Bimekizumab efficacy and safety through 5 years in patients with moderate to severe plaque psoriasis in the US and Canada

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Objective

To evaluate the long-term efficacy and safety of bimekizumab (BKZ) treatment through 5 years in patients with moderate to severe plaque psoriasis from the US and Canada.

Background

- Given the chronic nature of psoriasis, and the loss of response observed with biologic therapies over time, it is crucial to establish the long-term efficacy and safety of biologic therapies for psoriasis.[1]
- Treatment with BKZ, a monoclonal IgG1 antibody that inhibits interleukin (IL)-17F in addition to IL-17A, has previously demonstrated maintenance of high response rates through 4 years in patients with moderate to severe plaque psoriasis.[2,3]

Methods

- US/Canadian patients who completed the 52-week BE VIVID and 56-week BE SURE and BE READY phase 3 trials, and the 144-week BE BRIGHT open-label extension (OLE; 4 years' total treatment), could enter a second 48-week OLE (OLE2; **Figure 1**).[4–7]
- Patients entered the BE BRIGHT OLE2 with or without a treatment break, since some patients had completed the study before it was extended. Only patients who were randomized to BKZ at baseline and received BKZ continuously into OLE2, without a treatment break, were included in this analysis. All included patients received BKZ every 8 weeks (Q8W) on OLE2 entry (**Figure 1**).
- Efficacy data and treatment-emergent adverse events (TEAEs; incidence/100 patient-years [PY]) are reported over 5 years of BKZ treatment (to OLE2 Week 48; 244 or 248 weeks' total treatment).
- Data are reported in patients irrespective of dose (BKZ Total) and in patients who received BKZ 320 mg every 4 weeks (Q4W) to Week 16 then Q8W thereafter (BKZ Q4W/Q8W; the approved dosing regimen for most patients with psoriasis).[8]
- Patients discontinuing treatment due to lack of efficacy or treatment-related adverse events were considered non-responders; multiple imputation was used for other missing data (modified non-responder imputation [mNRI]).

Results

Baseline characteristics

- Of the 153 US/Canadian patients analyzed, 52 patients received BKZ Q4W/Q8W.
  - Baseline characteristics are shown in **Table 1**.

Efficacy

- At Year 1 (Week 52) and Year 5 (Week 244), respectively, 92.8% and 84.9% of BKZ Total patients achieved 90% improvement in Psoriasis Area and Severity Index (PASI 90); among the BKZ Q4W/Q8W subset, 96.2% and 88.5% of patients achieved PASI 90 (**Figure 2A**).
- At Year 1 and Year 5, respectively, 75.2% and 67.7% of BKZ Total patients achieved 100% improvement in Psoriasis Area and Severity Index (PASI 100); among the BKZ Q4W/Q8W subset, 78.8% and 76.9% of patients achieved PASI 100 (**Figure 2B**).
- Investigator's Global Assessment (IGA) 0/1 achievement rates followed a similar trend to that of PASI 90; Dermatology Life Quality Index (DLQI) 0/1 achievement rates were similar at Year 1 and Year 5 for BKZ Total patients, but were numerically higher for BKZ Q4W/Q8W patients at Year 5 versus Year 1 (**Figures 2C–D**).

Safety

- Over 5 years, serious TEAEs (3.6/100 PY) and discontinuations due to TEAEs (0.3/100 PY) were low; no deaths occurred. The most common TEAEs were nasopharyngitis (9.7/100 PY), oral candidiasis (7.6/100 PY), and coronavirus infection (6.1/100 PY), in line with BKZ's known safety profile (**Table 2**).[9]
- The vast majority (99.3%) of oral candidiasis events were mild to moderate; none led to discontinuation.
- BKZ Q4W/Q8W safety data were generally similar to BKZ Total data, although the patient group was small, so results should be interpreted with caution (**Table 2**).

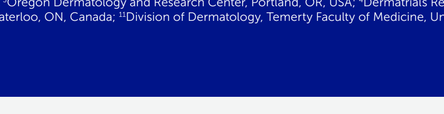
Conclusions

Bimekizumab demonstrated high rates of clinical and health-related quality of life responses, which were highly durable to Year 5, in patients from the US and Canada with moderate to severe plaque psoriasis.

Bimekizumab was well-tolerated in this patient subgroup, with no unexpected safety findings.

