

Bimekizumab efficacy from treatment initiation through 4 years in patients with plaque psoriasis: A comprehensive, long-term, pooled analysis from BE BRIGTH

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Objective

To provide the first disclosure of efficacy responses from treatment initiation of bimekizumab (BKZ) through 4 years in moderate to severe plaque psoriasis.

To provide a comprehensive view of efficacy in BKZ-treated patients over 4 years across clinical and health-related quality of life outcomes, using the largest available pool of 4-year global phase 3 clinical data at the time of this study.

Introduction

- Psoriasis is a chronic disease; assessing long-term treatment efficacy is imperative.¹
- BKZ is a monoclonal immunoglobulin G1 (IgG1) antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A.^{2,3}
- BKZ has demonstrated rapid and superior efficacy in the treatment of psoriasis versus ustekinumab, adalimumab, and secukinumab, with established long-term durability of response.⁴⁻⁸

Methods

- Data were pooled across the 52-week BE VIVID, 56-week BE SURE and BE READY trials, and their open-label extension (OLE) BE BRIGTH. Analyzed patients were randomized to BKZ 320 mg every 4 weeks (Q4W) to Week 16, received BKZ Q4W or every 8 weeks (Q8W) thereafter, and entered the OLE (Figure 1).⁴⁻⁸
- Proportions achieving $\geq 90\%$ / 100% improvement from baseline in Psoriasis Area and Severity Index (PASI 90/PASI 100), body surface area (BSA) $\leq 1\%$, and Dermatology Life Quality Index (DLQI) 0/1 are reported from initial study baseline through Year 4 (OLE Week 144).
- Missing data were imputed using modified non-responder imputation (mNRI). Patients who discontinued due to lack of efficacy/treatment-related adverse events were considered non-responders at subsequent timepoints; multiple imputation was used for other missing data.

Results

Baseline characteristics and patient disposition

- Baseline characteristics and patient disposition are presented in Table 1 and Figure 2, respectively.

Treatment response

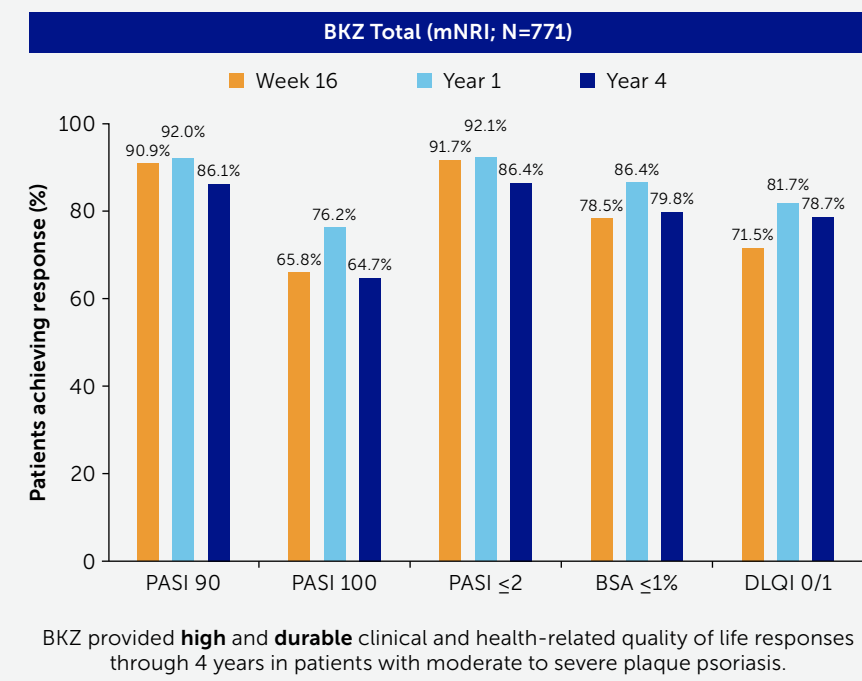
- BKZ treatment responses over 4 years are summarized in Figure 3.
- Among patients who received BKZ continuously from baseline and entered the OLE (N=771), 90.9%, 65.8%, 91.7%, 78.5%, and 71.5% of patients achieved PASI 90, PASI 100, PASI ≤ 2 , BSA $\leq 1\%$, and DLQI 0/1, respectively, at Week 16. Responses were highly durable throughout 4 years of BKZ treatment, with 86.1%, 64.7%, 86.4%, 79.8%, and 78.7% of patients reporting PASI 90, PASI 100, PASI ≤ 2 , BSA $\leq 1\%$, and DLQI 0/1, respectively, at Year 4.
- In the subset of patients who received BKZ Q4W/Q8W/Q8W (initial/maintenance/OLE; N=197), 88.0%, 72.6%, 89.2%, 83.2%, and 83.3% reported PASI 90, PASI 100, PASI ≤ 2 , BSA $\leq 1\%$, and DLQI 0/1, respectively, at Year 4.

