Bimekizumab Efficacy Across Subgroups of Patients With Moderate to Severe Plaque Psoriasis: Pooled Analysis From up to 3 Years of Treatment in 5 Phase 3/3b Clinical Trials

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Objective

To evaluate efficacy outcomes in patients with moderate to severe plaque psoriasis treated with bimekizumab (BKZ), using the largest pool of phase 3/3b data over 3 years

To assess efficacy outcomes across subgroups of age, weight, and baseline disease characteristics in patients with moderate to severe plaque psoriasis

Background

- Patient characteristics may impact psoriasis treatment response.[1]
- BKZ is a monoclonal IgG1 antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A.[2]
- Here, we report efficacy outcomes across patients with moderate to severe plaque psoriasis receiving BKZ through 3 years.

Methods

- Data were pooled from BE SURE, BE VIVID, BE READY, the first 96 weeks of their open-label extension (OLE) BE BRIGHT, and BE RADIANT (48-week double-blinded period, plus 96-week OLE; **Figure 1**).[3–7]
- Results from patients randomized to BKZ 320 mg every 4 weeks (Q4W) at baseline who continued to receive BKZ throughout the maintenance treatment period and into the OLE, regardless of dosing regimen, were analyzed (BKZ Total). The subset of patients who received BKZ Q4W until Week 16, then every 8 weeks (Q8W) thereafter (initial/maintenance/OLE), was also analyzed (BKZ Q4W/Q8W).
- Proportions of patients achieving ≥90/100% improvement from baseline in Psoriasis Area and Severity Index (PASI 90/100) at Year 3 (OLE Week 96) were calculated for subgroups based on the following characteristics:
  - Baseline age
  - Baseline weight
  - Psoriasis disease duration
  - Baseline disease severity
  - Baseline Investigator's Global Assessment (IGA) score
  - Prior biologic exposure
  - Prior anti-tumor necrosis factor (TNF) exposure
  - Prior anti-IL-17 exposure
  - Prior anti-IL-23 exposure (excluding anti-IL-12/23 therapies)
- Achievement of PASI 90 and PASI 100 at Year 3, respectively, was reported using modified non-responder imputation (mNRI). Patients discontinuing 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. Patients who entered the BE READY escape arm were considered as non-responders from the date of escape until the end of BE READY, after which they were considered in the same way as all other non-escape patients during the BE BRIGHT OLE.[5]

Results

- Of 1,362 patients randomized to Q4W at baseline, 1,107 continued to receive BKZ throughout the maintenance treatment period and into the OLE, irrespective of dosing regimen (BKZ Total); 374 patients received BKZ Q4W/Q8W. Baseline characteristics for all patients are presented in **Table 1**.
- PASI 90/100 responses were consistently high across subgroups (**Figures 2** and **3**).
- Patients with a weight of ≤100 kg achieved higher responses than patients with a weight >100 kg (**Figures 2** and **3**).

Conclusions

High and durable levels of complete and near-complete skin clearance were achieved through 3 years of bimekizumab treatment, regardless of baseline demographics, disease characteristics, or prior exposure to biologic therapies.

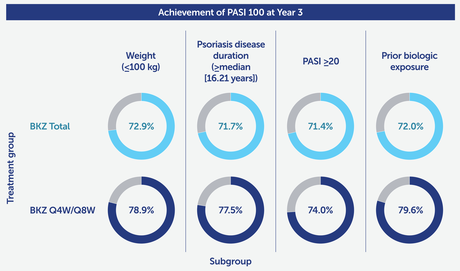
These results support bimekizumab as a treatment suitable for a wide variety of patients with moderate to severe plaque psoriasis.

Weight was the subgroup most associated with skin clearance rate, with patients ≤100 kg more likely to achieve PASI 90 and PASI 100 than patients >100 kg.[a]

[a]For some patients with a body weight ≥120 kg (who did not achieve complete skin clearance at Week 16), BKZ 320 mg Q4W after Week 16 may further improve treatment response.[4]

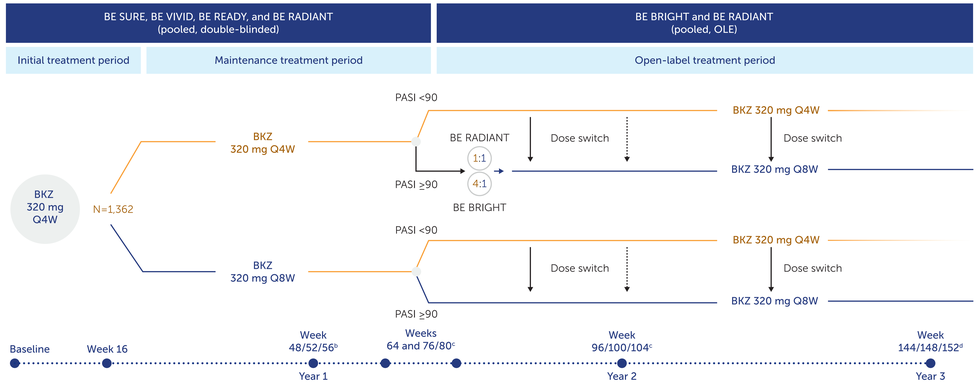
Summary

In a pooled analysis of 5 phase 3/3b clinical trials, efficacy outcomes were assessed in BKZ-treated patients with moderate to severe plaque psoriasis across various subgroups



