Bimekizumab efficacy in patients with plaque psoriasis: A post hoc stratification by weight over 4 years in BE BRIGHT

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OBJECTIVES

- To evaluate the **efficacy of bimekizumab (BKZ)** treatment in the **short-** and **long-term**, in patients with moderate to severe plaque psoriasis **stratified by weight** at baseline.
- To compare responses over 4 years in weight subgroups between all BKZ-treated patients (BKZ Total) and those who received BKZ every 4 weeks (Q4W) to Week 16, then every 8 weeks (Q8W) thereafter (BKZ Q4W/Q8W).

Background

- Weight may impact the response to biologic treatments in patients with moderate to severe plaque psoriasis.¹
- Here, we report the efficacy of BKZ in patients with moderate to severe psoriasis stratified by baseline weight (<90 kg or ≥90 kg).

Methods

- Data were pooled from the 52-week BE VIVID and 56-week BE SURE and BE READY phase 3 clinical trials, and their open-label extension (OLE), BE BRIGHT.^{2–5}
- Patients received BKZ 320 mg Q4W to Week 16, then they received Q4W or Q8W dosing; all received BKZ Q8W from Week 100/104 (OLE Week 48) or the next visit.

Subgroups and outcomes analyzed

Outcomes: Patients: Baseline weight -> **PASI 90, PASI 100, 771 patients** with <90 kg**BSA** ≤1%, and psoriasis who **DLQI 0/1** in received BKZ in **BKZ** Total and BE VIVID, BE SURE, or BKZ Q4W/Q8W BE READY and entered **Baseline weight** groups through the OLE ≥90 ka 4 vears

1. Kisielnicka A et al. Adv Dermatol Allergol 2020;37:168–73; 2. Reich K et al. Lancet 2021;397:487–98 (NCT03370133); 3. Warren RB et al. N Engl J Med 2021;385:130–41 (NCT03412747); 4. Gordon KB et al. Lancet 2021;397:475–86 (NCT03410992); 5. Strober B et al. Br J Dermatol 2023;188:749–59 (NCT03598790). BKZ: bimekizumab; BSA: body surface area; BSA ≤1%: ≤1% of BSA affected by psoriasis; DLQI: Dermatology Life Quality Index; DLQI 0/1: score of 0 or 1 in the DLQI; OLE: open-label extension; PASI: Psoriasis Area and Severity Index; PASI 90/100: ≥90%/100% improvement from baseline in PASI; Q4W: every 4 weeks; Q8W: every 8 weeks.

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Study Design

BE SURE, BE VIVID, a and BE READY **BE BRIGHT** (pooled, double-blinded) (open-label extension) Initial treatment Maintenance treatment Open-label treatment period period period **<PASI 90 BKZ 320 mg Q4W BKZ 320 mg** ≥PASI 90° Dose switch^c **04W BKZ 320 mg Q8W BKZ 320 mg** ≥PASI 90 Q4W <PASI 90 N=989 **BKZ 320 mg Q4W BKZ 320 mg** ≥PASI 90° . Dose switch^c **08W BKZ 320 mg Q8W** ≥PASI 90 Week Week Week Week **Baseline** Week 16 52/56b 76/80^c 100/104^c 196/200 Year 1 Year 2 Year 4

