1622

Bimekizumab clinical efficacy translates into benefits in patient-perceived symptoms and quality of life in patients with moderate to severe plaque psoriasis: Two-year data from BE RADIANT

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Objective

To examine how achievement of absolute Psoriasis Area and Severity Index (PASI) thresholds translates into patient-perceived symptom and health-related quality of life (HRQoL) benefits in bimekizumab (BKZ)-treated patients with moderate to severe plaque psoriasis, including patients switching from secukinumab (SEC).

Background

- BKZ, a monoclonal IgG1 antibody that selectively inhibits IL-17F in addition to IL-17A,[1] 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 SEC, with established long-term durability of response.[2–6]
- Psoriasis can negatively impact patients' HRQoL through physical and psychological burdens.[7]
- In previous analyses, BKZ has shown greater improvements in clinical outcomes vs SEC,[5] which translated into greater improvements in HRQoL over 1 year.[8] It is important to understand whether improvements in skin clearance and disease control are perceived by patients, and whether they translate into improved HRQoL, in the longer term.
- The Psoriasis Symptoms and Impacts Measure (P-SIM) is a novel, reliable and well-defined patient-reported outcome (PRO) tool which captures key symptoms of psoriasis (including itching, skin pain and scaling; scored from 0 [no symptom] to 10 [very severe symptom] on a numeric rating scale).[9]
- The Dermatology Life Quality Index (DLQI) is an established PRO measure of skin disease impact on HRQoL.[10]

Methods

- These analyses include 96-week (2-year) data from the BE RADIANT phase 3b trial, comprising a 48-week (1-year) double-blinded period followed by 48 weeks of its ongoing open-label extension (OLE; **Figure 1**).[5]
- Upon OLE entry, BKZ-randomised patients continued to receive BKZ (BKZ/BKZ) and SEC-randomised patients underwent a mandatory switch to BKZ (SEC/BKZ). OLE BKZ dosing (320 mg Q4W or Q8W) was assigned based on Week 48 PASI response and maintenance period treatment/dose.
- Percentages of patients with simultaneous achievement of PASI=0/PASI ≤2 (complete skin clearance/disease control)[11] and P-SIM=0 (itching, skin pain or scaling items)[9] or DLQI 0/1 (no effect of skin disease on a patient's life)[10] at Week 96 are reported as observed case (OC).
- Results are reported for BKZ/BKZ and SEC/BKZ patients, in addition to the subset of BKZ/BKZ patients who received BKZ Q4W/Q8W/Q8W (initial/maintenance/OLE) dosing.

Results

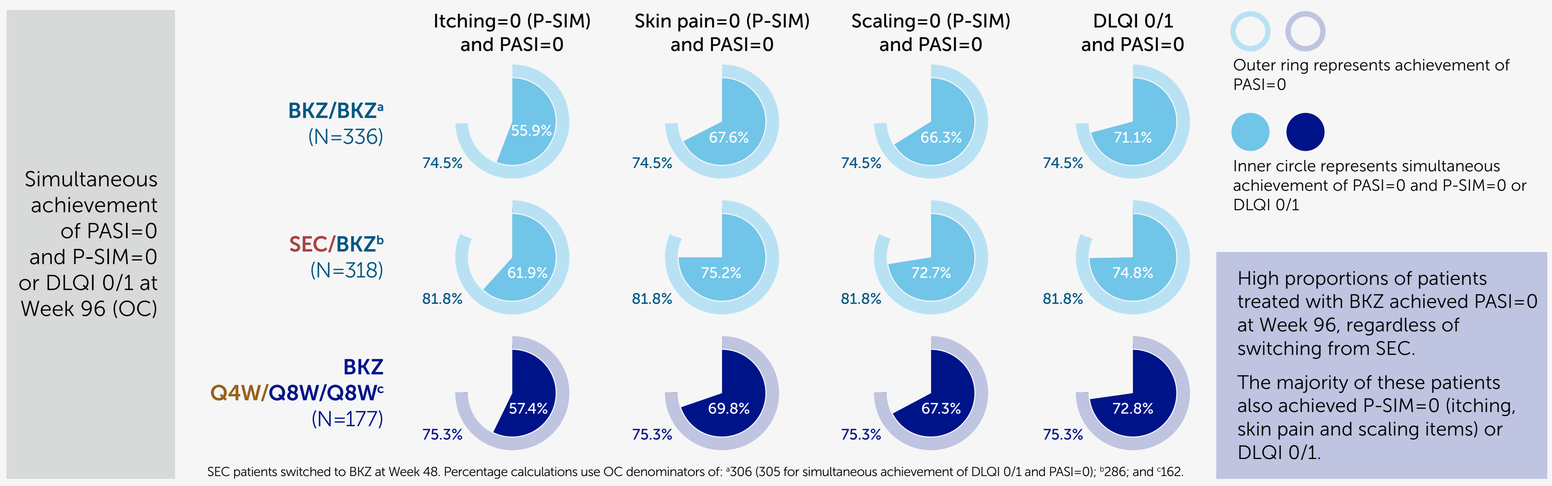
- At Week 48, 654 patients (336 BKZ, 318 SEC) entered the OLE.
- Baseline characteristics were similar between those initially randomised to BKZ and SEC and the subset of patients who received BKZ Q4W/Q8W/Q8W dosing (**Table 1**).
- At Week 48, BKZ-randomised patients had greater rates of simultaneous achievement of PASI=0/PASI ≤2 and P-SIM=0 or DLQI 0/1 versus SEC-randomised patients (**Figures 2A–D**,**Table 2**).
- At Week 96, the proportions of patients receiving BKZ/BKZ, SEC/BKZ and BKZ Q4W/Q8W/Q8W who achieved PASI=0 and PASI ≤2 were high and comparable (**Table 2**).
- High simultaneous achievement rates of PASI=0/PASI ≤2 and P-SIM=0 or DLQI 0/1 were maintained through to Week 96 for continuous BKZ-treated patients; SEC-randomised patients experienced increases in rates after switching to BKZ (**Figures 2A–D**, **Table 2**).