Treatment with BKZ resulted in high, durable levels of skin clearance, irrespective of baseline demographics, disease characteristics, or prior exposure to biologic therapies, with weight as the subgroup most associated with skin clearance rate

Figure 1 Study design overview

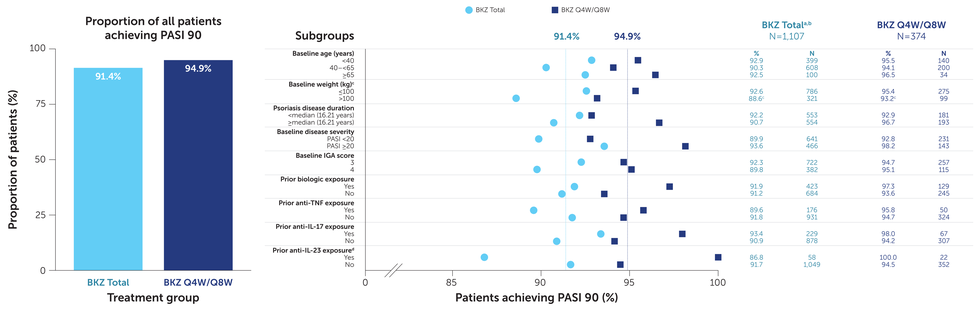


[a]Only BKZ-randomized patients are included in this study design; BKZ-randomized patients who were rerandomized to placebo at Week 16 in BE READY (n=105) were not included in these analyses. [b]Different week numbers are presented due to different feeder study lengths; Week 48/52/56 refers to OLE Week 0 and corresponds to BE RADIANT/BE VIVID/BE SURE and BE READY, respectively. Patients receiving BKZ 320 mg Q4W who achieved PASI 90 at the end of the feeder studies were randomized 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. [c]In BE RADIANT, at Week 64 or the next scheduled clinic visit, all patients switched to BKZ Q8W via protocol amendment; in BE BRIGHT at Week 76/80, patients achieving PAS 90 could switch to Q8W at the investigator's discretion. All patients were reassigned to BKZ Q8W at Week 100/104 (OLE Week 48) or the next scheduled visit via protocol amendment. [d]For the Week 144/148/152 timepoint: Week 144 corresponds to BE RADIANT OLE Week 96; Week 148 corresponds to BE VIVID/BE BRIGHT OLE Week 96; and Week 152 corresponds to BE SURE/BE BRIGHT and BE READY/BE BRIGHT OLE Week 96.

Table 1 Baseline characteristics

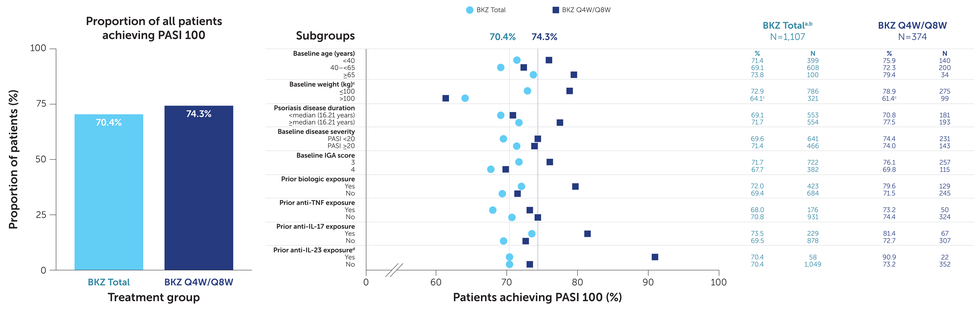
	BKZ Total N=1,107	BKZ Q4W/Q8W N=374
Age (years), mean ± SD	45.5 ± 13.7	45.0 ± 14.1
Male, n (%)	777 (70.2)	266 (71.1)
White, n (%)	968 (87.4)	354 (94.7)
Weight (kg), mean ± SD	89.8 ± 21.2	89.2 ± 20.8
Psoriasis disease duration (years), mean ± SD	18.5 ± 12.8	18.7 ± 12.4
PASI score, mean ± SD	20.9 ± 7.6	20.4 ± 7.4
BSA (%), mean ± SD	26.5 ± 15.7	24.5 ± 13.5
IGA score, n (%)		
3: Moderate	722 (65.2)	257 (68.7)
4: Severe	382 (34.5)	115 (30.7)
DLQI total score, mean ± SD	10.6 ± 6.4	10.7 ± 6.3
Any prior systemic therapy, n (%)	859 (77.6)	285 (76.2)
Any prior biologic therapy, n (%)	423 (38.2)	129 (34.5)

Figure 2 Achievement of PASI 90 at Year 3 by subgroups (mNRI)



Results differ slightly from the accepted abstract due to updated mNRI methodology. [a]BKZ Total included all patients randomized to BKZ who received BKZ throughout the maintenance period and into the OLE, regardless of the dosing regimen they received. [b]All patients were reassigned to BKZ Q8W by Year 2/next scheduled visit via protocol amendment. [c]For some patients with a body weight ≥120 kg (who did not achieve complete skin clearance at Week 16), BKZ 320 mg Q4W after Week 16 may further improve treatment response.[4] [d]Anti-IL-23 category did not include anti-IL-12/23 therapies.

Figure 3 Achievement of PASI 100 at Year 3 by subgroups (mNRI)



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

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