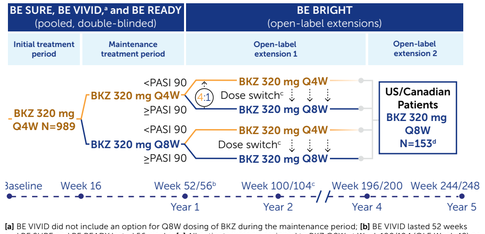
Summary

High clinical and health-related quality of life responses to bimekizumab were maintained through 5 years in patients from the US and Canada with moderate to severe plaque psoriasis



Bimekizumab was well-tolerated through 5 years of treatment, with no unexpected safety findings

Figure 1 BE BRIGHT study design



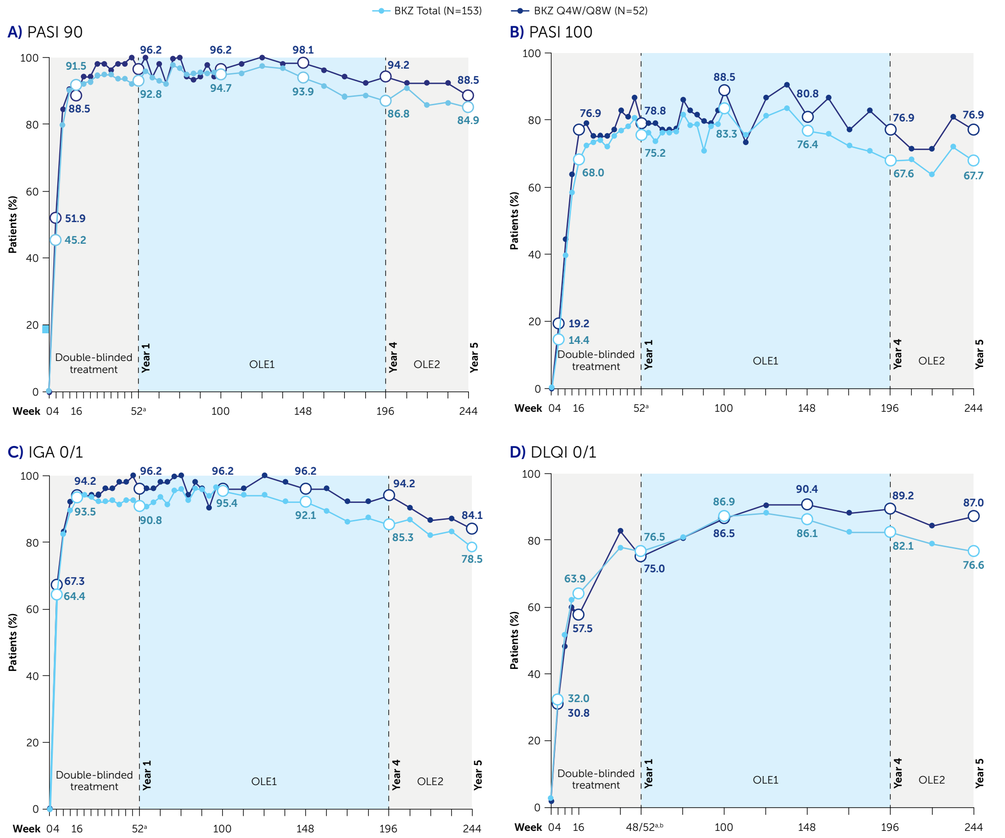
[a] BE VIVID did not include an option for Q8W dosing of BKZ during the maintenance period; **[b]** BE VIVID lasted 52 weeks and BE SURE and BE READY lasted 56 weeks; **[c]** All patients were re-assigned to BKZ Q8W at Week 100/104 (OLE Week 48) or the next scheduled visit via protocol amendment; **[d]** 46 patients had a treatment break and are not included in this analysis.

Table 1 Baseline characteristics

	BKZ Total N=153	BKZ Q4W/Q8W N=52
Age (years), mean (SD)	45.7 (13.6)	46.8 (15.5)
Sex, **male**, n (%)	102 (66.7)	35 (67.3)
Racial group, **white**, n (%)	124 (81.0)	44 (84.6)
Weight[a] (kg), mean (SD)	93.9 (22.6)	90.4 (21.3)
BMI[a] (kg/m^2), mean (SD)	31.7 (7.0)	30.4 (6.3)
Duration of psoriasis (years), mean (SD)	19.0 (13.8)	18.9 (14.0)
PASI, mean (SD)	19.7 (6.8)	18.4 (5.8)
BSA (%), mean (SD)	24.4 (14.6)	20.1 (10.7)
IGA, n (%)		
3: moderate	104 (68.0)	38 (73.1)
4: severe	49 (32.0)	14 (26.9)
DLQI total, mean (SD)	10.5 (6.0)	11.1 (5.8)
Any prior systemic therapy, n (%)	100 (65.4)	31 (59.6)
Any prior biologic therapy, n (%)	47 (30.7)	11 (21.2)
anti-TNF	24 (15.7)	7 (13.5)
anti-IL-17	18 (11.8)	4 (7.7)
anti-IL-23	4 (2.6)	0
anti-IL-12/23	8 (5.2)	1 (1.9)

