Bimekizumab 3-year efficacy in high-impact areas in moderate to severe plaque psoriasis: Pooled results from five phase 3/3b trials

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Background

- Psoriatic lesions of the scalp, palms, and soles, and psoriatic changes in the nails are associated with reduced health-related quality of life and treatment challenges.[1]
- As psoriasis is a chronic disease, and loss of response is observed with some therapies over time, studying long-term efficacy of new treatments is important.[2]
- High levels of complete clearance in these high-impact areas have previously been reported over 2 years of BKZ treatment;[3] here, we report responses over 3 years.

Objective

To evaluate scalp, palmoplantar, and nail outcomes over 3 years from five bimekizumab (BKZ) phase 3/3b trials in patients with moderate to severe plaque psoriasis.

Methods

- Data were pooled from BE VIVID/BE READY/BE SURE (52/56/56 weeks), 96 weeks of their open-label extension (OLE), BE BRIGHT, and 144 weeks of the BE RADIANT phase 3b trial (**Figure 1**).[4–8]
- Data are reported for patients randomized to BKZ 320 mg every 4 weeks (Q4W) to Week 16, who then received BKZ Q4W or Q8W in the maintenance and OLE periods (BKZ Total); data are also reported for the subgroup of patients who received BKZ Q4W/Q8W/Q8W (initial/maintenance/OLE) dosing.
- Included patients had moderate to severe scalp or palmoplantar involvement (i.e., scalp or palmoplantar [pp-] Investigator's Global Assessment [IGA] score ≥3) or a modified Nail Psoriasis Severity Index (mNAPSI) score >10 at baseline (see **Summary**).
- Proportions of patients who achieved complete regional clearance (scalp IGA 0, pp-IGA 0, mNAPSI 0) are reported through Year 3 (OLE Week 96).
- 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 NRI and as observed case (OC).

Results

- Baseline characteristics for included patients are presented in **Table 1**.
- Among patients with scalp IGA ≥3 at baseline, high levels of complete clearance were attained after 16 weeks and sustained through 3 years (**Figure 2A**).
- Similar trends were observed in the proportions of patients achieving complete palmoplantar clearance among those with pp-IGA ≥3 at baseline (**Figure 2B**).
- Among patients with mNAPSI >10 at baseline, levels of complete clearance increased through Year 1 and were sustained to Year 3; rates of clearance were reflective of the longer timescale required for nail growth and repair (**Figure 2C**).
- Similar trends were observed in the subgroup of patients who received BKZ Q4W/Q8W/Q8W dosing (**Figure 2A–C**).

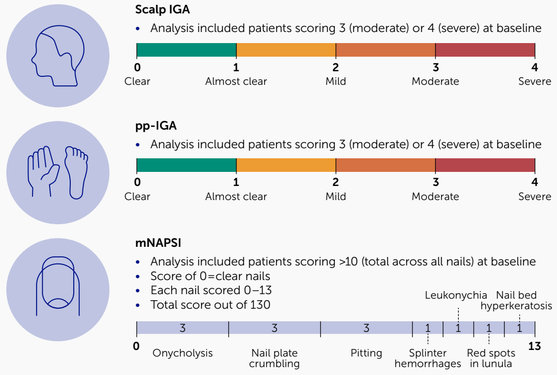
Conclusions

A high percentage of BKZ-treated patients achieved and maintained complete clearance of scalp and palmoplantar psoriasis over 3 years. The majority of patients achieved complete nail clearance, with numerical increases from Year 1 to Year 3.

Clearance rates were high, regardless of BKZ dosing regimen.

Summary

Tools used to assess high-impact area disease severity



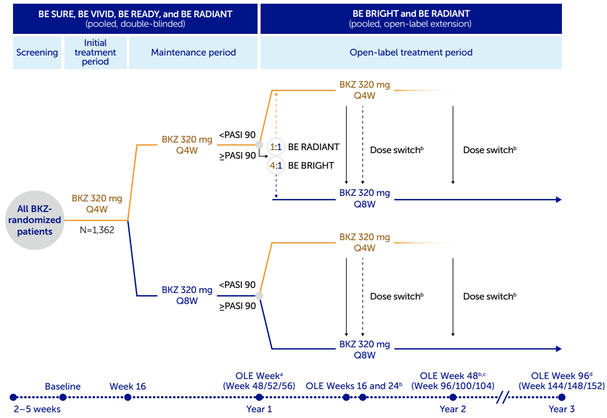
Over 3 years, high percentages of patients treated with bimekizumab achieved complete clearance of scalp (83.7%), palmoplantar (91.6%), and nail (69.5%) psoriasis, regardless of dosing regimen.

