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

April Armstrong,[1] Steven Feldman,[2] Paolo Gisondi,[3] Mona Ståhle,[4] Leah Davis,[5] Cynthia Madden,[5] Susanne Wiegratz,[6] Delphine Deherder,[7] Ulrich Mrowietz[8]

Objective

To evaluate whether response to bimekizumab (BKZ) in patients with psoriasis is impacted by hypertension, elevated body mass index (BMI) or hyperglycaemia.

Background

- Patients with moderate to severe plaque psoriasis have a higher prevalence of cardiometabolic comorbidities than the general population.[1,2]
- It is therefore important to understand if treatments are effective in associated patient subgroups.
- BKZ, a monoclonal IgG1 antibody that selectively inhibits interleukin (IL)-17F in addition to IL 17A,[3] 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]
- Here, we report efficacy of BKZ in patients with moderate to severe psoriasis with concurrent hypertension, elevated BMI or hyperglycaemia, across four phase 3/3b trials.

Methods

- Data were pooled from the 52-week BE VIVID, 56-week BE SURE and BE READY, and 48-week BE RADIANT phase 3/3b trials (**Figure 1**).[4–7]
- Psoriasis Area and Severity Index (PASI) ≤2 and 100% improvement from baseline (PASI 100) responses were evaluated in patients with psoriasis and concurrent hypertension (systolic >130 mmHg or diastolic >85 mmHg), elevated BMI (>30 kg/m^2), or hyperglycaemia (≥140 mg/dL or ≥7.8 mmol/L), based on objective measurements at baseline.
- PASI ≤2 and PASI 100 responses were also evaluated for all patients who received ≥1 dose of BKZ in the maintenance period (BKZ Total).
- Data are reported using non-responder imputation (NRI).

Results

- Among 1,186 BKZ-randomised patients included from the four studies, 575, 520 and 90 had hypertension, elevated BMI and hyperglycaemia at baseline, respectively (**Table 1**).
- High levels of PASI ≤2 response were observed at Week 16 in those with hypertension, elevated BMI and hyperglycaemia, and response rates were consistent with the overall response for all BKZ-treated patients (**Figure 2A**).
- High PASI ≤2 response rates were sustained to Week 48 across all subgroups. Response rates in patients with elevated BMI and hypertension were similar to the overall BKZ-treated population and were numerically lower for hyperglycaemic patients. (**Figure 2A**).
- PASI 100 response rates in those with hypertension, elevated BMI and hyperglycaemia were consistent with the overall response for all BKZ-treated patients at Week 16 and response rates generally increased to Week 48.
- PASI 100 response rates at Week 48 were high across all subgroups and were similar to the overall BKZ-treated population. Numerically lower response rates were observed for hyperglycaemic patients (**Figure 2B**).

Conclusions

BKZ was efficacious for the treatment of patients with psoriasis who had concurrent baseline hypertension, elevated BMI or hyperglycaemia.

Response rates were high across all subgroups and generally similar to all BKZ-treated patients. Numerically lower responses were reported for hyperglycaemic patients at Week 48.

Summary

Treatment with BKZ was efficacious in patients with psoriasis and concurrent cardiometabolic comorbidities, as measured by PASI ≤2 and PASI 100 response over 1 year

