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

Andrew Blauvelt,[1] Saakshi Khattri,[2] Phoebe Rich,[3] Ronald Vender,[4] Kenneth B. Gordon,[5] Balint Szilagyi,[6] Heather Herr,[7] Bertram Knapp,[6] Delphine Deherder,[8] Sarah Kavanagh,[9] Kim Papp[10,11]

[1]Blauvelt Consulting, LLC, Portland, OR, USA; [2]The Mount Sinai Hospital, NY, USA; [3]Oregon Dermatology and Research Center, Portland, OR, USA; [4]Dermatrials Research Inc., Hamilton, ON, Canada; [5]Department of Dermatology, Medical College of Wisconsin, Milwaukee, WI, USA; [6]UCB, Monheim am Rhein, Germany; [7]UCB, Smyrna, GA, USA; [8]UCB, Braine-l'Alleud, Belgium; [9]UCB, Morrisville, NC, USA; [10]Probity Medical Research and Alliance Clinical Trials, Waterloo, ON, Canada; [11]Division of Dermatology, Temerty Faculty of Medicine, University of Toronto, Toronto, ON, 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.

Methods

- US/Canadian patients who completed the BE BRIGHT open-label extension (OLE; 4 years' total treatment), could enter a second 48-week OLE (OLE2).[a,1–4]
- Patients entered the BE BRIGHT OLE2 with or without a treatment break. Only patients who were randomized to BKZ at baseline and received BKZ continuously into OLE2, without a treatment break, were included in this analysis.
- Efficacy and safety 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).[5]

[a] The BE BRIGHT study was extended, only in the US and Canada, for an additional 48 weeks; some patients had completed the study before it was extended, so their treatment was interrupted. **1.** Reich K et al. Lancet 2021;397:487–98 (NCT03370133); **2.** Warren RB et al. N Engl J Med 2021;385:130–41 (NCT03412747); **3.** Gordon KB et al. Lancet 2021;397:475–86 (NCT03410992); **4.** Strober B et al. Br J Dermatol 2023;188:749–59 (NCT03598790); **5.** Food and Drug Administration, Bimekizumab Prescribing Information, 2023. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/761151s000lbl.pdf [Accessed January 2025]. BKZ: bimekizumab; OLE: open-label extension; OLE2: second open-label extension; Q4W: every 4 weeks; Q8W: every 8 weeks.

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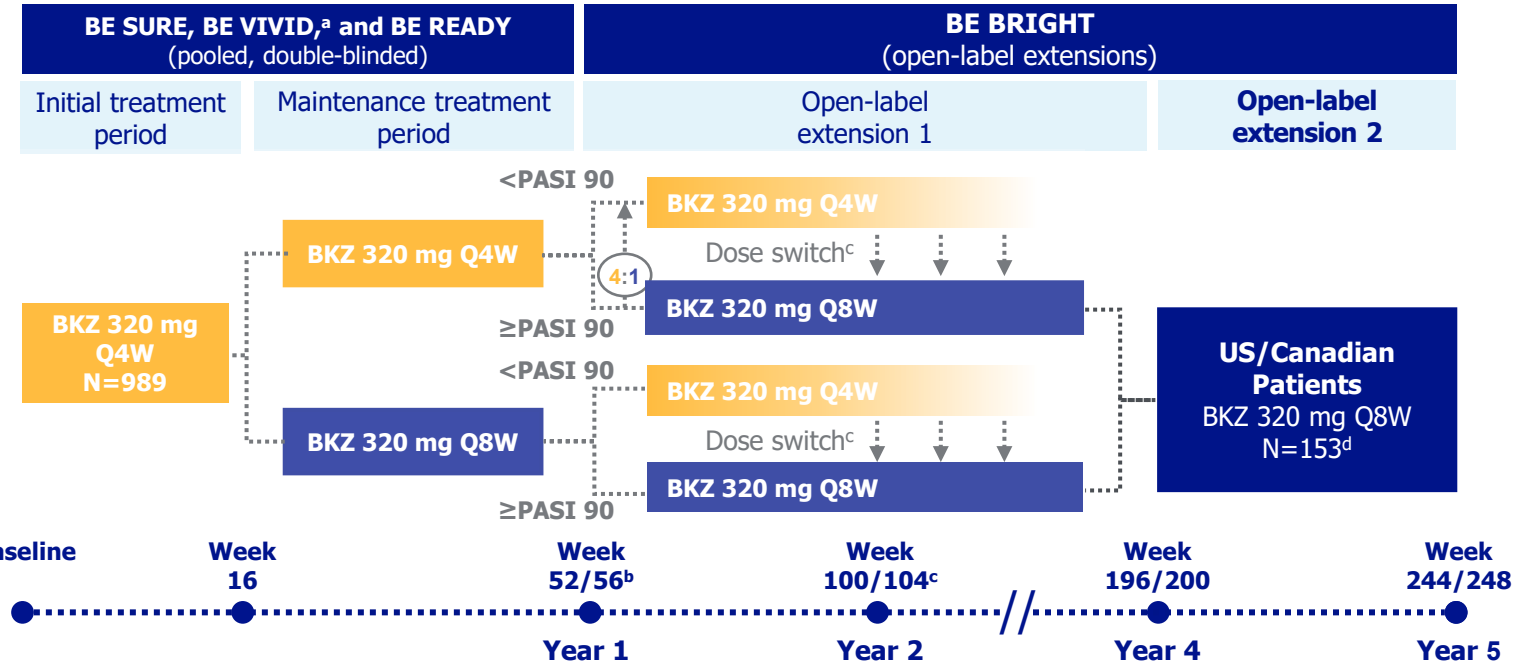
Study Design