Conclusions

In patients who received bimekizumab and enrolled in the OLE, high rates of clinical and health-related quality of life responses were achieved rapidly and were highly durable in the long term through 4 years.

PASI 90, PASI 100, PASI ≤ 2 , BSA $\leq 1\%$, and DLQI 0/1 response rates were consistent in the subset of patients enrolled in the OLE who received bimekizumab 320 mg Q4W to Week 16 then Q8W thereafter, the approved dosing regimen for the majority of patients with plaque psoriasis.^{9,10}

Summary



BKZ provided high and durable clinical and health-related quality of life responses through 4 years in patients with moderate to severe plaque psoriasis.

Figure 1 Study design overview

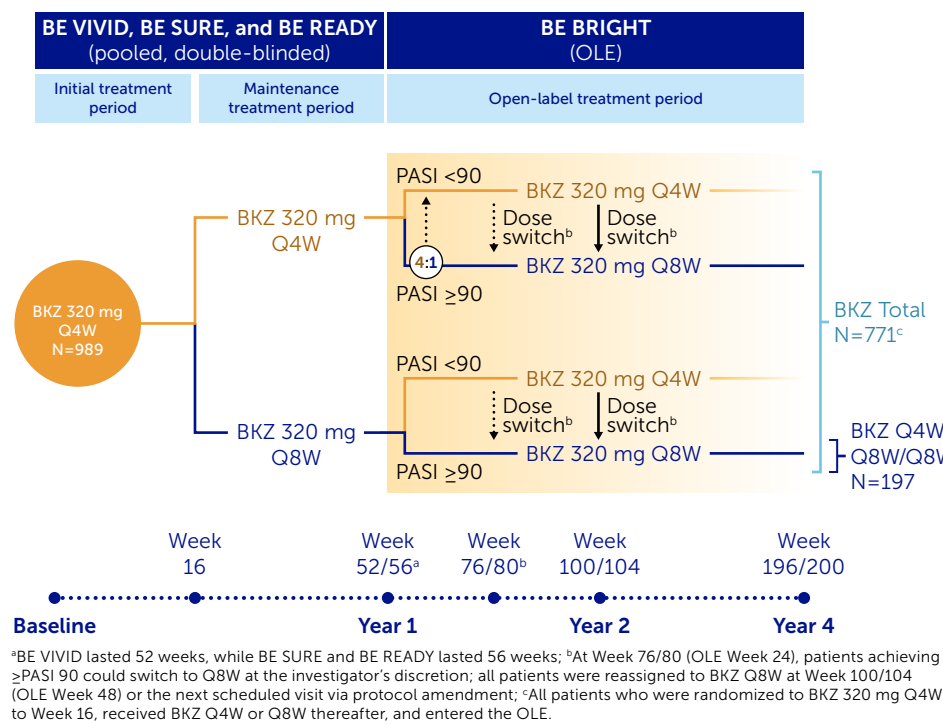
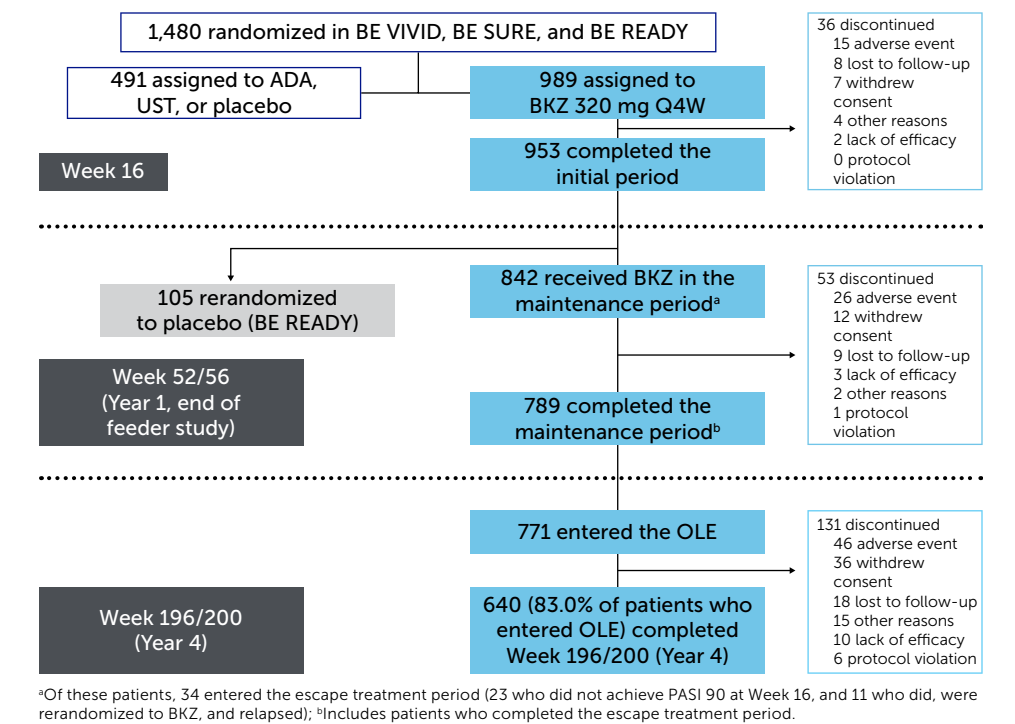