Conclusions

BKZ patients experienced higher rates of clinical responses, which translated into greater patient-perceived symptom and HRQoL benefits, versus SEC at 1 year.

High rates of response were sustained through 2 years in patients treated continuously with BKZ. SEC-randomised patients achieved increased rates of simultaneous achievement of PASI=0/PASI ≤2 and P-SIM=0 or DLQI 0/1 after switching to BKZ. Responses were similarly high in those who received BKZ Q4W/Q8W/Q8W dosing, the approved regimen for the vast majority of patients.

Summary

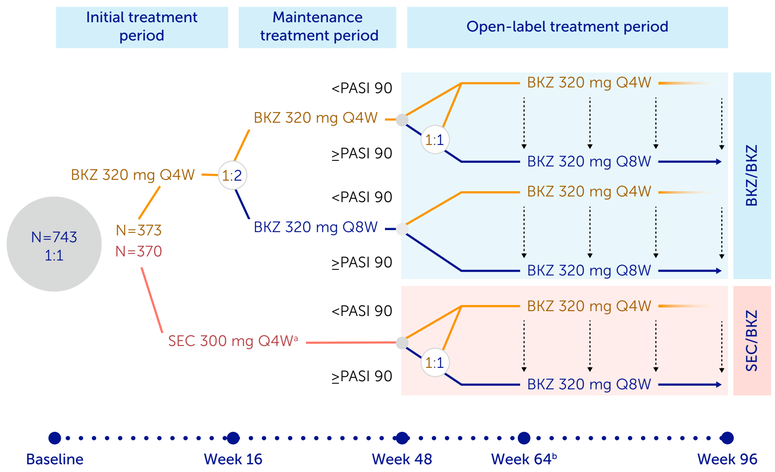


SEC patients switched to BKZ at Week 48. Percentage calculations use OC denominators of: [a]306 (305 for simultaneous achievement of DLQI 0/1 and PASI=0); [b]286; and [c]162.

High proportions of patients treated with BKZ achieved PASI=0 at Week 96, regardless of switching from SEC.

The majority of these patients also achieved P-SIM=0 (itching, skin pain and scaling items) or DLQI 0/1.

Figure 1 BE RADIANT study design



[a]SEC was dosed weekly to Week 4, then Q4W thereafter; [b]Following a protocol amendment, patients receiving BKZ 320 mg Q4W were switched to BKZ Q8W at Week 64 or the next scheduled clinic visit. In the BKZ/BKZ group, BKZ Q4W and Q8W maintenance and open-label treatment arms are pooled and in the SEC/BKZ group, BKZ Q4W and Q8W open-label treatment arms are pooled.