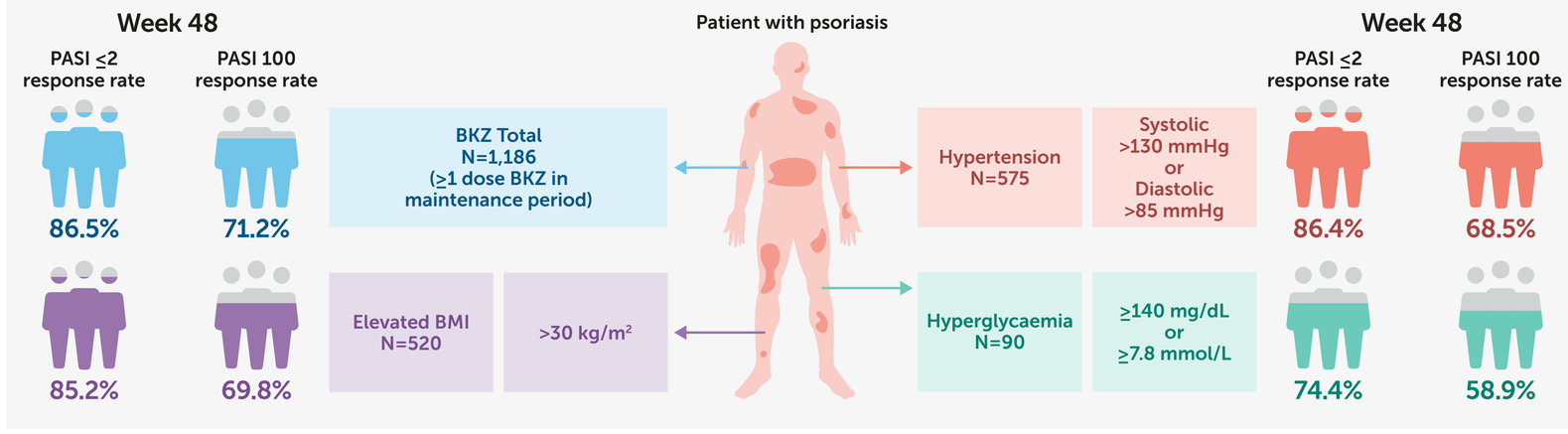
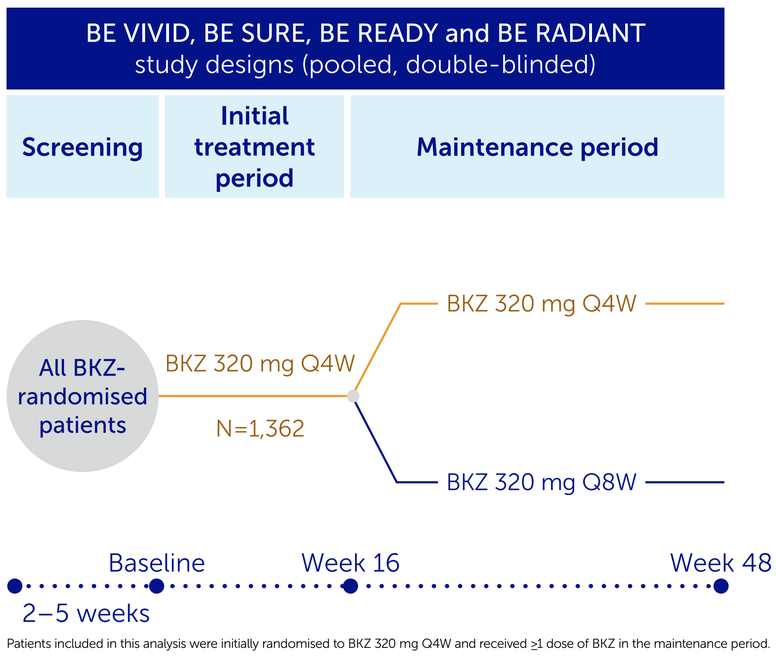


Figure 1 Study design (included patients)



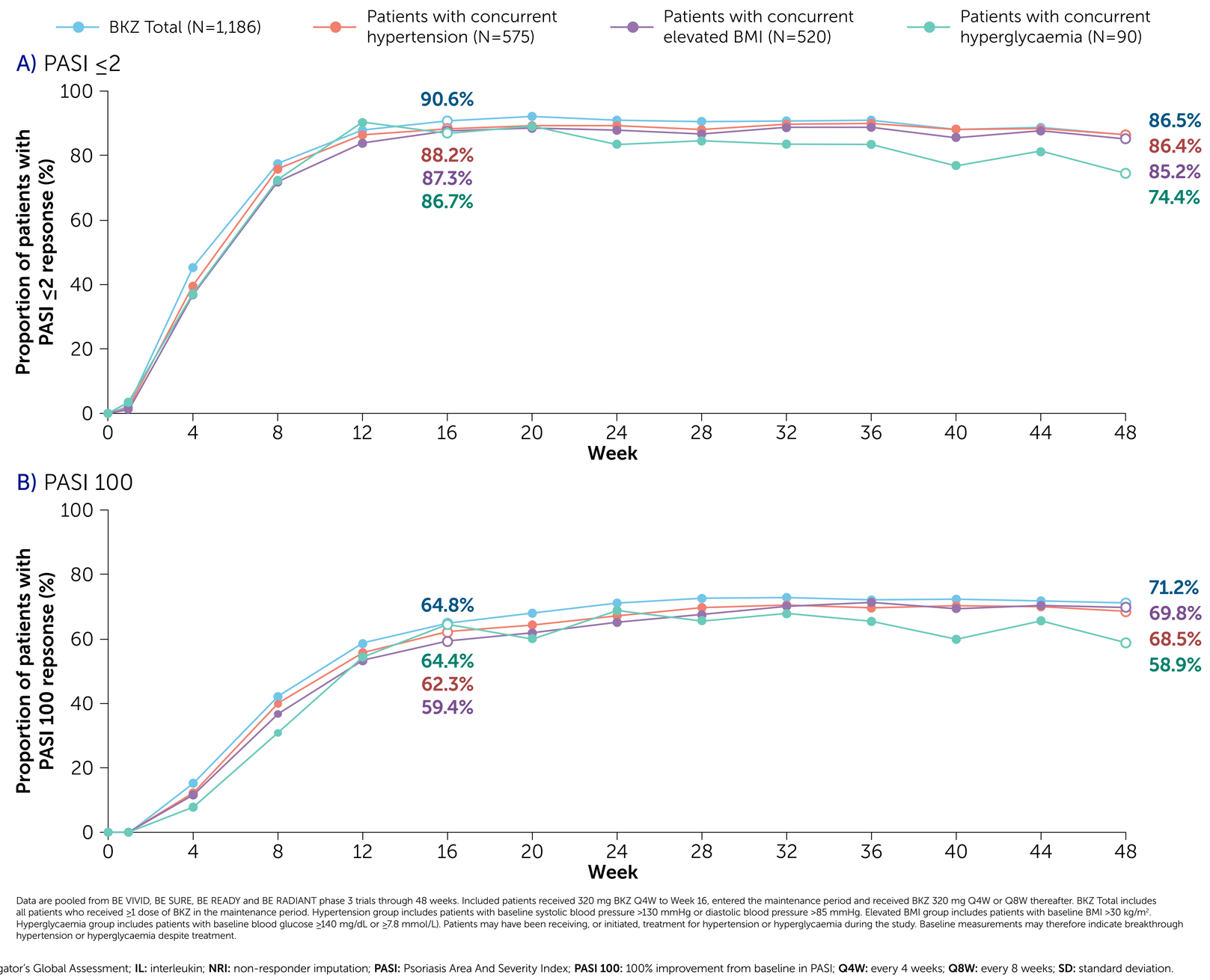
Patients included in this analysis were initially randomised to BKZ 320 mg Q4W and received ≥1 dose of BKZ in the maintenance period.

