

Bimekizumab 4-year efficacy in high-impact areas in moderate to severe plaque psoriasis: Pooled results from BE BRIGHT

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Objective

To assess the efficacy of bimekizumab (BKZ) over a 4-year period, focusing on psoriatic manifestations in the scalp, nail, and palmoplantar areas, which are known to significantly affect patients' quality of life.

Introduction

- Scalp and palmoplantar psoriasis and psoriatic changes in the nails can have a large impact on functional ability and health-related quality of life; these are referred to as high-impact areas.¹
- Though skin lesions can repair relatively quickly, nail repair can take between 6 and 9 months.²
- BKZ, a monoclonal immunoglobulin G1 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 adalimumab, ustekinumab, and secukinumab, with established long-term durability of response.⁴⁻⁷
- High levels of complete clearance in these high-impact areas have previously been reported over 3 years of BKZ treatment;⁸ here, outcomes are reported over 4 years, to further explore the long-term efficacy of BKZ in these areas.

Methods

- Data were pooled from the 52-week BE VIVID and 56-week BE READY and BE SURE phase 3 feeder studies, and 3 years of their open-label extension (OLE), BE BRIGHT.^{4,5,7,9}
- Included patients were randomised to receive BKZ 320 mg every 4 weeks (Q4W) to Week 16, then received BKZ either Q4W or every 8 weeks (Q8W) throughout the maintenance period into the OLE (BKZ Total).
- Data from a patient subset who received BKZ Q4W to Week 16 then Q8W thereafter (Q4W/Q8W), the approved dosing regimen for most patients with psoriasis,¹⁰ are also reported.
- High-impact areas were assessed using the following measures:
 - Scalp Investigator's Global Assessment (scalp IGA), a 5-point scale ranging from 0 to 4;
 - Modified Nail Psoriasis Severity Index (mNAPSI), ranging from 0 to 130 (total fingernail score);
 - Palmoplantar IGA, a 5-point scale ranging from 0 to 4.
- Proportions of patients with moderate to severe scalp or palmoplantar involvement (scalp or palmoplantar IGA ≥ 3) or mNAPSI >10 at baseline (who achieved complete clearance in these areas (scalp IGA 0, mNAPSI 0, palmoplantar IGA 0) are reported through Year 4 using modified non-responder imputation (mNRI):
 - Patients who discontinued treatment due to lack of efficacy or treatment-related adverse events were considered non-responders; multiple imputation was used for other missing data.
- Observed case (OC) data are also presented.

