

Bimekizumab efficacy in patients with moderate to severe plaque psoriasis and hypertension, elevated body mass index, or hyperglycemia: Results through 3 years of treatment in 5 phase 3/3b trials

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Synopsis

- Patients with moderate to severe plaque psoriasis have a higher risk of cardiometabolic comorbidities than the general population.^{1,2}
- It is therefore important to understand if treatments are effective in subgroups of patients with such comorbidities.
- Bimekizumab (BKZ), a monoclonal IgG1 antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A.³
- BKZ has demonstrated rapid and superior efficacy in the treatment of patients with moderate to severe plaque psoriasis in head-to-head studies versus ustekinumab, adalimumab, and secukinumab, with established long-term durability of response.⁴⁻⁸

Objective

To evaluate responses to BKZ in patients with psoriasis and baseline hypertension, elevated body mass index (BMI), or hyperglycemia through 3 years.

Methods

- Data were pooled from the following trials: BE SURE, BE VIVID, BE READY, their open-label extension (OLE) BE BRIGHT, and BE RADIANT (48-week double-blinded period, plus 96-week OLE) (Figure 1).⁴⁻⁸
- Psoriasis Area and Severity Index (PASI) ≤ 2 , PASI 90 ($\geq 90\%$ improvement from baseline in PASI), and PASI 100 responses were evaluated over 3 years in patients with psoriasis and concurrent:
 - Hypertension (systolic blood pressure >130 mmHg or diastolic blood pressure >85 mmHg);
 - Elevated BMI (>30 kg/m²); or
 - Hyperglycemia (blood glucose ≥ 140 mg/dL or ≥ 7.8 mmol/L), based on objective measurements at baseline.
- Patients may have been receiving, or initiated, treatment for hypertension or hyperglycemia during the study. Baseline measurements may therefore indicate breakthrough hypertension or hyperglycemia despite treatment.
- PASI ≤ 2 , PASI 90, and PASI 100 responses were also reported for all patients who received continuous BKZ treatment in the initial and maintenance periods, and then entered their respective OLE (BKZ Total).
- Data are reported using modified non-responder imputation (mNRI): patients who discontinued due to lack of efficacy or treatment-related adverse events were considered non-responders at subsequent timepoints; multiple imputation was used for all other missing data. Data are also reported using non-responder imputation (NRI) and as the observed case (OC) for all outcomes.