Table 1 Baseline characteristics

	BKZ Total N=771*	BKZ Q4W/Q8W/Q8W N=197
Age (years), mean \pm SD	45.4 \pm 13.5	45.0 \pm 14.1
Male, n (%)	550 (71.3)	141 (71.6)
White, n (%)	656 (85.1)	185 (93.9)
Weight (kg), mean \pm SD	89.7 \pm 21.2	88.5 \pm 20.8
BMI (kg/m ²), mean \pm SD	29.9 \pm 6.6	29.3 \pm 6.2
Duration of psoriasis (years), mean \pm SD	18.6 \pm 12.7	18.9 \pm 12.0
PASI, mean \pm SD	21.1 \pm 7.6	20.4 \pm 6.9
BSA (%), mean \pm SD	27.0 \pm 15.6	24.5 \pm 12.2
IGA, n (%)		
3: moderate	508 (65.9)	142 (72.1)
4: severe	262 (34.0)	55 (27.9)
DLQI total score, mean \pm SD	10.5 \pm 6.3	10.8 \pm 6.0
Any prior systemic therapy, n (%)	618 (80.2)	154 (78.2)
Any prior biologic therapy, n (%)	309 (40.1)	73 (37.1)
anti-TNF	113 (14.7)	19 (9.6)
anti-IL-17	193 (25.0)	48 (24.4)
anti-IL-23	37 (4.8)	13 (6.6)
anti-IL-12/23	43 (5.6)	13 (6.6)

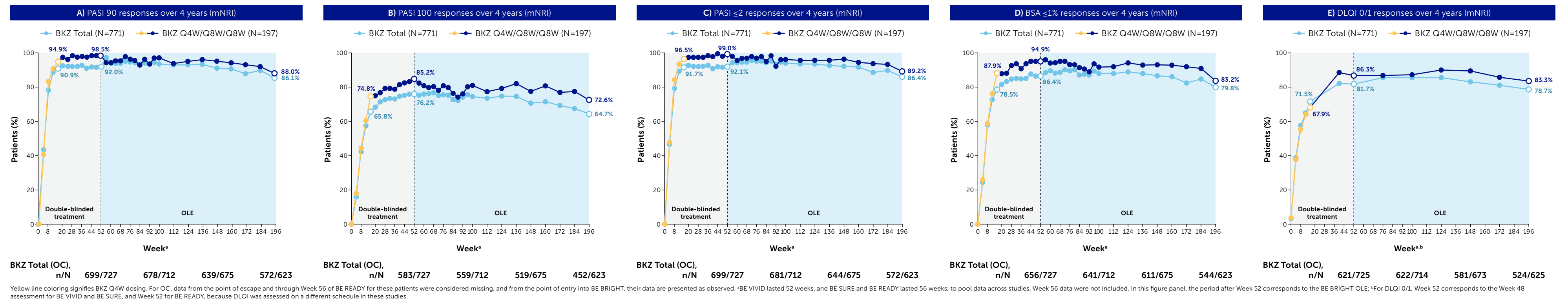
*Baseline characteristics shown for all patients who were randomized to BKZ 320 mg Q4W to Week 16, received BKZ Q4W or Q8W thereafter, and entered the OLE.

Figure 2 Patient disposition



*Of these patients, 34 entered the escape treatment period (23 who did not achieve PASI 90 at Week 16, and 11 who did, were rerandomized to BKZ, and relapsed); *Includes patients who completed the escape treatment period.

Figure 3 Response to BKZ over 4 years measured by (A) PASI 90, (B) PASI 100, (C) PASI ≤ 2 , (D) BSA $\leq 1\%$, and (E) DLQI 0/1 [mNRI; OC]



Yellow line coloring signifies BKZ Q4W dosing. For OC, data from the point of escape and through Week 56 of BE READY for these patients were considered missing, and from the point of entry into BE BRIGTH, their data are presented as observed. *BE VIVID lasted 52 weeks, and BE SURE and BE READY lasted 56 weeks; to pool data across studies, Week 56 data were not included. In this figure panel, the period after Week 52 corresponds to the BE BRIGTH OLE. *For DLQI 0/1, Week 52 corresponds to the Week 48 assessment for BE VIVID and BE SURE, and Week 52 for BE READY, because DLQI was assessed on a different schedule in these studies.

ADA: adalimumab; BKZ: bimekizumab; BMI: body mass index; BSA: body surface area; DLQI: Dermatology Life Quality Index; IGA: Investigator's Global Assessment; IL: interleukin; mNRI: modified non-responder imputation; OC: observed cases; OLE: open-label extension; PASI: Psoriasis Area and Severity Index; PASI 90/100: $\geq 90\%$ / 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; UST: ustekinumab.

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