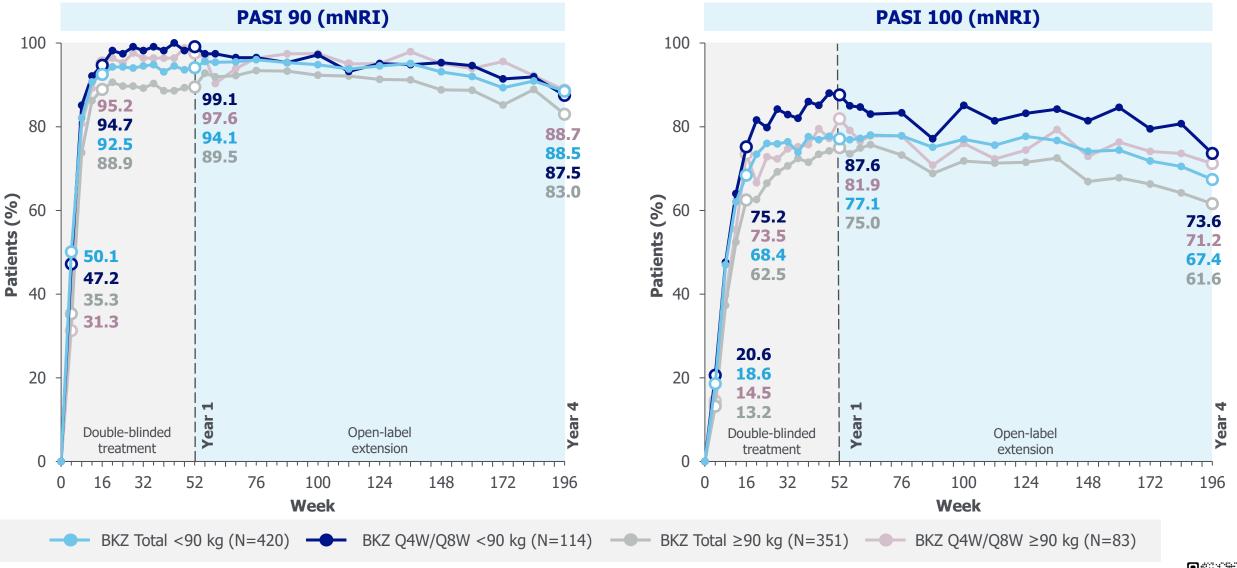
- Responses were evaluated post-hoc through Year 4 (Week 196/200) in the 771 patients who received continuous BKZ and entered the OLE, regardless of dosing regimen (BKZ Total), and in the 197 patients who received BKZ Q4W to Week 16, then Q8W into the OLE (Q4W/Q8W; the approved dosing regimen for most patients with psoriasis).¹
- Data are reported using modified non-responder imputation (mNRI): 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.^d

Baseline Characteristics

	<90 kg		≥90 kg	
	BKZ Total N=420	BKZ Q4W/Q8W N=114	BKZ Total N=351	BKZ Q4W/Q8W N=83
Age (years), mean (SD)	44.8 (14.1)	44.0 (15.1)	46.2 (12.6)	46.3 (12.5)
Sex, male, n (%)	262 (62.4)	68 (59.6)	288 (82.1)	73 (88.0)
Racial group, white, n (%)	343 (81.7)	107 (93.9)	313 (89.2)	78 (94.0)
Weight (kg), mean (SD)	74.1 (10.4)	75.0 (11.0)	108.3 (14.9)	107.0 (16.3)
BMI (kg/m²), mean (SD)	25.6 (3.9)	25.9 (4.2)	34.9 (5.4)	34.0 (5.4)
Duration of psoriasis (years), mean (SD)	18.1 (12.9)	19.8 (13.1)	19.2 (12.4)	17.7 (10.2)
PASI, mean (SD)	20.7 (7.5)	20.0 (6.7)	21.6 (7.8)	21.0 (7.2)
BSA (%), mean (SD)	27.1 (15.4)	24.0 (11.3)	27.0 (15.9)	25.2 (13.3)
IGA, n (%) ^e 3: moderate 4: severe	293 (69.8) 126 (30.0)	82 (71.9) 32 (28.1)	215 (61.3) 136 (38.7)	60 (72.3) 23 (27.7)
DLQI total score, mean (SD)	10.5 (6.3)	10.5 (6.2)	10.6 (6.3)	11.2 (5.7)
Any prior systemic therapy, n (%)	346 (82.4)	90 (78.9)	272 (77.5)	64 (77.1)
Any prior biologic therapy, n (%)	164 (39.0)	37 (32.5)	145 (41.3)	36 (43.4)

[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] At Week 76/80 (OLE Week 24), patients achieving ≥PASI 90 could be switched to Q8W at the investigator's discretion; all patients were re-assigned to BKZ Q8W at Week 100/104 (OLE Week 48) or the next scheduled visit via protocol amendment; [d] 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 as all other non-escape patients during the BE BRIGHT OLE; [e] One patient in the <90 kg BKZ Total group scored IGA 2 at baseline. 1. 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; BMI: body mass index; BSA: body surface area; DLQI: Dermatology Life Quality Index; IGA: Investigator's Global Assessment; mNRI: modified non-responder imputation; OLE: open-label extension; PASI: Psoriasis Area and Severity Index; PASI 90: ≥90% improvement from baseline in PASI; Q4W: every 4 weeks; Q8W: every 8 weeks; SD: standard deviation.