Table 1 Baseline characteristics

	BKZ/BKZ[a] (N=336)	SEC/BKZ[b] (N=318)	BKZ Q4W/Q8W/Q8W[c] (N=177)
Age (years), mean ± SD	45.5 ± 14.3	44.5 ± 14.5	44.9 ± 14.2
Male, n (%)	227 (67.6)	209 (65.7)	125 (70.6)
White, n (%)	312 (92.9)	301 (94.7)	169 (95.5)
Weight (kg), mean ± SD	90.2 ± 21.0	89.1 ± 19.5	89.9 ± 20.7
Duration of psoriasis (years), mean ± SD	18.4 ± 13.1	17.5 ± 12.1	18.5 ± 12.8
PASI, mean ± SD	20.3 ± 7.7	19.5 ± 6.1	20.4 ± 8.0
BSA (%), mean ± SD	25.3 ± 16.0	23.0 ± 13.3	24.6 ± 14.8
IGA, n (%)			
3: moderate	214 (63.7)	234 (73.6)	115 (65.0)
4: severe	120 (35.7)	84 (26.4)	60 (33.9)
DLQI total score, mean ± SD	10.9 ± 6.7	11.2 ± 7.3	10.5 ± 6.7
P-SIM item score, mean ± SD			
Itching	6.6 ± 2.8	6.6 ± 2.7	6.2 ± 2.9
Skin pain	4.5 ± 3.3	4.6 ± 3.1	4.2 ± 3.3
Scaling	6.7 ± 2.5	6.7 ± 2.4	6.4 ± 2.7
Any prior systemic therapy, n (%)	241 (71.7)	237 (74.5)	131 (74.0)
Prior biologic therapy, n (%)	114 (33.9)	105 (33.0)	56 (31.6)

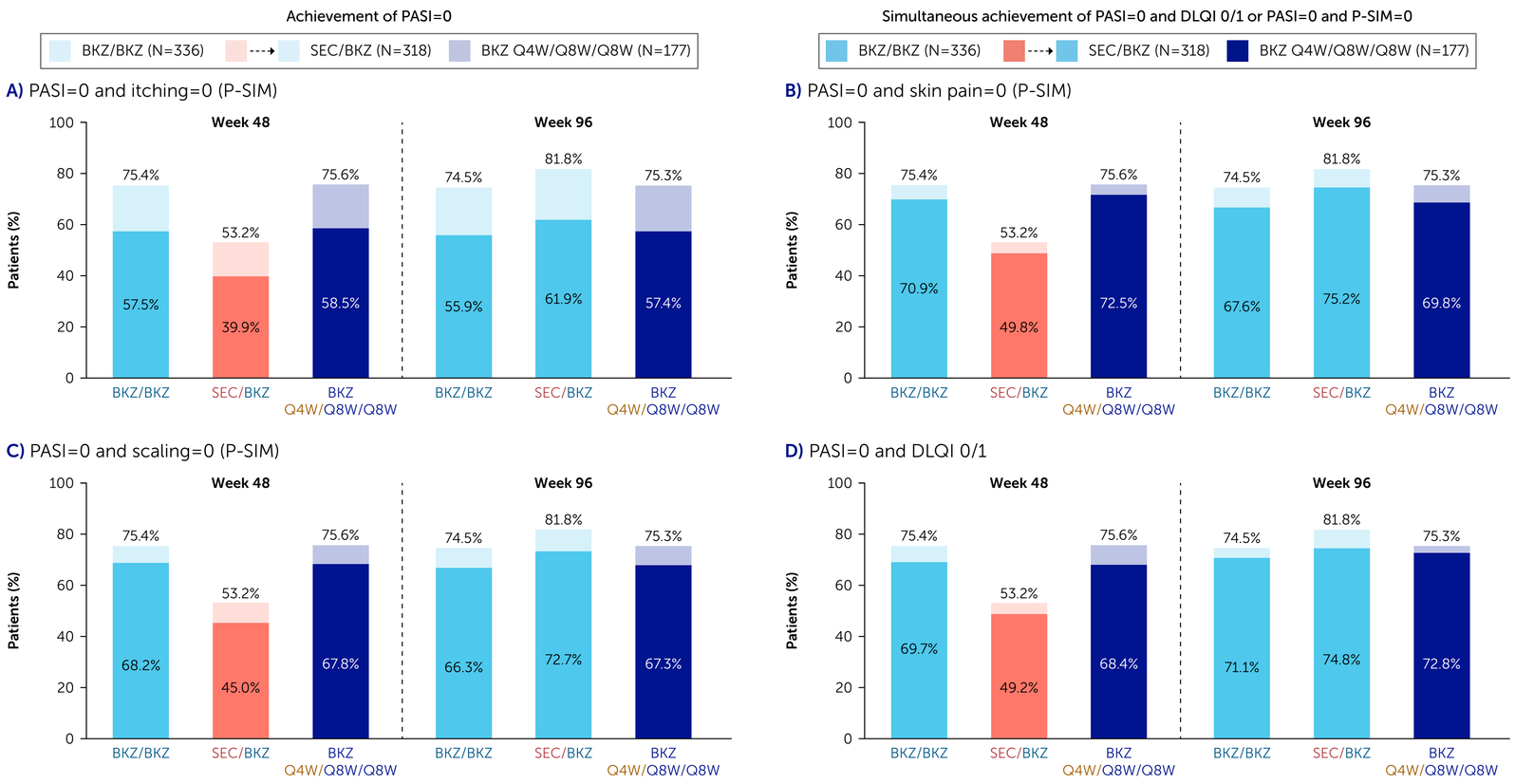
[a]BKZ/BKZ patients were randomised to receive BKZ and continued on BKZ in the OLE; [b]SEC/BKZ patients were randomised to SEC and switched to BKZ on OLE entry; [c]BKZ Q4W/Q8W/Q8W patients were randomised to BKZ Q4W for the initial treatment period, received BKZ Q8W during the maintenance period and BKZ Q8W from OLE entry.