Results

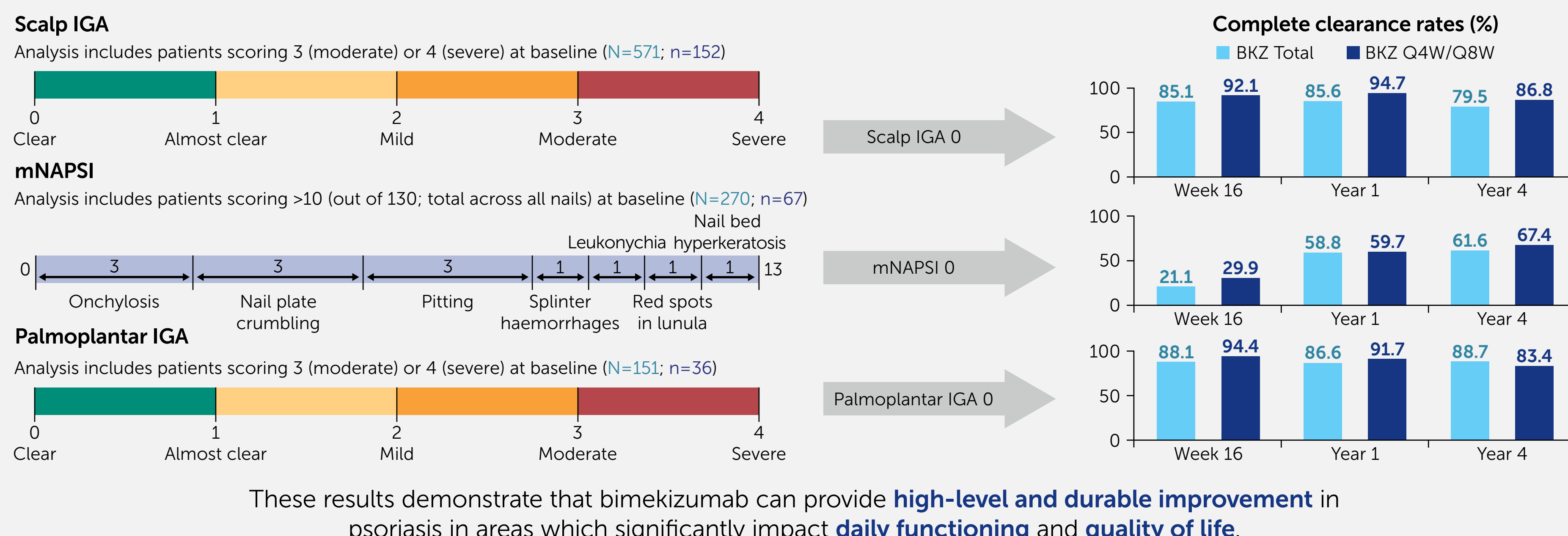
- Baseline characteristics are shown in **Table 1**.
- In total, 771 patients received BKZ from baseline into the OLE.
 - 571 (74.1%), 270 (35.0%), and 151 (19.6%) had baseline scalp IGA ≥ 3 , mNAPSI >10 , and palmoplantar IGA ≥ 3 , respectively.
- Of those patients, 197 received BKZ Q4W/Q8W.
 - 152 (77.2%), 67 (34.0%), and 36 (18.3%) had baseline scalp IGA ≥ 3 , mNAPSI >10 , and palmoplantar IGA ≥ 3 , respectively.
- A large majority of BKZ Total patients achieved complete clearance in scalp psoriasis at Year 1 (85.6%) and most maintained a clear scalp to Year 4 (79.5%; **Figure 1A**).
- More than half of BKZ Total patients achieved complete clearance in nail psoriasis at Year 1, and this rate increased to Year 2 and was sustained to Year 4, reflecting the longer timescale required for nail growth and repair (**Figure 1B**).²
- A large majority of BKZ Total patients achieved complete clearance in palmoplantar psoriasis at Year 1 (86.6%) and maintained this to Year 4 (88.7%; **Figure 1C**).
- Similar trends over the 4 years were observed in BKZ Q4W/Q8W patients (**Figure 1A-C**).

Conclusions

A high percentage of bimekizumab-treated patients achieved and maintained complete clearance of scalp and palmoplantar psoriasis over 4 years. Most achieved complete nail clearance by Year 1, with rates numerically increasing to Year 2 and remaining high through Year 4. Complete clearance rates were high regardless of dosing regimen.

Summary

Complete clearance rates in high-impact areas after 4 years of bimekizumab treatment (mNRI)



