Bimekizumab continuous maintenance of response at every visit through two years in patients with moderate to severe plaque psoriasis: Post-hoc results from five phase 3/3b trials

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Objective

To assess the continual maintenance of ≥90% improvement from baseline in Psoriasis Area and Severity Index (PASI 90) responses with bimekizumab (BKZ) at every single visit from Week 16 through two years of treatment in patients with moderate to severe plaque psoriasis.

Background

- In patients who have already achieved skin clearance, surveys have shown that long-lasting maintenance of response is a key treatment goal.[1,2]
- Considering this goal, and the loss of clinical response often seen over time,[3] it is important to evaluate long-term treatment efficacy.
- BKZ, a monoclonal IgG1 antibody that selectively inhibits IL-17F in addition to IL-17A,[4] has demonstrated rapid and superior efficacy in the treatment of patients with moderate to severe plaque psoriasis in head-to-head studies versus ustekinumab, adalimumab and secukinumab, with established long-term durability of response.[5–9]

Methods

- Two-year data were pooled from the 52-week BE VIVID and 56-week BE READY and BE SURE phase 3 trials, 48 weeks of their ongoing open-label extension (OLE), BE BRIGHT, as well as the BE RADIANT phase 3b trial (48-week double-blinded period and 48 weeks of the ongoing OLE; **Figure 1**).[5–9]
- Included patients were randomised to receive BKZ 320 mg every 4 weeks (Q4W) to Week 16, then either BKZ Q4W or Q8W until OLE entry (Week 48/52/56; Year 1), at which point, patients received BKZ Q4W or Q8W based on PASI response and prior maintenance dose (**Figure 1**).
- Continuous maintenance of PASI 90 response at every single visit through OLE Week 48 (2 years) in Week 16 PASI 90 responders is reported.
- Data are reported using modified non-responder imputation (mNRI); patients who discontinued treatment due to lack of efficacy or treatment-related adverse events were considered non-responders at subsequent timepoints; multiple imputation was used for all other missing data.
- Week 16 PASI 90 responder rate is reported for context (NRI).

Results

- At Week 16, 86.9% (1,184/1,362) BKZ-randomised patients achieved PASI 90 (NRI); 995 entered the OLEs and are included in these analyses.
  - Baseline characteristics of these patients are shown in **Table 1**.
- Of the Week 16 PASI 90 responders who entered the OLE, 93.7% also achieved PASI 90 at 2 years; 90.6% continuously maintained PASI 90 at every single visit through 1 year (Week 48) and 81.9% at every single visit through 2 years (**Figure 2**; mNRI).
  - 6.8% only lost PASI 90 at 1 visit, 3.0% only lost PASI 90 at 2 visits, and 8.3% lost PASI 90 at >2 visits.
- The flow of PASI responses among Week 16 PASI 90 responders showing maintenance, loss or regain of response between study visits is shown in **Figure 3**.

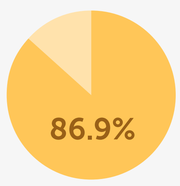
Conclusions

Over 2 years of BKZ treatment, a large proportion of Week 16 PASI 90 responders continuously maintained disease control. Of those who did lose PASI 90 response, the majority lost response at only one or two visits.

Summary

We report the proportions of patients who **continuously maintained** their PASI 90 response from Week 16 through 2 years

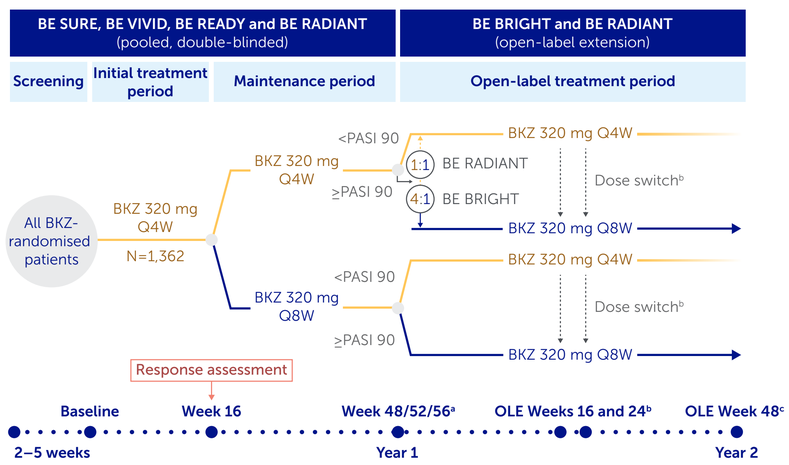
Week 16 PASI 90 response → Response at every study visit → 2 years



