Bimekizumab long-term efficacy in patients with plaque psoriasis from BE BRIGHT: Mean percentage improvement in clinical outcomes over 4 years

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Objective

To evaluate the clinical efficacy of bimekizumab (BKZ), using mean percentage improvements from baseline in commonly used clinical outcomes, including those measuring health-related quality of life (HRQoL), through 4 years of treatment.

Background

- BKZ has demonstrated rapid and superior efficacy in the treatment of moderate to severe plaque psoriasis vs ustekinumab, adalimumab, and secukinumab, with established long-term durability of response.[1–5]
- Assessments of mean percentage improvements in clinical outcomes can be used by clinicians alongside standard improvement thresholds, such as absolute or relative PASI (Psoriasis Area and Severity Index), to better understand skin responses.
- Marked mean percentage improvements (>40% from baseline) in PASI in patients receiving BKZ treatment have previously been reported as early as Week 1, and increasing to Week 16.[6]

Methods

- Data were pooled from the 52-week BE VIVID, the 56-week BE READY and BE SURE phase 3 trials, and their open-label extension (OLE), BE BRIGHT.[2–5]
- Mean percentage improvement from baseline in PASI (scored 0–72), body surface area affected by psoriasis (BSA; scored 0–100%), Dermatology Life Quality Index (DLQI; scored 0–30), and Investigator's Global Assessment (IGA; scored 0–4) are reported to Year 4.
- Data are reported for all patients who received continuous BKZ treatment from baseline and entered the OLE, regardless of dosing regimen (BKZ Total), and for the subset who received BKZ every 4 weeks (Q4W) to Week 16 then every 8 weeks (Q8W) continuously into the OLE (Q4W/Q8W), the approved dosing regimen for the majority of patients.[7,8]
- Missing data and any data following discontinuation of treatment due to lack of efficacy or treatment-related adverse events were imputed using a multiple imputation (MI) model. Observed case (OC) data are also presented.

Results

- 771 patients continuously treated with BKZ through to the end of the first year entered the OLE (BKZ Total). Of these, 197 received BKZ Q4W/Q8W.
- Baseline characteristics for included patients are presented in **Table 1**. Baseline PASI, BSA, DLQI, and IGA scores in the subsets receiving BKZ Total and BKZ Q4W/Q8W were similar.
- Mean percentage improvements in PASI, BSA, DLQI, and IGA were rapid, seen as early as Week 4, were high by Week 16 (end of the initial treatment period) and were durable in the long-term (**Figure 1A–D**).
- At Year 4, mean percentage improvements were 96.3%, 95.0%, 87.9%, and 86.3%, respectively (Year 4 absolute mean scores: PASI 0.7; BSA 1.2%; DLQI 0.9; and IGA 0.5).
- Similar results were reported in the subset who received BKZ Q4W/Q8W (**Figure 1A–D**).

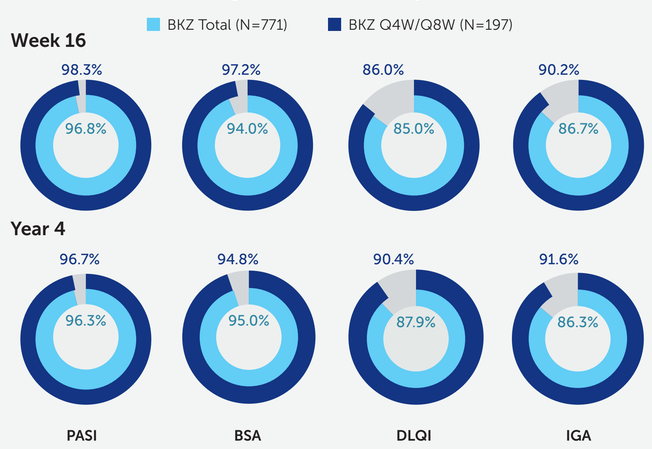
Conclusions

Mean percentage improvements in PASI, BSA, DLQI, and IGA were high by Week 16 of BKZ treatment and durable through 4 years, including in the subset who received BKZ Q4W/Q8W, which is the approved dosing regimen for most patients.[7,8]

These findings build on previous reports that demonstrated marked mean percentage improvements in PASI as early as Week 1,[6] with these results indicating durability in the long-term through 4 years.

Summary

Mean percentage improvements in clinical outcomes, including HRQoL, over 4 years (MI)



In patients who received BKZ and enrolled in the OLE, **large improvements in clinical outcomes, including HRQoL**, were achieved rapidly and were **highly durable** in the long-term through 4 years.