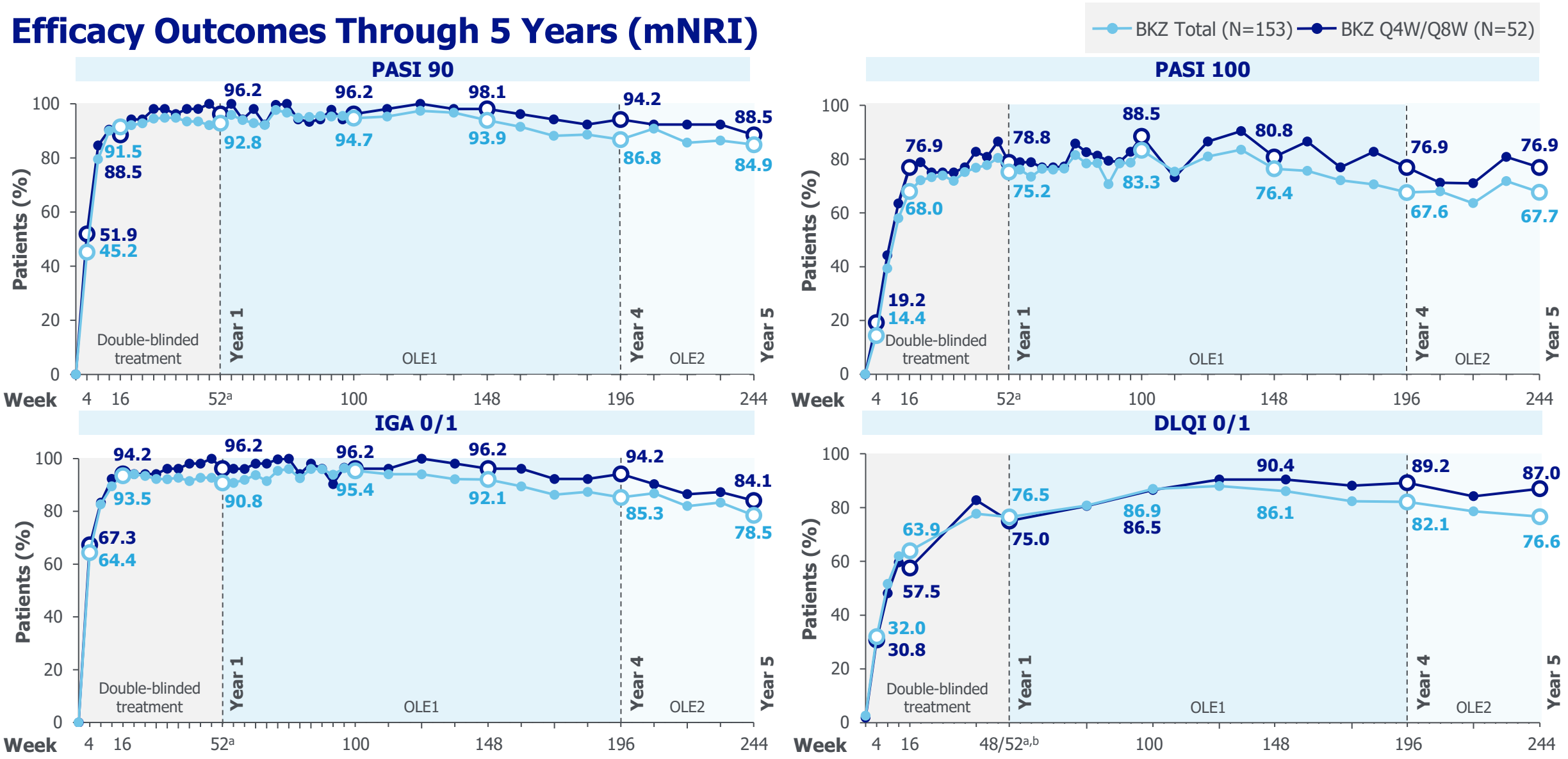
- Efficacy data and treatment-emergent adverse events (TEAEs; incidence/100 patient-years [PY]) are reported over 5 years of BKZ treatment.
- Patients discontinuing treatment due to lack of efficacy or treatment-related adverse events were considered non-responders; multiple imputation was used for other missing data (modified non-responder imputation [mNRI]).