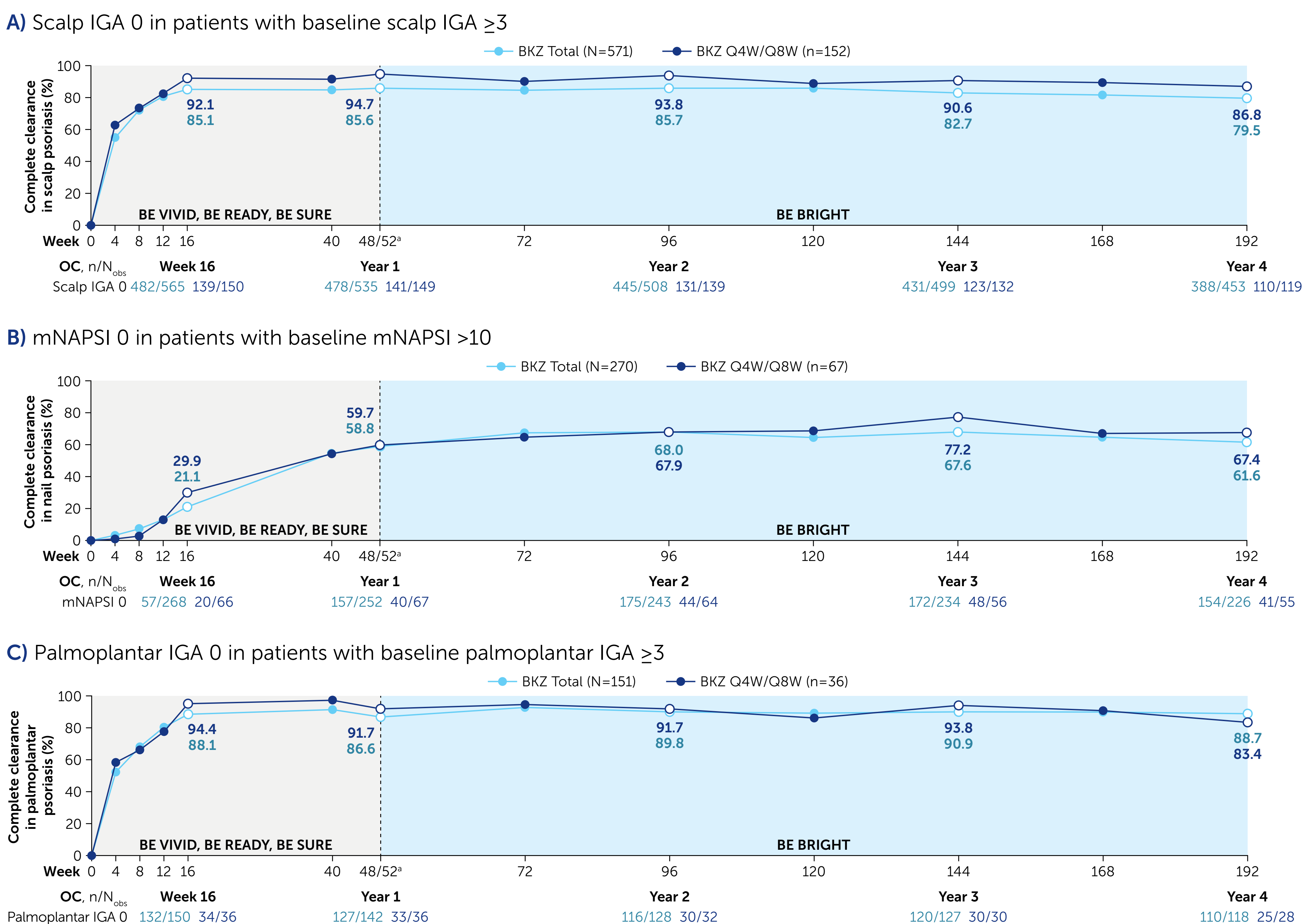
These results demonstrate that bimekizumab can provide high-level and durable improvement in psoriasis in areas which significantly impact daily functioning and quality of life.