Table 1 Baseline characteristics

	Scalp IGA ≥3		pp-IGA ≥3		mNAPSI >10	
	BKZ Total (N=821)	BKZ Q4W/Q8W/Q8W (N=277)	BKZ Total (N=193)	BKZ Q4W/Q8W/Q8W (N=52)	BKZ Total (N=377)	BKZ Q4W/Q8W/Q8W (N=129)
Age (years), mean ± SD	44.8 ± 13.7	44.0 ± 13.9	45.0 ± 12.9	43.8 ± 11.5	44.8 ± 13.1	44.5 ± 13.2
Male, n (%)	569 (69.3)	192 (69.3)	144 (74.6)	41 (78.8)	316 (83.8)	107 (82.9)
White, n (%)	715 (87.1)	259 (93.5)	162 (83.9)	49 (94.2)	328 (87.0)	123 (95.3)
Weight (kg), mean ± SD	89.8 ± 21.4	88.8 ± 21.0	85.9 ± 18.7	87.0 ± 17.4	92.2 ± 20.7	92.1 ± 20.6
Duration of psoriasis (years), mean ± SD	18.1 ± 12.6	18.6 ± 12.4	17.7 ± 12.1	18.8 ± 9.8	18.9 ± 12.4	18.8 ± 12.2
PASI, mean ± SD	21.4 ± 8.0	20.9 ± 7.7	23.9 ± 9.0	26.9 ± 10.6	22.4 ± 8.5	21.6 ± 8.0
BSA (%), mean ± SD	26.6 ± 16.0	24.5 ± 13.5	30.5 ± 17.4	31.6 ± 15.6	28.9 ± 17.6	25.7 ± 13.8
IGA score, n (%)						
3: moderate	527 (64.2)	189 (68.2)	109 (56.5)	24 (46.2)	212 (56.2)	75 (58.1)
4: severe	294 (35.8)	88 (31.8)	83 (43.0)	27 (51.9)	163 (43.2)	53 (41.1)
DLQI total score, mean ± SD	10.8 ± 6.5	10.7 ± 6.6	11.3 ± 7.1	11.8 ± 7.0	10.7 ± 6.6	11.1 ± 6.0
Scalp IGA score, mean ± SD	3.2 ± 0.4	3.2 ± 0.4	3.0 ± 0.8	3.1 ± 0.7	2.8 ± 1.0	2.8 ± 0.9
mNAPSI score, mean ± SD	11.6 ± 17.8	11.1 ± 16.2	21.9 ± 28.0	22.9 ± 23.7	31.0 ± 20.5	28.2 ± 16.9
pp-IGA score, mean ± SD	0.9 ± 1.3	0.8 ± 1.2	3.2 ± 0.4	3.2 ± 0.4	1.3 ± 1.4	1.1 ± 1.4
Any prior systemic therapy, n (%)	635 (77.3)	209 (75.5)	163 (84.5)	45 (86.5)	297 (78.8)	100 (77.5)
Prior biologic therapy, n (%)	306 (37.3)	95 (34.3)	70 (36.3)	18 (34.6)	139 (36.9)	41 (31.8)

Baseline data are reported for patients who had scalp IGA ≥3, pp-IGA ≥3, or mNAPSI >10 at baseline and entered the OLEs.

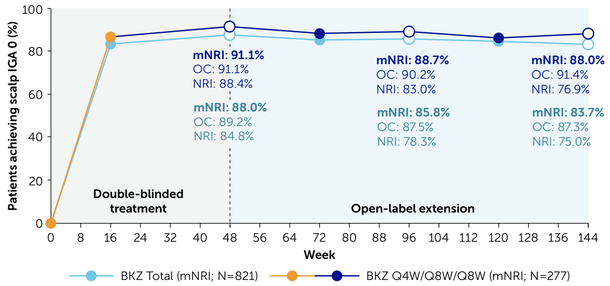
Figure 1 Study design (included patients)