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[e] (kg), mean (SD)	93.9 (22.6)	90.4 (21.3)
BMI[e] (kg/m²), 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 4: severe	 104 (68.0) 49 (32.0)	 38 (73.1) 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 (%) anti-TNF anti-IL-17 anti-IL-23 anti-IL-12/23	47 (30.7) 24 (15.7) 18 (11.8) 4 (2.6) 8 (5.2)	11 (21.2) 7 (13.5) 4 (7.7) 0 1 (1.9)

[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; **[e]** 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/m² [BKZ Total] and 29.3 ± 6.2 kg/m² [BKZ Q4W/Q8W]).[1] **1.** Strober B et al. AAD 2024; Late-Breaking Presentation 061013. 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; OLE: open-label extension; OLE2: second open-label extension; PASI: Psoriasis Area and Severity Index; PASI 90: ≥90% improvement from baseline in PASI; PY: patient-years; Q4W: every 4 weeks; Q8W: every 8 weeks; SD: standard deviation; TEAE: treatment-emergent adverse event; TNF: tumor necrosis factor.

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. BKZ: bimekizumab; DLQI: Dermatology Life Quality Index; DLQI 0/1: score of 0 or 1 in DLQI; IGA 0/1: score of 0 or 1 in Investigator's Global Assessment; mNRI: modified non-responder imputation; OLE: open-label extension; OLE2: second 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.

Scan to access observed case data
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Safety Outcomes Through 5 Years

Overview of TEAEs, 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)

- Serious TEAEs through 5 years and discontinuations due to TEAEs during OLE2 were low. TEAEs were in line with BKZ's known safety profile.[1] The vast majority (99.3%) of oral candidiasis events were mild to moderate.
- 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.

TEAEs of Interest, EAIR/100 PY (95% CI)	**BKZ Total N=153 757 PY[a]**	**BKZ Q4W/Q8W N=52 259 PY[b]**
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] 7.57/100 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. **1.** Gordon KB et al. Br J Dermatol 2024;190:477–85.
ALT: alanine aminotransferase; AST: aspartate aminotransferase; BKZ: bimekizumab; CI: confidence interval; EAIR: exposure-adjusted incidence rate; IBD: inflammatory bowel disease; MACE: major adverse cardiac event; NMSC: non-melanoma skin cancer; OLE2: second open-label extension; PY: patient-years; Q4W: every 4 weeks; Q8W: every 8 weeks; SIB: suicidal ideation and behavior; TEAE: treatment-emergent adverse event; ULN: upper limit of normal.

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 psoriasis.

Bimekizumab was well-tolerated in this patient subgroup, with no unexpected safety findings.[1]

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1. Gordon KB et al. Br J Dermatol 2024;190:477–85.