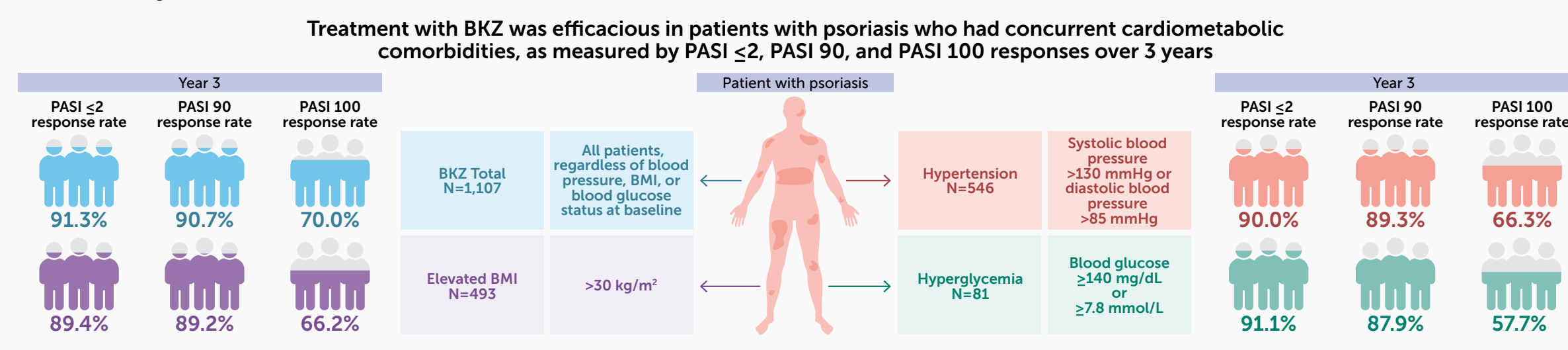
Results

- 1,107 patients continuously treated with BKZ through to the end of the first year entered the OLEs.
- Of these patients, 546, 493, and 81 had hypertension, elevated BMI, and hyperglycemia at baseline, respectively (Table 1).
- High PASI ≤ 2 response rates were observed at Week 16 in those with hypertension, elevated BMI, or hyperglycemia, and were sustained to Year 3 (Week 144) (Figure 2A; Table 2).
- Response rates were consistent with the overall response rate among all BKZ-treated patients.
- Similar trends were observed for PASI 90 and PASI 100 response rates, which were also high at Week 16 and durable to Year 3 across analyzed groups (Figure 2B-C; Table 2).
- Numerically lower PASI 100 response rates were observed at Year 3 for patients with baseline hyperglycemia.

Conclusions

High and durable levels of complete/near-complete skin clearance were achieved through 3 years of BKZ treatment in psoriasis patients, including those who had baseline hypertension, elevated BMI, or hyperglycemia.

Summary



Definitions for comorbidities were based on the criteria for metabolic syndrome where possible and aligned to other similar studies in the field.⁹

Table 1 Baseline characteristics

	BKZ Total* (N=1,107)	Patients with concurrent hypertension (N=546)	Patients with concurrent elevated BMI (N=493)	Patients with concurrent hyperglycemia (N=81)
Age (years), mean \pm SD	45.5 \pm 13.7	47.7 \pm 12.9	48.1 \pm 12.5	52.5 \pm 10.7
White, n (%)	968 (87.4)	477 (87.4)	439 (89.0)	61 (75.3)
Weight (kg), mean \pm SD	89.8 \pm 21.2	94.4 \pm 21.6	106.5 \pm 17.4	98.8 \pm 22.4
Duration of psoriasis (years), mean \pm SD	18.5 \pm 12.8	19.6 \pm 12.7	19.5 \pm 13.2	21.8 \pm 14.0
PASI, mean \pm SD	20.9 \pm 7.6	21.1 \pm 7.8	21.3 \pm 7.8	20.7 \pm 8.0
BSA, mean \pm SD	26.5 \pm 15.7	27.5 \pm 16.4	26.8 \pm 16.2	25.0 \pm 13.4
IGA, n (%)				
3: moderate	722 (65.2)	341 (62.5)	298 (60.4)	55 (67.9)
4: severe	382 (34.5)	205 (37.5)	194 (39.4)	26 (32.1)
DLQI total score, mean \pm SD	10.6 \pm 6.4	10.3 \pm 6.5	10.3 \pm 6.4	10.0 \pm 5.9
Any prior systemic therapy, n (%)	859 (77.6)	426 (78.0)	363 (73.6)	61 (75.3)
Any prior biologic therapy, n (%)	423 (38.2)	207 (37.9)	195 (39.6)	34 (42.0)
Anti-TNF	176 (15.9)	93 (17.0)	94 (19.1)	15 (18.5)
Anti-IL-17	229 (20.7)	109 (20.0)	94 (19.1)	20 (24.7)
Anti-IL-12/23	66 (6.0)	35 (6.4)	31 (6.3)	7 (8.6)
Anti-IL-23	58 (5.2)	27 (4.9)	26 (5.3)	3 (3.7)

*BKZ Total includes all patients who received continuous BKZ treatment in the initial and maintenance periods, and entered the OLEs.

