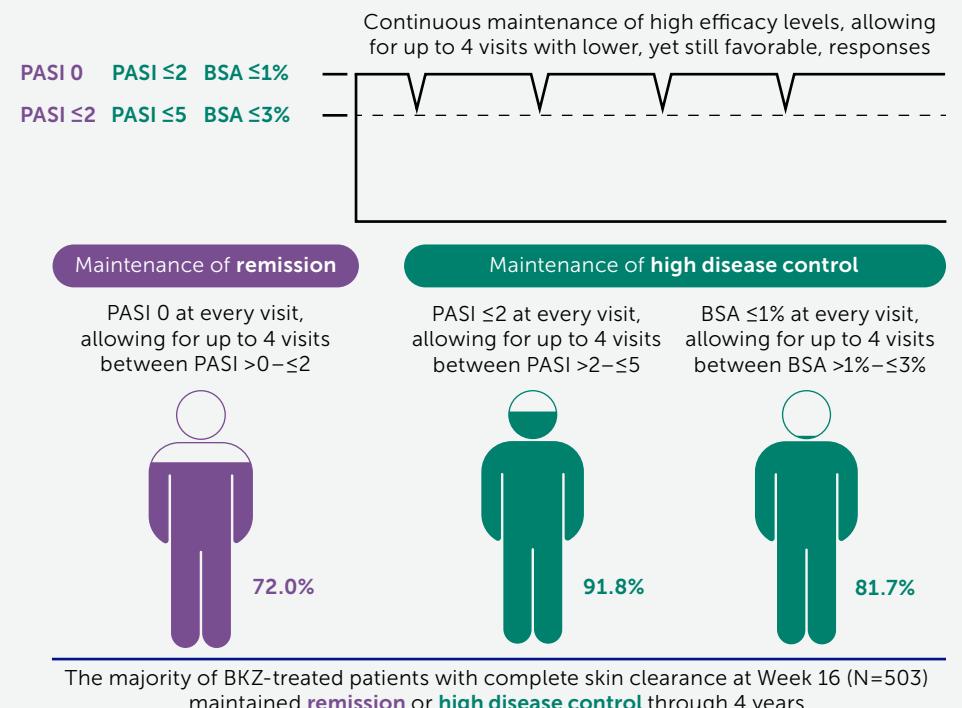


Figure 1 Study design

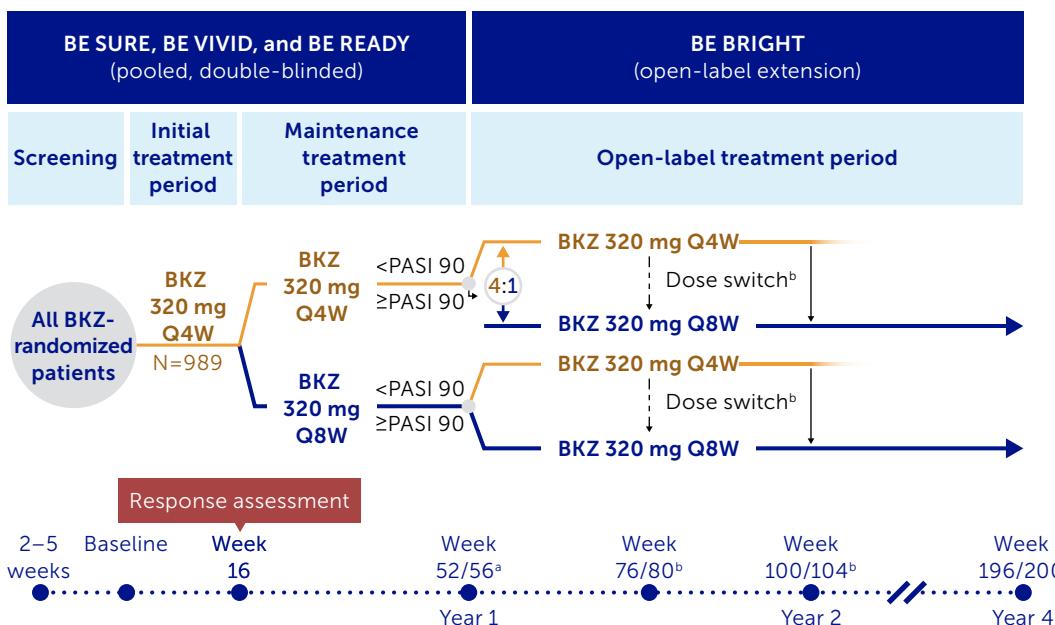
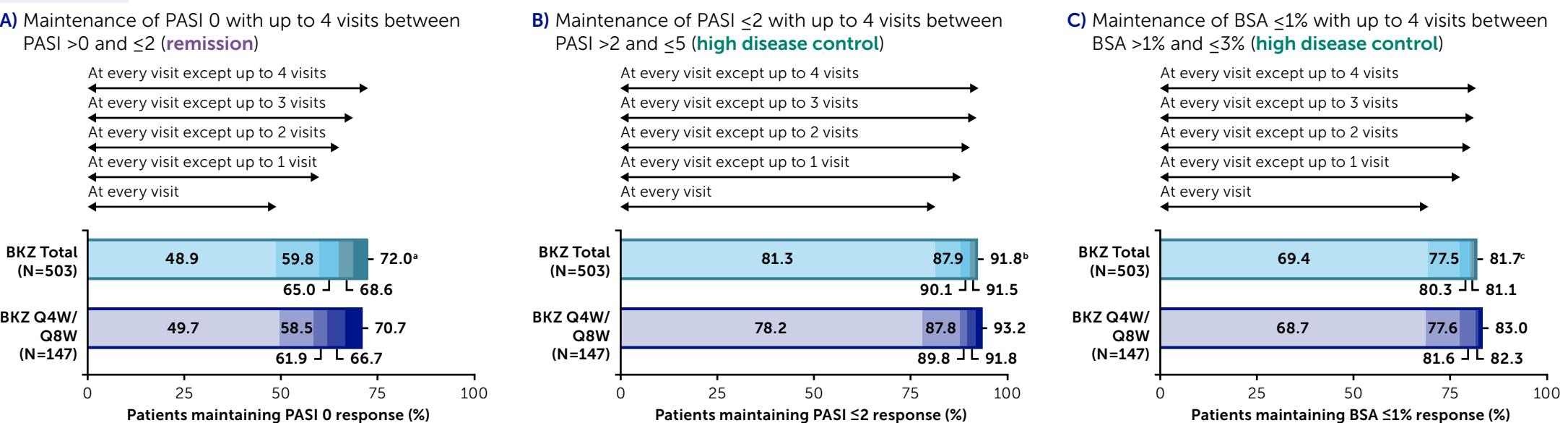


Figure 2 Week 16 PASI 0 responders who maintained remission/high disease control through 4 years (mNRI-LOCF)



Response levels were assessed at every study visit from Week 16 to Year 4 (29/30 further visits [study-dependent]). Continuous maintenance of PASI 0/PASI ≤2/BSA ≤1% was defined as having PASI 0/PASI ≤2/BSA ≤1% at every visit up to and including Week 196/200, and allowing for up to 1/2/3/4 visits where patients did not maintain PASI 0/PASI ≤2/BSA ≤1% but retained PASI 0/PASI ≤2/BSA ≤3%, respectively. To be included in the analysis, patients had to have an observed Week 16 PASI 0 response. One patient in the BE READY trial did not have a Week 16 PASI assessment; however, this patient had a PASI 0 response at Week 12 and Week 20 of BE READY, which was maintained through Week 56, and so they were included in the analysis. [a] Among 17 patients who lost PASI 0 at 4 visits but retained PASI ≤2, 1 patient lost their response at 4 consecutive visits; [b] Among 2 patients who lost PASI ≤2 at 4 visits but retained PASI ≤5, neither lost their response at 4 consecutive visits; [c] Among 3 patients who lost BSA ≤1% at 4 visits but retained BSA ≤3%, 1 patient lost their response at 4 consecutive visits.

BKZ: bimekizumab; BSA: body surface area; DLQI: Dermatology Life Quality Index; IGA: Investigator's Global Assessment; IL: interleukin; LOCF: last observation carried forward; mNRI-LOCF: modified non-responder imputation-last observation carried forward; OLE: open-label extension; PASI: Psoriasis Area and Severity Index; Q1: first quartile; Q3: third quartile; Q4W: every 4 weeks; Q8W: every 8 weeks; SD: standard deviation; TNF: tumor necrosis factor.

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