86.9% (1,184/1,362) of BKZ-randomised patients achieved **PASI 90 at Week 16** (NRI)

81.9% of **BKZ Week 16 PASI 90 responders** never lost response at any study visit through 2 years (mNRI)

Figure 1 Study design



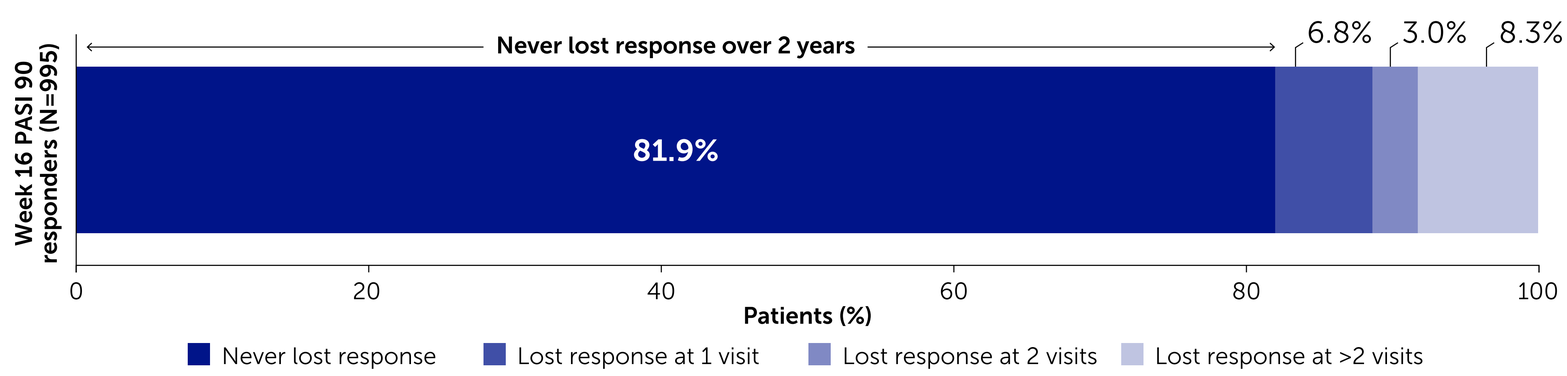
[a]Patients receiving BKZ 320 mg Q4W who achieved ≥PASI 90 at the end of the feeder studies were randomised 1:1 in BE RADIANT and 4:1 in BE BRIGHT to BKZ 320 mg Q4W or Q8W; patients receiving BKZ 320 mg Q8W who achieved ≥PASI 90 at the end of the feeder studies remained on Q8W dosing; 995 patients achieved ≥PASI 90 at the end of the feeder studies and entered the OLEs; [b]In BE RADIANT, at OLE Week 16 or the next scheduled clinic visit, patients switched to BKZ Q8W after the implementation of a protocol amendment; in BE BRIGHT, at OLE Week 24, patients achieving ≥PASI 90 could switch to Q8W at the investigator's discretion; [c]OLE Week 48 (the end of Year 2) corresponds to BE RADIANT Week 96, BE VIVID/BE BRIGHT Week 100, and BE READY/BE BRIGHT and BE SURE/BE BRIGHT Week 104.

Table 1 Baseline characteristics

	BKZ Total[a] Week 16 PASI 90 Responders (N=995)
Age (years), mean ± SD	45.0 ± 13.5
Male, n (%)	695 (69.8)
White, n (%)	872 (87.6)
Weight (kg), mean ± SD	89.1 ± 20.8
Duration of psoriasis (years), mean ± SD	18.2 ± 12.6
PASI, mean ± SD	21.2 ± 7.7
BSA (%), mean ± SD	26.9 ± 16.0
IGA, n (%)	
3: moderate	652 (65.5)
4: severe	341 (34.3)
DLQI total, mean ± SD	10.7 ± 6.4
Any prior systemic therapy, n (%)	772 (77.6)
Prior biologic therapy, n (%)	383 (38.5)