Table 2 Simultaneous achievement of PASI thresholds and P-SIM=0 (itching, skin pain and scaling) or DLQI 0/1 at Weeks 48 and 96 (OC)

		Patients achieving PASI thresholds, % (n/N)		Patients achieving PASI threshold and itching=0 (P-SIM), % (n/N)		Patients achieving PASI threshold and skin pain=0 (P-SIM), % (n/N)		Patients achieving PASI threshold and scaling=0 (P-SIM), % (n/N)		Patients achieving PASI threshold and DLQI 0/1, % (n/N)	
		PASI=0	PASI ≤2	PASI=0	PASI ≤2	PASI=0	PASI ≤2	PASI=0	PASI ≤2	PASI=0	PASI ≤2
Week 48	BKZ/BKZ (N=336)	75.4 (248/329)	94.2 (310/329)	57.5 (188/327)	66.7 (218/327)	70.9 (232/327)	85.0 (278/327)	68.2 (223/327)	78.0 (255/327)	69.7 (228/327)	84.4 (276/327)
	SEC/BKZ (N=318)	53.2 (167/314)	84.1 (264/314)	39.9 (125/313)	53.7 (168/313)	49.8 (156/313)	73.2 (229/313)	45.0 (141/313)	55.9 (175/313)	49.2 (154/313)	74.4 (233/313)
	BKZ Q4W/Q8W/Q8W (N=177)	75.6 (130/172)	98.8 (170/172)	58.5 (100/171)	71.3 (122/171)	72.5 (124/171)	91.8 (157/171)	67.8 (116/171)	81.9 (140/171)	68.4 (117/171)	88.3 (151/171)
Week 96	BKZ/BKZ (N=336)	74.5 (228/306)	95.8 (293/306)	55.9 (171/306)	65.4 (200/306)	67.6 (207/306)	84.0 (257/306)	66.3 (203/306)	77.5 (237/306)	71.1 (217/305)	87.5 (267/305)
	SEC/BKZ (N=318)	81.8 (234/286)	96.2 (275/286)	61.9 (177/286)	66.4 (190/286)	75.2 (215/286)	83.6 (239/286)	72.7 (208/286)	77.6 (222/286)	74.8 (214/286)	84.6 (242/286)
	BKZ Q4W/Q8W/Q8W (N=177)	75.3 (122/162)	96.9 (157/162)	57.4 (93/162)	68.5 (111/162)	69.8 (113/162)	87.0 (141/162)	67.3 (109/162)	80.2 (130/162)	72.8 (118/162)	89.5 (145/162)

Within the columns, N represents the number of patients with an assessment of the relevant outcome at that timepoint. For simultaneous achievement of two outcomes, N represents the number of patients with both a PASI and DLQI, or PASI and P-SIM, assessment at that time point. n represents the number of patients who achieved the relevant outcome at that timepoint. For simultaneous achievement, n represents the number of patients with simultaneous achievement of PASI=0/PASI ≤2 and P-SIM=0 (itching, skin pain or scaling items) or DLQI 0/1.

Figure 2 Achievement of PASI=0 in combination with P-SIM=0 and DLQI 0/1 at Weeks 48 and 96 (OC)



Data are reported as observed case (numbers of patients contributing to percentage calculations are displayed in Table 2). Lighter shaded bars indicate achievement of PASI=0 and darker shaded bars indicate simultaneous achievement of PASI=0 and P-SIM=0 (itching, skin pain and scaling) or DLQI 0/1.

BKZ: bimekizumab; **BSA:** body surface area; **DLQI:** Dermatology Life Quality Index; **HRQoL:** health-related quality of life; **IGA:** Investigator's Global Assessment; **OC:** observed case; **OLE:** open-label extension; **PASI:** Psoriasis Area and Severity Index; **PASI 90:** ≥90% improvement from baseline in PASI; **PRO:** patient-reported outcome; **P-SIM:** Psoriasis Symptoms and Impacts Measure; **Q4W:** every 4 weeks; **Q8W:** every 8 weeks; **SEC:** secukinumab; **SD:** standard deviation.

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