Table 1 Baseline characteristics

	Scalp IGA ≥ 3		mNAPSI >10		Palmoplantar IGA ≥ 3	
	BKZ Total N=571	BKZ Q4W/Q8W n=152	BKZ Total N=270	BKZ Q4W/Q8W n=67	BKZ Total N=151	BKZ Q4W/Q8W n=36
Age (years), mean \pm SD	44.9 \pm 13.6	44.2 \pm 14.3	44.7 \pm 12.8	44.2 \pm 12.0	45.0 \pm 12.8	44.0 \pm 12.0
Sex, male, n (%)	402 (70.4)	104 (68.4)	230 (85.2)	57 (85.1)	120 (79.5)	31 (86.1)
Racial group, white, n (%)	485 (84.9)	140 (92.1)	228 (84.4)	64 (95.5)	126 (83.4)	35 (97.2)
Weight (kg), mean \pm SD	89.6 \pm 21.5	87.3 \pm 20.6	91.6 \pm 20.6	89.9 \pm 19.8	85.2 \pm 19.3	85.9 \pm 16.8
Duration of psoriasis (years), mean \pm SD	18.2 \pm 12.6	19.1 \pm 12.5	18.5 \pm 11.5	18.2 \pm 10.1	17.1 \pm 11.5	18.8 \pm 10.0
PASI, mean \pm SD	21.6 \pm 7.9	20.7 \pm 7.0	22.6 \pm 8.3	21.1 \pm 6.9	23.8 \pm 8.3	26.3 \pm 8.7
BSA (%), mean \pm SD	27.2 \pm 15.9	24.6 \pm 11.8	29.5 \pm 17.1	25.1 \pm 11.3	29.8 \pm 16.1	31.4 \pm 12.2
DLQI total, mean \pm SD	10.7 \pm 6.4	10.9 \pm 6.3	10.7 \pm 6.6	11.8 \pm 5.5	10.9 \pm 6.7	10.6 \pm 5.8
Scalp IGA, mean \pm SD	3.2 \pm 0.4	3.2 \pm 0.4	2.8 \pm 1.0	2.8 \pm 0.8	2.9 \pm 0.9	3.0 \pm 0.8
mNAPSI, mean \pm SD	12.1 \pm 18.2	11.1 \pm 15.2	32.1 \pm 21.3	29.2 \pm 17.2	22.4 \pm 28.6	20.7 \pm 22.4
Palmoplantar IGA, mean \pm SD	1.0 \pm 1.3	0.9 \pm 1.3	1.4 \pm 1.4	1.3 \pm 1.4	3.2 \pm 0.4	3.2 \pm 0.4
IGA, n (%)						
3: moderate	368 (64.4)	107 (70.4)	156 (57.8)	41 (61.2)	89 (58.9)	18 (50.0)
4: severe	203 (35.6)	45 (29.6)	113 (41.9)	26 (38.8)	62 (41.1)	18 (50.0)
Prior systemic therapy, n (%)	459 (80.4)	119 (78.3)	218 (80.7)	54 (80.6)	128 (84.8)	30 (83.3)
Prior biologic therapy, n (%)	219 (38.4)	54 (35.5)	99 (36.7)	22 (32.8)	50 (33.1)	10 (27.8)
Anti-TNF	74 (13.0)	12 (7.9)	40 (14.8)	5 (7.5)	24 (15.9)	0
Anti-IL-17	134 (23.5)	35 (23.0)	69 (25.6)	18 (26.9)	30 (19.9)	10 (27.8)
Anti-IL-12/23	35 (6.1)	11 (7.2)	12 (4.4)	5 (7.5)	3 (2.0)	1 (2.8)
Anti-IL-23	30 (5.3)	10 (6.6)	7 (2.6)	3 (4.5)	5 (3.3)	1 (2.8)

1a) One patient in the BKZ Total group with mNAPSI >10 at baseline scored IGA 2.

Figure 1 Complete clearance of scalp, nail, and palmoplantar psoriasis over 4 years (mNRI and OC)



1a) Week 48/52 data are from Week 48 of BE SURE and BE READY, and Week 52 of BE VIVID, due to differences in assessment schedules.

BKZ: bimekizumab; BSA: body surface area; DLQI: Dermatology Life Quality Index; IGA: Investigator's Global Assessment; IL: interleukin; mNAPSI: modified Nail Psoriasis Severity Index; mNRI: modified non-responder imputation; N_{obs}: observed N; OC: observed case; OLE: open-label extension; PASI: Psoriasis Area and Severity Index; Q4W: every 4 weeks; Q8W: every 8 weeks; SD: standard deviation; TNF: tumour necrosis factor.

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