Bimekizumab Efficacy Across Subgroups of Patients with Moderate to Severe Plaque Psoriasis: Pooled Results from Three Multicenter, Randomized, Double-Blinded Phase 3 Trials

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Objectives

To assess 52-week treatment efficacy across subgroups of patients with moderate to severe plaque psoriasis who achieved absolute PASI≤2 and PASI=0 after 16 weeks of BKZ treatment.

Introduction

- Patient characteristics and baseline disease severity can impact the response to treatment with biologic therapies.[1]
- Bimekizumab (BKZ) is a monoclonal IgG1 antibody that selectively inhibits both interleukin (IL)-17A and IL-17F.[2,3]
- BKZ has demonstrated superior efficacy to placebo, ustekinumab, adalimumab, and secukinumab for the treatment of patients with moderate to severe plaque psoriasis.[4–7]

Methods

- Data were pooled from three phase 3 trials: BE VIVID (NCT03370133), BE READY (NCT03410992), and BE SURE (NCT03412747).[4–6]
- Included patients achieved Psoriasis Area and Severity Index (PASI)≤2 or PASI=0 at Week 16 after randomization to BKZ 320 mg every 4 weeks (Q4W), receiving either BKZ 320 mg Q4W or every 8 weeks (Q8W) from Week 16.
- Maintenance of Week 16 PASI≤2 and PASI=0 responses at Week 52 are reported for selected patient subgroups by age, weight, disease duration, disease severity, and prior biologic exposure.
- Missing data were imputed as non-response (NRI).

Results

- Patient demographics and baseline characteristics are reported in **Table 1**.
- 989 patients were randomized to BKZ at Week 0. These analyses include 749 patients who achieved PASI≤2 at Week 16 (511 and 238 then received BKZ 320 mg Q4W and Q8W), of whom 537 achieved PASI=0 (355 and 182 then received BKZ 320 mg Q4W and Q8W) **(Figure 1)**.
- Maintenance of PASI≤2 at Week 52 among Week 16 responders was achieved by >86% of patients across the selected subgroups. Maintenance of response was similar between Q4W/Q8W dosing groups **(Figure 2A)**.
- Maintenance of PASI=0 at Week 52 among Week 16 responders was achieved by >81% of patients across the selected subgroups. Maintenance of response was similar between Q4W/Q8W dosing groups **(Figure 2B)**.

Summary

Patients in pooled subgroups were assessed for maintenance of Week 16 absolute PASI≤2 and PASI=0 responses through Week 52

Patient demographics

Age
- <40 years
- 40–<65 years
- ≥65 years

Weight
- ≤100 kg
- >100 kg

Disease characteristics

Duration
- <Median
- ≥Median

Severity
- PASI≤15
- PASI>15
- IGA=3
- IGA=4

Prior biologic exposure

Anti-TNF
- Yes/No

Anti-IL-17
- Yes/No

BKZ 320 mg Q4W (N=511) — 90.0%

BKZ 320 mg Q8W (N=238) — 90.3%

PASI≤2 maintained

BKZ 320 mg Q4W (N=355) — 83.1%

BKZ 320 mg Q8W (N=182) — 88.5%

PASI=0 maintained

Among Week 16 responders, high levels of skin clearance were maintained across subgroups through Week 52 with both BKZ Q4W and Q8W maintenance dosing regimens

Table 1 Baseline demographics and disease characteristics

	BKZ 320 mg Q4W		BKZ 320 mg Q8W	
	PASI≤2 (N=511)	PASI=0 (N=355)	PASI≤2 (N=238)	PASI=0 (N=182)
Age (years), mean ± SD	44.5 ± 13.3	44.7 ± 13.3	44.8 ± 13.5	44.8 ± 13.4
Male, n (%)	351 (68.7)	246 (69.3)	171 (71.8)	127 (69.8)
Caucasian, n (%)	416 (81.4)	298 (83.9)	219 (92.0)	169 (92.9)
Weight (kg), mean ± SD	88.0 ± 20.9	86.3 ± 19.0	89.5 ± 20.4	88.7 ± 19.6
Duration of psoriasis (years), mean ± SD	17.4 ± 12.2	17.1 ± 11.9	19.2 ± 12.4	19.2 ± 12.6
PASI, mean ± SD	21.6 ± 7.8	21.5 ± 7.3	19.9 ± 6.5	20.4 ± 6.9
BSA (%), mean ± SD	27.7 ± 16.3	27.2 ± 15.6	24.3 ± 12.6	24.6 ± 12.9
IGA, n (%)				
3: moderate	331 (64.8)	230 (64.8)	172 (72.3)	127 (69.8)
4: severe	179 (35.0)	124 (34.9)	66 (27.7)	55 (30.2)
DLQI, mean ± SD	10.4 ± 6.5	10.7 ± 6.4	10.7 ± 6.3	11.0 ± 6.4
Prior biologic therapy, n (%)	200 (39.1)	147 (41.4)	90 (37.8)	71 (39.0)
anti-TNF	75 (14.7)	57 (16.1)	23 (9.7)	17 (9.3)
anti-IL-17	124 (24.3)	90 (25.4)	57 (23.9)	41 (22.5)
anti-IL-12/23	22 (4.3)	14 (3.9)	19 (8.0)	15 (8.2)
anti-IL-23	21 (4.1)	16 (4.5)	13 (5.5)	13 (7.1)