Table 2 Summary of efficacy outcomes (NRI and OC)

	BKZ Total (N=1,107)		Patients with concurrent hypertension (N=546)		Patients with concurrent elevated BMI (N=493)		Patients with concurrent hyperglycemia (N=81)	
	NRI, n (%) ^a	OC, n/Nsub (%) ^b	NRI, n (%) ^a	OC, n/Nsub (%) ^b	NRI, n (%) ^a	OC, n/Nsub (%) ^b	NRI, n (%) ^a	OC, n/Nsub (%) ^b
PASI ≤ 2								
Week 16	1,002 (90.5)	1,002/1,096 (91.4)	483 (88.5)	483/543 (89.0)	431 (87.4)	431/491 (87.8)	71 (87.7)	71/81 (87.7)
Year 1	998 (90.2)	998/1,047 (95.3)	487 (89.2)	487/518 (93.8)	432 (87.6)	432/463 (93.3)	65 (80.2)	65/72 (90.3)
Year 3	907 (81.9)	907/957 (94.8)	443 (81.1)	443/475 (93.3)	386 (78.3)	386/419 (92.1)	64 (79.0)	64/66 (97.0)
PASI 90								
Week 16	998 (90.2)	998/1,096 (91.1)	484 (88.6)	484/543 (89.1)	430 (87.2)	430/491 (87.6)	70 (86.4)	70/81 (86.4)
Year 1	998 (90.2)	998/1,047 (95.3)	489 (89.6)	489/518 (94.4)	431 (87.4)	431/463 (93.1)	65 (80.2)	65/72 (90.3)
Year 3	902 (81.5)	902/957 (94.3)	440 (80.6)	440/475 (92.6)	385 (78.1)	385/419 (91.9)	61 (75.3)	61/66 (92.4)
PASI 100								
Week 16	721 (65.1)	721/1,096 (65.8)	342 (62.6)	342/543 (63.0)	297 (60.2)	297/491 (60.5)	52 (64.2)	52/81 (64.2)
Year 1	826 (74.6)	826/1,047 (78.9)	388 (71.1)	388/518 (74.9)	356 (72.2)	356/463 (76.9)	51 (63.0)	51/72 (70.8)
Year 3	733 (66.2)	733/957 (76.6)	344 (63.0)	344/475 (72.4)	306 (62.1)	306/419 (73.0)	43 (53.1)	43/66 (65.2)