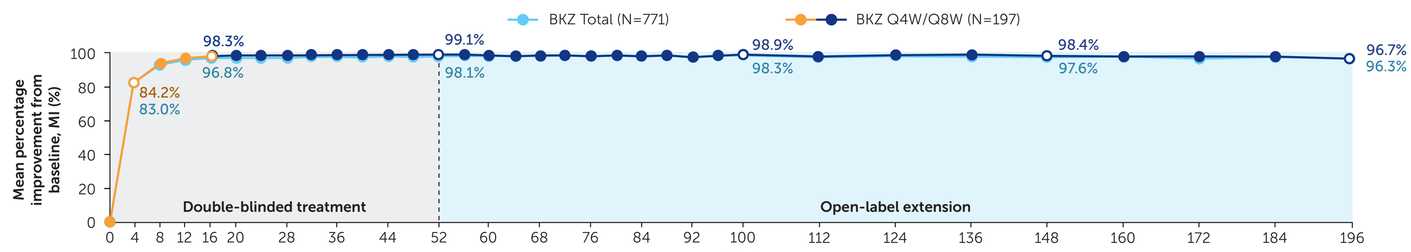
Table 1 Baseline characteristics

	BKZ Total N=771	BKZ Q4W/Q8W N=197
Age (years), mean ± SD	45.4 ± 13.5	45.0 ± 14.1
Male, n (%)	550 (71.3)	141 (71.6)
White, n (%)	656 (85.1)	185 (93.9)
Weight (kg), mean ± SD	89.7 ± 21.2	88.5 ± 20.8
BMI (kg/m²), mean ± SD	29.9 ± 6.6	29.3 ± 6.2
Duration of psoriasis (years), mean ± SD	18.6 ± 12.7	18.9 ± 12.0
PASI, mean ± SD	21.1 ± 7.6	20.4 ± 6.9
BSA (%), mean ± SD	27.0 ± 15.6	24.5 ± 12.2
IGA, n (%)[a]		
3: moderate	508 (65.9)	142 (72.1)
4: severe	262 (34.0)	55 (27.9)
DLQI, mean ± SD	10.5 ± 6.3	10.8 ± 6.0
Any prior systematic 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)

Data are reported for all patients who were treated continuously with BKZ through the initial treatment and maintenance periods, and entered the OLE. [a] One patient in the BKZ Total group had an IGA score of 2 (mild).

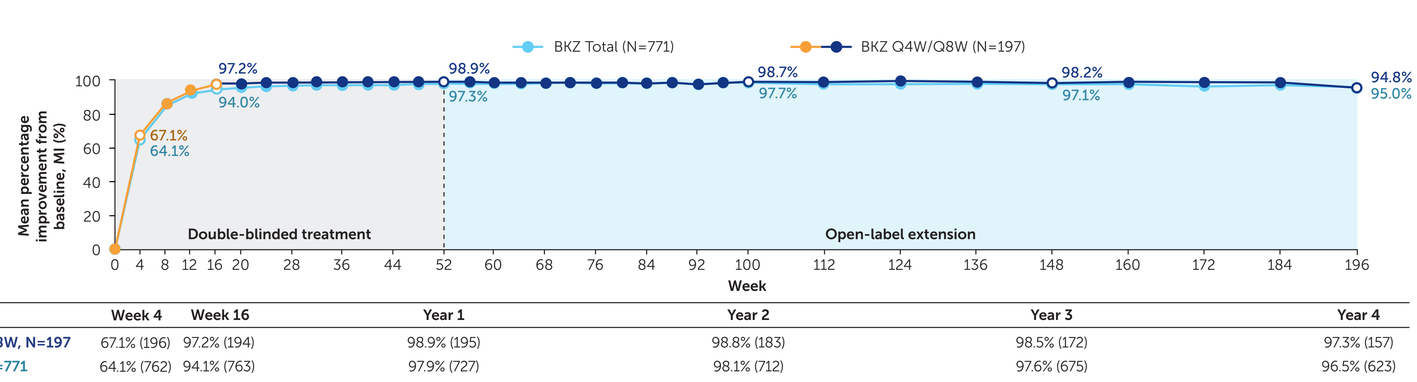
Figure 1 Mean percentage improvements from baseline in clinical outcomes, including HRQoL, with BKZ through 4 years (MI, OC)

A) PASI



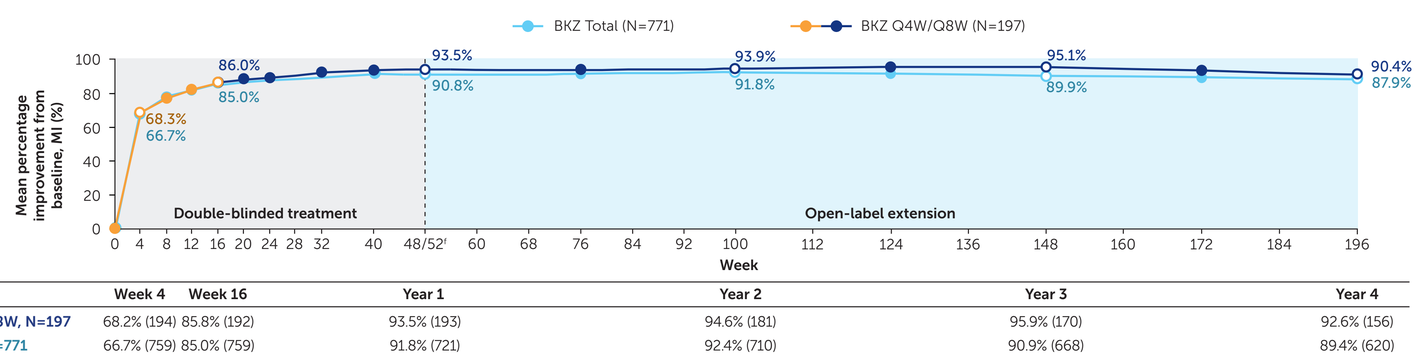
OC, % (N_{obs})[a]	Week 4	Week 16	Year 1[b]	Year 2[c]	Year 3[d]	Year 4[e]
BKZ Q4W/Q8W, N=197	84.2% (196)	98.4% (194)	99.1% (195)	99.0% (183)	98.8% (172)	97.7% (157)
BKZ Total. N=771	83.2% (762)	96.8% (764)	98.6% (727)	98.5% (712)	98.2% (675)	97.3% (623)