Figure 1 Study design: Pooled subgroup analyses

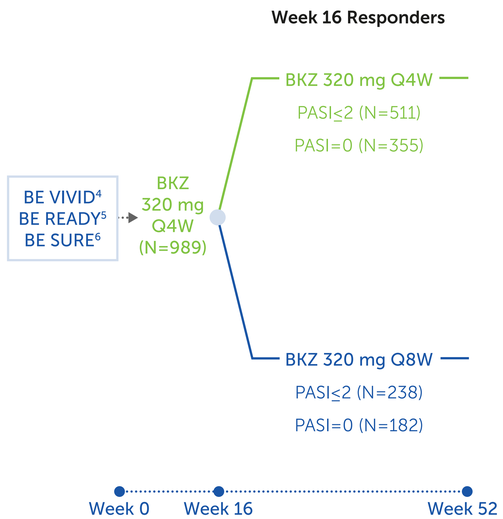
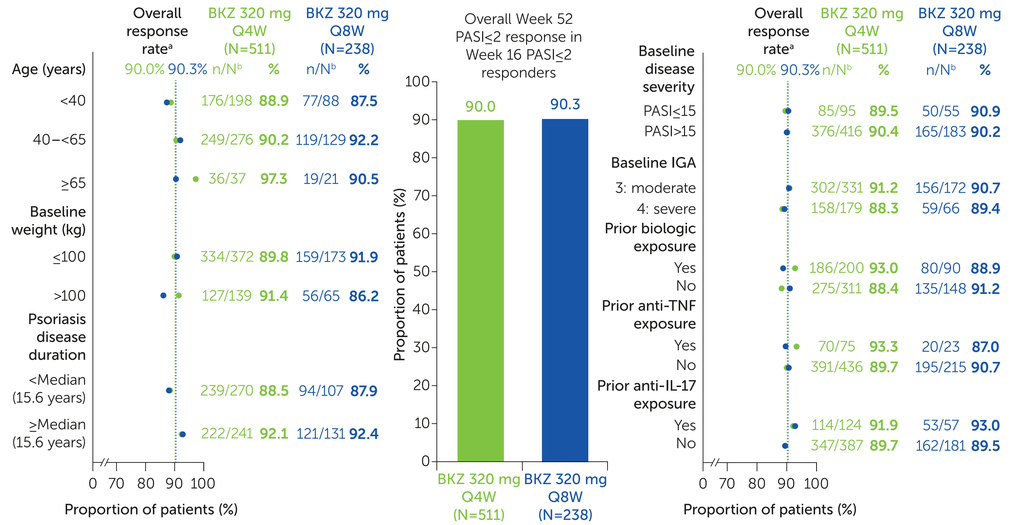


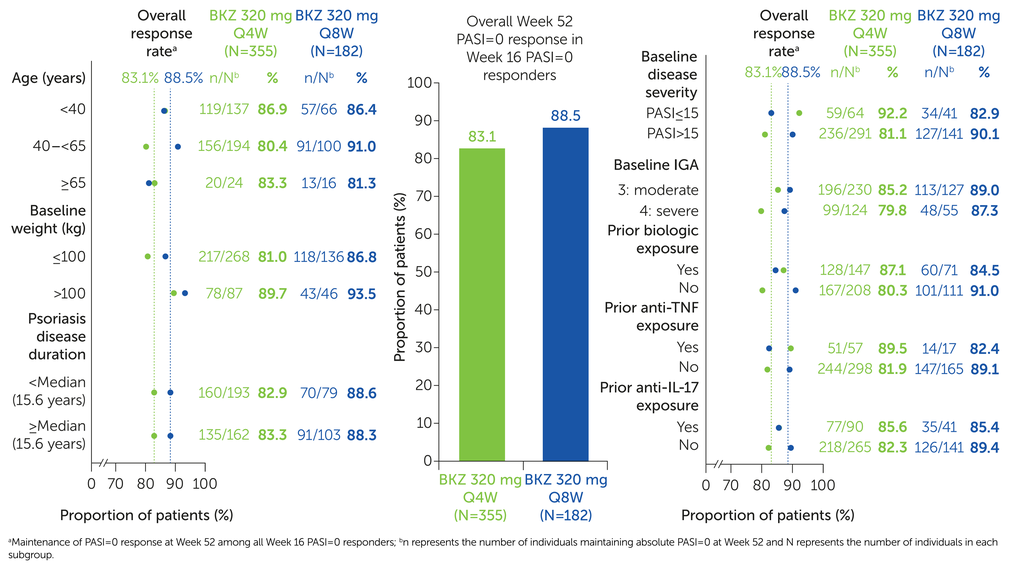
Figure 2 Maintenance of Week 16 absolute PASI responses at Week 52 (NRI)

A) PASI≤2



[a]Maintenance of PASI≤2 response at Week 52 among all Week 16 PASI≤2 responders; [b]n represents the number of patients maintaining absolute PASI≤2 at Week 52 and N represents the total number of patients in each subgroup.

B) PASI=0



[a]Maintenance of PASI=0 response at Week 52 among all Week 16 PASI=0 responders; [b]n represents the number of individuals maintaining absolute PASI=0 at Week 52 and N represents the number of individuals in each subgroup.

BKZ: bimekizumab; BSA: body surface area; DLQI: Dermatology Life Quality Index; IGA: Investigator's Global Assessment; IL: interleukin; max: maximum; min: minimum; NRI: non-responder imputation; OC: observed case; PASI: Psoriasis Area and Severity Index; Q4W: every 4 weeks; Q12W: every 12 weeks; SD: standard deviation; TNF: tumor necrosis factor; UST: ustekinumab.

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Conclusions

Among Week 16 PASI≤2 and PASI=0 responders, high levels of skin clearance were maintained through Week 52 with both BKZ Q4W and Q8W maintenance dosing regimens.

Responses were maintained regardless of patient subgroups: age, weight, disease duration, disease severity, and prior biologic exposure.

These results support BKZ as a suitable treatment for moderate to severe plaque psoriasis across all subgroups of patients analyzed.