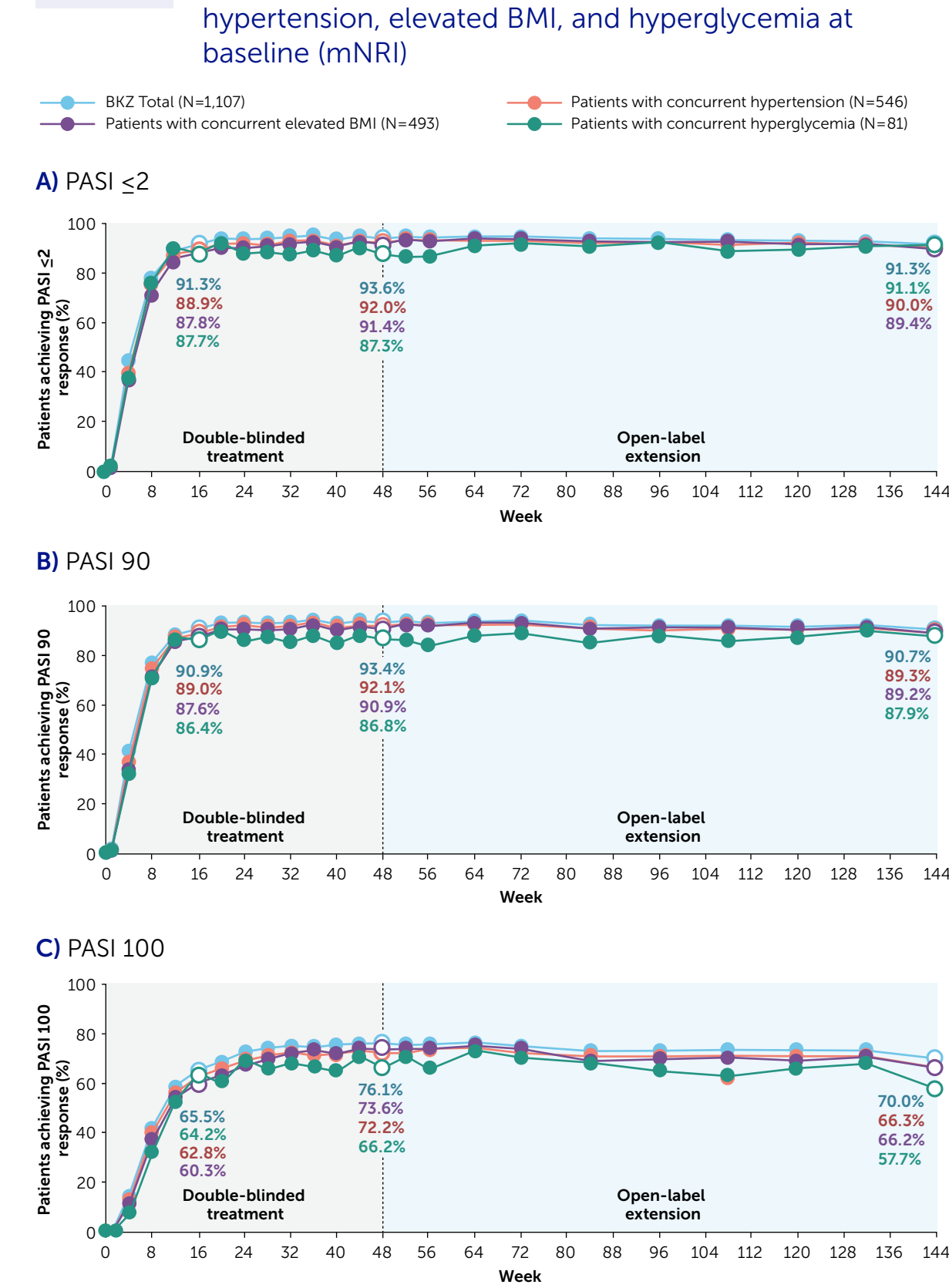
Data are pooled from BE SURE, BE VIVID, BE READY, their OLE BE BRIGHT, and BE RADIANT phase 3 trials through 3 years. Year 1 refers to Week 48. Year 3 refers to Week 144. BKZ Total includes all patients who received continuous BKZ treatment in the initial and maintenance periods, and entered the OLE. Hypertension group includes patients with baseline systolic blood pressure >130 mmHg or diastolic blood pressure >85 mmHg. Elevated BMI group includes patients with baseline BMI >30 kg/m². Hyperglycemia group includes patients with baseline blood glucose ≥ 140 mg/dL or ≥ 7.8 mmol/L. Definitions for comorbidities were based on the criteria for metabolic syndrome where possible and aligned to other similar studies in the field.⁹ *Patients with missing data at a given week were counted as non-responders. ^aNsub represents the number of subjects with a non-missing measurement, and percentages were calculated accordingly.

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; NRI: non-responder imputation; OC: observed case; OLE: open-label extension; PASI: Psoriasis Area and Severity Index; PASI 90/100: $\geq 90\%/100\%$ improvement from baseline in PASI; Q4W: every 4 weeks; Q8W: every 8 weeks; SD: standard deviation; TNF: tumor necrosis factor.

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Figure 2 Response to BKZ treatment in patients with concurrent hypertension, elevated BMI, and hyperglycemia at baseline (mNRI)



Data are pooled from BE SURE, BE VIVID, BE READY, their OLE BE BRIGHT, and BE RADIANT phase 3 trials through 3 years. The feeder studies ran for different lengths of time (BE RADIANT: 48 weeks; BE VIVID: 52 weeks; BE SURE and BE READY: 56 weeks); to pool the data across all studies, Week 52/56 data from the feeder studies were not included. Therefore, timepoints after Week 48 in this figure are from the BE BRIGHT and BE RADIANT OLEs. BKZ Total includes all patients who received continuous BKZ treatment in the initial and maintenance periods, and entered the OLE. Hypertension group includes patients with baseline systolic blood pressure >130 mmHg or diastolic blood pressure >85 mmHg. Elevated BMI group includes patients with baseline BMI >30 kg/m². Hyperglycemia group includes patients with baseline blood glucose ≥ 140 mg/dL or ≥ 7.8 mmol/L. Definitions for comorbidities were based on the criteria for metabolic syndrome where possible and aligned to other similar studies in the field.⁹



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