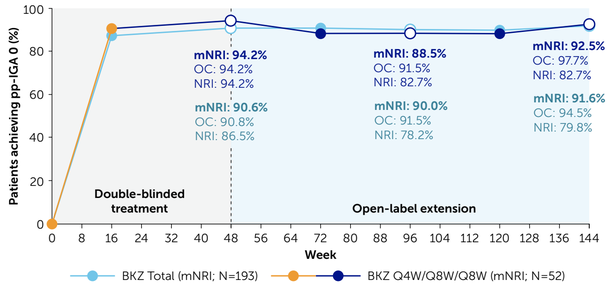
As this analysis only includes patients randomized to receive BKZ at baseline, only BKZ-randomized patients are included in this study design. [a]Patients receiving BKZ 320 mg Q4W who achieved ≥PASI 90 at the end of the feeder studies (BE RADIANT: Week 48; BE VIVID: Week 52; BE READY and BE SURE: Week 56) were randomized 1:1 in BE RADIANT and 4:1 in BE BRIGHT to BKZ 320 mg Q4W or Q8W; patients receiving BKZ 320 mg Q8W who achieved ≥PASI 90 at the end of the feeder studies remained on Q8W dosing; [b]In BE RADIANT, at OLE Week 16 or the next scheduled clinic visit, all patients switched to BKZ Q8W after the implementation of a protocol amendment; in BE BRIGHT, at OLE Week 24, patients achieving ≥PASI 90 could switch to Q8W at the investigator's discretion, and all patients were re-assigned to BKZ Q8W at OLE Week 48 or the next scheduled visit via protocol amendment; [c]OLE Week 48 (the end of Year 2) corresponds to BE RADIANT Week 96, BE VIVID/BE BRIGHT Week 100, and BE READY/BE BRIGHT and BE SURE/BE BRIGHT Week 104; [d]OLE Week 96 (the end of Year 3) corresponds to BE RADIANT Week 144, BE VIVID/BE BRIGHT Week 148, and BE READY/BE BRIGHT and BE SURE/BE BRIGHT Week 152.

Figure 2 Complete clearance of scalp, palmoplantar, or nail psoriasis over 3 years (mNRI, NRI, OC)

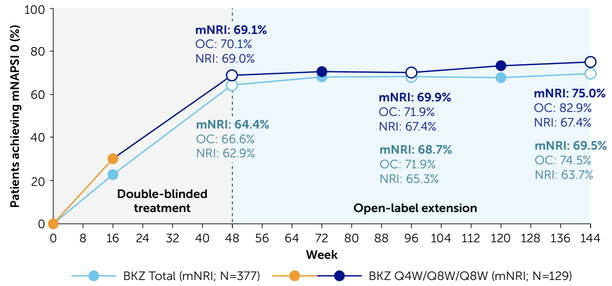
A) Scalp IGA 0 in patients with baseline scalp IGA ≥3



B) pp-IGA 0 in patients with baseline pp-IGA ≥3



C) mNAPSI 0 in patients with baseline mNAPSI >10



BKZ Total patients were randomized to receive BKZ 320 mg Q4W to Week 16, then received BKZ either Q4W or Q8W in the maintenance period and OLE. BKZ Q4W/Q8W/Q8W patients received BKZ 320 mg Q4W to Week 16, then BKZ Q8W throughout the maintenance period and on OLE entry. Due to differences in assessment schedules, no scalp, palmoplantar, or nail outcomes were collected at Week 48 in BE VIVID; therefore, Week 52 data from BE VIVID were included at the Week 48 timepoint. The BE READY and BE SURE feeder studies had a duration of 56 weeks, BE VIVID had a duration of 52 weeks, and BE RADIANT had a duration of 48 weeks; to pool the data across all four studies, Week 52/56 data from the feeder studies were otherwise not included. Therefore, timepoints after Week 48 in this figure are from the BE BRIGHT/BE RADIANT OLEs.

BKZ: bimekizumab; **BSA:** body surface area; **DLQI:** Dermatology Life Quality Index; **IGA:** Investigator's Global Assessment; **mNAPSI:** modified Nail Psoriasis Severity Index; **mNRI:** modified non-responder imputation; **NRI:** non-responder imputation; **OC:** observed case; **OLE:** open-label extension; **PASI 90:** ≥90% improvement from baseline in Psoriasis Area and Severity Index; **pp:** palmoplantar; **Q4W:** every 4 weeks; **Q8W:** every 8 weeks; **SD:** standard deviation.

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