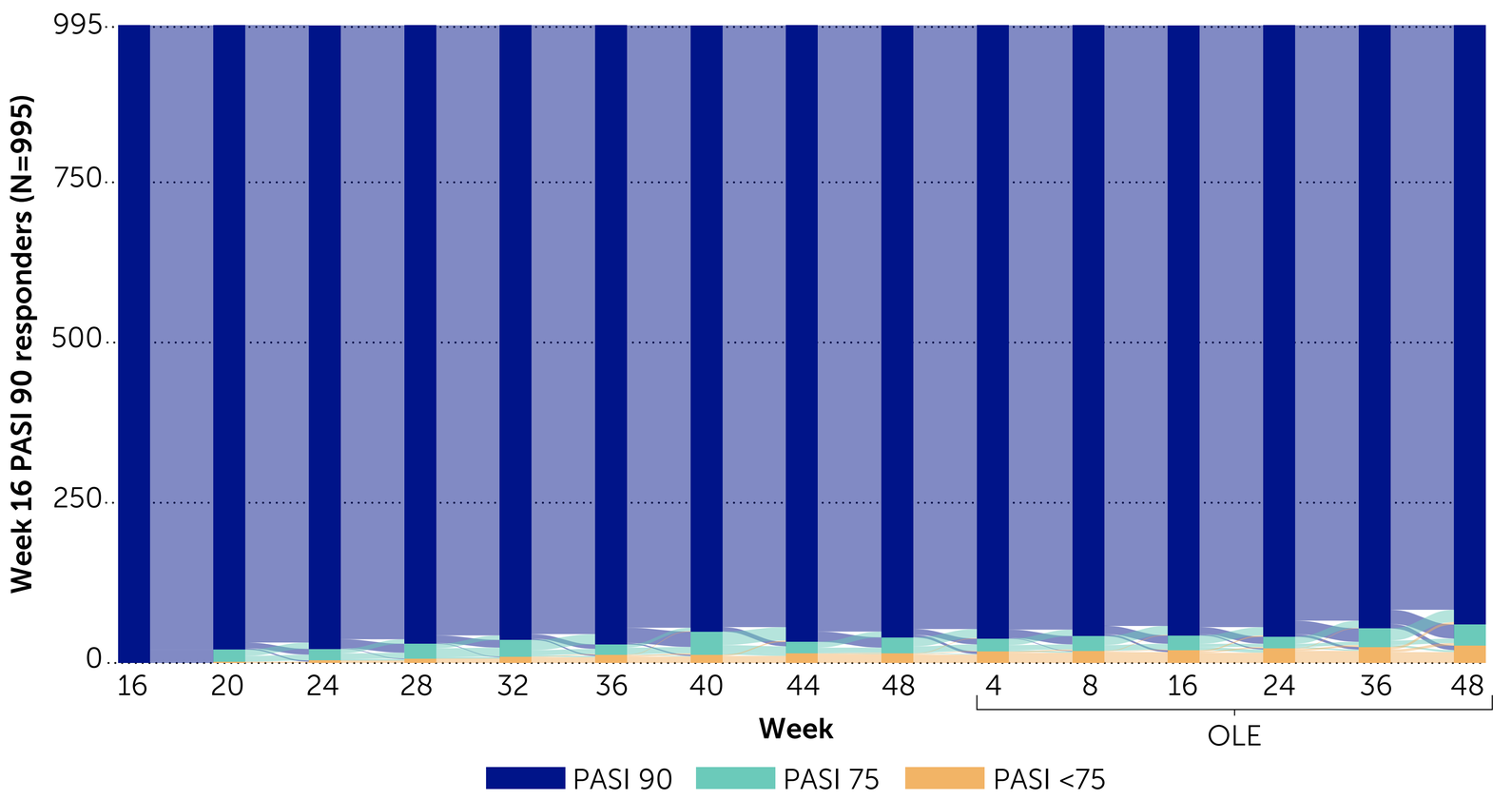
[a]Data were pooled for all patients who achieved a PASI 90 response at Week 16 and entered the relevant OLE (BKZ Total).

Figure 2 Week 16 PASI 90 responders who either never lost response or lost response at 1 visit, 2 visits or >2 visits through 2 Years (mNRI)



Out of 1,184 BKZ-randomised patients who achieved PASI 90 at Week 16, 995 entered the OLE and are included in these analyses. Of those that had an observed loss of PASI 90 (N=435), 81.0% only lost PASI 90 response at 1 or 2 visits over 2 years (mNRI).

Figure 3 Flow of PASI responses among Week 16 PASI 90 responders showing maintenance, loss or regain of response between study visits (mNRI)



Bar heights are proportional to the number of patients achieving/maintaining PASI 90, PASI 75 or PASI <75 at each visit through OLE Week 48 (2 years). Flows represent the number of patients transitioning to a different PASI response category between visits (colour of transition aligns with previous response category).

BKZ: bimekizumab; **BSA:** body surface area; **DLQI:** Dermatology Life Quality Index; **IGA:** Investigator's Global Assessment; **mNRI:** modified non-responder imputation; **NRI:** non-responder imputation; **OC:** observed case; **OLE:** open-label extension; **PASI:** Psoriasis Area and Severity Index; **PASI 75/90/100:** ≥75%/≥90%/100% improvement from baseline in PASI; **Q4W:** every 4 weeks; **Q8W:** every 8 weeks; **SD:** standard deviation.

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