B) BSA



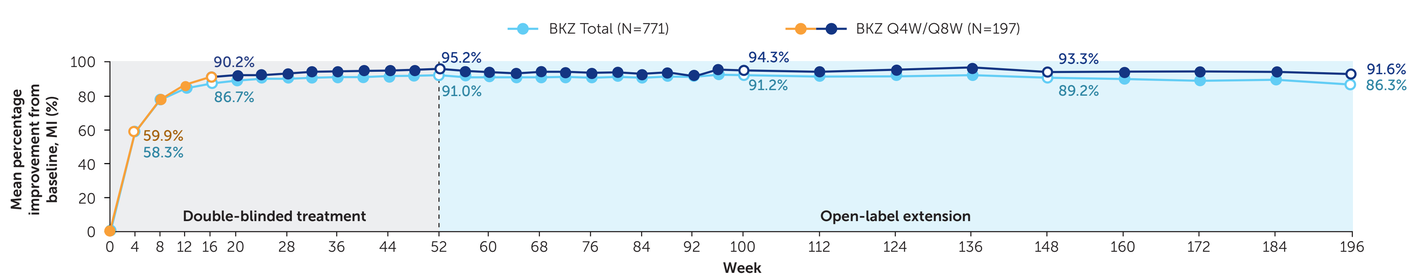
OC, % (N_{obs})[a]	Week 4	Week 16	Year 1	Year 2	Year 3	Year 4
BKZ Q4W/Q8W, N=197	67.1% (196)	97.2% (194)	98.9% (195)	98.8% (183)	98.5% (172)	97.3% (157)
BKZ Total, N=771	64.1% (762)	94.1% (763)	97.9% (727)	98.1% (712)	97.6% (675)	96.5% (623)

C) DLQI



OC, % (N_{obs})[a]	Week 4	Week 16	Year 1	Year 2	Year 3	Year 4
BKZ Q4W/Q8W, N=197	68.2% (194)	85.8% (192)	93.5% (193)	94.6% (181)	95.9% (170)	92.6% (156)
BKZ Total, N=771	66.7% (759)	85.0% (759)	91.8% (721)	92.4% (710)	90.9% (668)	89.4% (620)

D) IGA



OC, % (N_{obs})[a]	Week 4	Week 16	Year 1	Year 2	Year 3	Year 4
BKZ Q4W/Q8W, N=197	59.8% (196)	90.5% (194)	95.3% (195)	94.7% (183)	94.4% (172)	92.5% (157)
BKZ Total, N=771	58.3% (762)	86.8% (764)	92.2% (727)	91.8% (712)	90.7% (675)	87.9% (621)

Data are reported for patients who entered the OLE only. For data presented in the figures, missing data and any data following discontinuation of treatment due to lack of efficacy or treatment-related adverse events were imputed using a MI model. Gold line coloring signifies BKZ Q4W dosing. For the subset who received BKZ Q4W/Q8W, Year 4 absolute means for PASI, BSA, DLQI, and IGA were 0.6, 1.2%, 0.7, and 0.3, respectively. For OC, data from patients who entered the BE READY escape arm were considered missing from the date of escape until the end of BE READY, after which their data are presented as observed; [a] N_{obs} represents the number of patients with observed data at a given timepoint; [b] BE VIVID lasted 52 weeks and BE SURE and BE READY lasted 56 weeks; to pool data across studies, Week 52 was considered as the last common timepoint before OLE entry (Year 1); [c] Week 100/104; [d] Week 148/152; [e] Week 196/200; [f] Due to lack of common timepoints at which the DLQI was assessed, Week 48 (BE SURE and BE READY)/52 (BE VIVID) was used as a composite last timepoint before OLE entry (Year 1) when pooling the studies.

BKZ: bimekizumab; **BMI:** body mass index; **BSA:** body surface area; **DLQI:** Dermatology Life Quality Index; **HRQoL:** health-related quality of life; **IGA:** Investigator's Global Assessment; **IL:** interleukin; **MI:** multiple imputation; **N_{obs}:** N observed; **OC:** observed cases; **OLE:** open-label extension; **PASI:** Psoriasis Area and Severity Index; **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:** tumour necrosis factor.

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