Table 1 Baseline characteristics

	BKZ Total[a] (N=1,186)	Patients with concurrent hypertension (N=575)	Patients with concurrent elevated BMI (N=520)	Patients with concurrent hyperglycaemia (N=90)
Age (years), mean ± SD	45.3 ± 13.8	47.9 ± 13.0	47.9 ± 12.6	52.8 ± 10.6
Caucasian, n (%)	1,034 (87.2)	502 (87.3)	464 (89.2)	69 (76.7)
Weight (kg), mean ± SD	89.4 ± 21.9	93.8 ± 21.5	106.6 ± 18.9	98.4 ± 22.8
Duration of psoriasis (years), mean ± SD	18.2 ± 12.6	19.6 ± 12.7	19.3 ± 13.1	21.4 ± 13.4
PASI, mean ± SD	20.8 ± 7.6	21.0 ± 7.7	21.3 ± 7.7	20.7 ± 7.9
BSA (%), mean ± SD	26.3 ± 15.7	27.5 ± 16.2	26.8 ± 16.0	24.9 ± 14.0
IGA, n (%)				
3: moderate	778 (65.6)	367 (63.8)	317 (61.0)	60 (66.7)
4: severe	405 (34.1)	208 (36.2)	202 (38.8)	30 (33.3)
DLQI score, mean ± SD	10.6 ± 6.4	10.3 ± 6.5	10.2 ± 6.4	9.8 ± 5.9
Any prior systemic therapy, n (%)	914 (77.1)	449 (78.1)	384 (73.8)	66 (73.3)
Any prior biologic therapy, n (%)	442 (37.3)	218 (37.9)	204 (39.2)	38 (42.2)

[a]All patients who were initially randomised to BKZ 320 mg Q4W and received ≥1 dose of BKZ in the maintenance period.

Figure 2 Response to BKZ treatment in patients with concurrent hypertension, elevated BMI and hyperglycaemia (NRI)



Data are pooled from BE VIVID, BE SURE, BE READY and BE RADIANT phase 3 trials through 48 weeks. Included patients received 320 mg BKZ Q4W to Week 16, entered the maintenance period and received BKZ 320 mg Q4W or Q8W thereafter. BKZ Total includes all patients who received ≥1 dose of BKZ in the maintenance period. 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/m^2. Hyperglycaemia group includes patients with baseline blood glucose ≥140 mg/dL or ≥7.8 mmol/L). Patients may have been receiving, or initiated, treatment for hypertension or hyperglycaemia during the study. Baseline measurements may therefore indicate breakthrough hypertension or hyperglycaemia despite treatment.

BKZ: bimekizumab; **BMI:** body mass index; **BSA:** body surface area; **DLQI:** Dermatology Life Quality Index; **IGA:** Investigator's Global Assessment; **IL:** interleukin; **NRI:** non-responder imputation; **PASI:** Psoriasis Area And Severity Index; **PASI 100:** 100% improvement from baseline in PASI; **Q4W:** every 4 weeks; **Q8W:** every 8 weeks; **SD:** standard deviation.

Institutions: [1]Keck School of Medicine of USC, Dermatology, Los Angeles, California, USA; [2]Wake Forest University School of Medicine, Dermatology, Winston-Salem, North Carolina, USA; [3]Dermatology and Venereology, Department of Medicine, Università di Verona, Verona, Italy; [4]Department of Medicine, Karolinska Institutet, Solna, Sweden; [5]UCB Pharma, Morrisville, North Carolina, USA; [6]UCB Pharma, Monheim, Germany; [7]UCB Pharma, Braine-l'Alleud, Belgium; [8]Psoriasis-Center, Department of Dermatology, University Medical Center Schleswig-Holstein, Campus Kiel, Germany.

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