PASI 90/100 Responses by Weight in BKZ-Treated Patients Over 4 Years

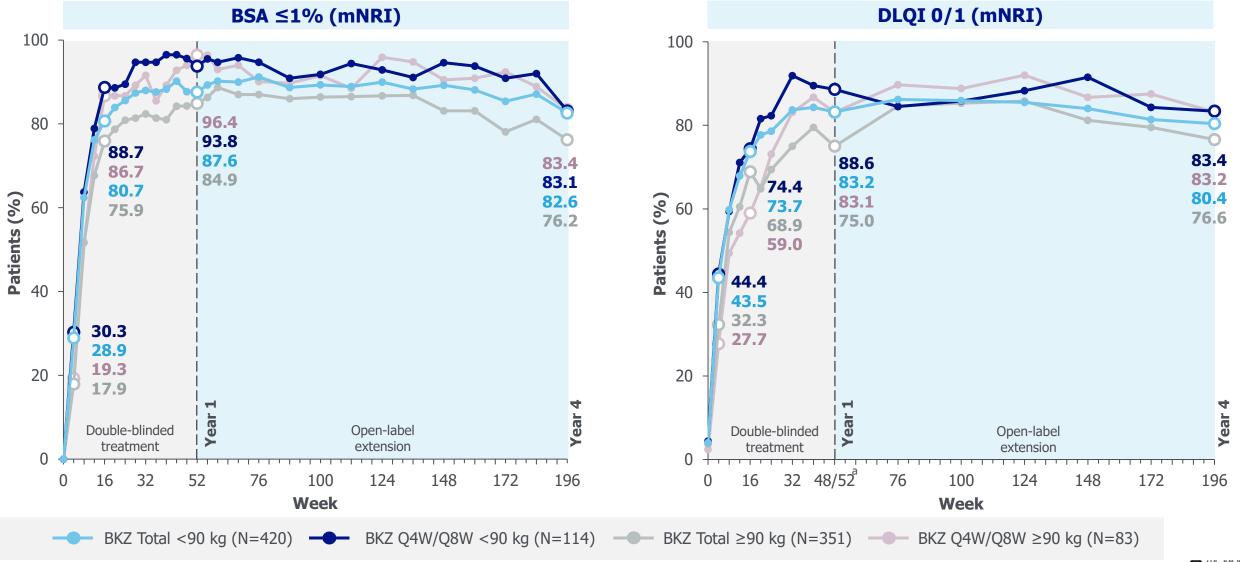


BE VIVID lasted 52 weeks and BE SURE and BE READY lasted 56 weeks; to pool data across studies, Week 56 data were not included. In these figures, the period after Week 52 corresponds to the BE BRIGHT OLE. BKZ: bimekizumab; mNRI: modified non-responder imputation; OLE: open-label extension; PASI: Psoriasis Area and Severity Index; PASI 90/100: ≥90%/100% improvement from baseline in PASI; Q4W: every 4 weeks; Q8W: every 8 weeks.

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BSA ≤1% and DLQI 0/1 Responses by Weight in BKZ-Treated Patients Over 4 Years



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 corresponds to the BE BRIGHT OLE. [a] Week 48/52 is a combined timepoint representing the last DLQI assessment in BE SURE and BE READY (Week 48) and BE VIVID (Week 52) due to a lack of common timepoints at which DLQI was assessed. BKZ: bimekizumab; BSA: body surface area; BSA ≤1%: ≤1% of BSA affected by psoriasis; DLQI: Dermatology Life Quality Index; DLQI 0/1: score of 0 or 1 in DLQI; mNRI: modified non-responder imputation; OLE: open-label extension; Q4W: every 4 weeks; O8W: every 8 weeks.

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CONCLUSIONS

Through 4 years of treatment, bimekizumab demonstrated high rates of short- and long-term clinical and health-related quality of life responses in patients with psoriasis, regardless of weight subgroup.

Efficacy and health-related quality of life responses in patients who received the approved bimekizumab dosing regimen for most patients with psoriasis (Q4W/Q8W)¹ were consistent with the overall bimekizumab-treated population, in both weight subgroups.

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1. Food and Drug Administration, Bimekizumab Prescribing Information, 2023. Available at: https://www.accessdata.fda.gov/drugsatfda docs/label/2023/761151s000lbl.pdf [Accessed January 2025].