[a] The mean weight of US/Canadian patients in OLE2 was numerically higher than the global BE BRIGHT population (mean weight was 89.7 ± 21.2 kg [BKZ Total] and 88.5 ± 20.8 kg [BKZ Q4W/Q8W]; mean BMI was 29.9 ± 6.6 kg/m^2 [BKZ Total] and 29.3 ± 6.2 kg/m^2 [BKZ Q4W/Q8W]).[10]

Figure 2 Efficacy outcomes through 5 years (mNRI)



[a] 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 these figures, the period after Week 52 (or Week 48/52) corresponds to the BE BRIGHT OLE; **[b]** Week 48/52 is a combined timepoint representing Week 48 in BE SURE and BE READY and Week 52 in BE VIVID, due to a lack of common timepoints at which DLQI was assessed.

Table 2 Rates of TEAEs through 5 years

EAIR/100 PY (95% CI)	BKZ Total N=153 757 PY[a]	BKZ Q4W/Q8W N=52 259 PY[b]
TEAE summary		
Any TEAE	171.4 (145.0, 201.2)	199.3 (147.9, 262.7)
Serious TEAEs	3.6 (2.3, 5.3)	2.0 (0.7, 4.8)
Discontinuation due to TEAEs in OLE2	0.3 (0.0, 1.0)	0.4 (0.0, 2.2)
Severe TEAEs	4.0 (2.7, 5.8)	3.2 (1.4, 6.4)
TEAEs leading to death in OLE2	0	0
Most common TEAEs		
Nasopharyngitis	9.7 (7.3, 12.7)	9.5 (5.6, 15.0)
Oral candidiasis	7.6 (5.5, 10.2)	9.4 (5.6, 14.9)
Coronavirus infection	6.1 (4.4, 8.2)	5.3 (2.8, 9.1)
Upper respiratory tract infection	5.8 (4.0, 8.0)	6.8 (3.7, 11.3)
TEAEs of interest		
Serious infections	1.2 (0.6, 2.3)	0.8 (0.1, 2.9)
Active tuberculosis	0	0
Fungal infections	9.4 (7.0, 12.3)	10.9 (6.7, 16.8)
Candida infections	7.6 (5.5, 10.2)	9.5 (5.6, 14.9)
Oral candidiasis	7.6 (5.5, 10.2)	9.4 (5.6, 14.9)
Definite or probable adjudicated IBD	0.1 (0.0, 0.7)	0
Adjudicated MACE	0.8 (0.3, 1.8)	0.4 (0.0, 2.2)
Malignancies	0.7 (0.2, 1.6)	0.8 (0.1, 2.9)
Excluding NMSC	0.3 (0.0, 1.0)	0.4 (0.0, 2.2)
Adjudicated SIB	0	0
Neutropenia	0.1 (0.0, 0.7)	0
ALT or AST >3x ULN	1.1 (0.5, 2.2)	0.4 (0.0, 2.2)
ALT or AST >5x ULN[c]	0.4 (0.1, 1.2)	0
Serious hypersensitivity reactions	0	0
Injection site reactions	2.1 (1.2, 3.5)	3.4 (1.5, 6.8)

[a] 757/100 PY = 757 PY; **[b]** 2.59/100 PY = 259 PY; **[c]** Patients with elevations >5x ULN were a subset of patients with elevations >3x ULN.

ALT: alanine aminotransferase; **AST:** aspartate aminotransferase; **BKZ:** bimekizumab; **BMI:** body mass index; **BSA:** body surface area; **CI:** confidence interval; **DLQI:** Dermatology Life Quality Index; **EAIR:** exposure-adjusted incidence rate; **IBD:** inflammatory bowel disease; **IGA:** Investigator's Global Assessment; **IL:** interleukin; **MACE:** major adverse cardiac event; **mNRI:** modified non-responder imputation; **NMSC:** non-melanoma skin cancer; **OLE:** open-label extension; **OLE2:** second open-label extension; **PASI:** Psoriasis Area and Severity Index; **PASI 90:** ≥90% improvement from baseline in PASI; **PASI 100:** 100% improvement from baseline in Psoriasis Area and Severity Index; **PY:** patient-years; **Q4W:** every 4 weeks; **Q8W:** every 8 weeks; **SIB:** suicidal ideation and behavior; **SD:** standard deviation; **TEAE:** treatment-emergent adverse event; **TNF:** tumor necrosis factor; **ULN:** upper limit of normal.

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