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

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Synopsis

- Scalp and palmoplantar psoriasis, as well as 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]
- Bimekizumab (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.

Objective

To assess the efficacy of 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.

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 randomized 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

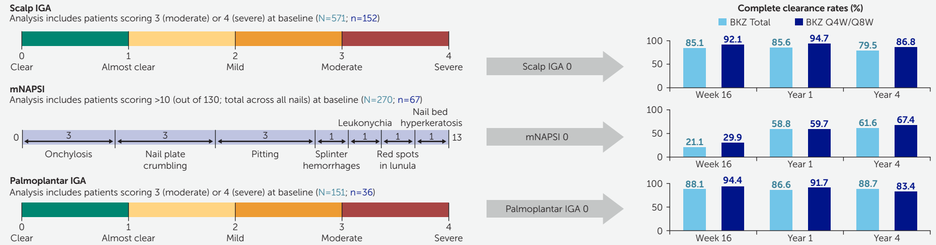
- Baseline characteristics are shown in **Table 1**.
- In total, 771 patients received BKZ from baseline into the OLE.
  - 571 (74.1%), 270 (35.0%), and 151 (19.6%) had baseline scalp IGA ≥3, mNAPSI >10, and palmoplantar IGA ≥3, respectively.
- Of those patients, 197 received BKZ Q4W/Q8W.
  - 152 (77.2%), 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**.

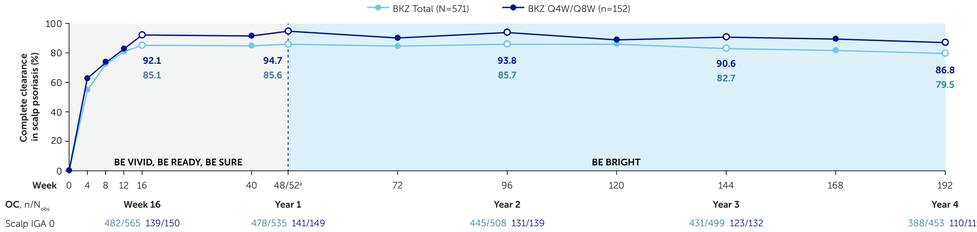
Table 1 Baseline characteristics

	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 ± SD	44.9 ± 13.6	44.2 ± 14.3	44.7 ± 12.8	44.2 ± 12.0	45.0 ± 12.8	44.0 ± 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 ± SD	89.6 ± 21.5	87.3 ± 20.6	91.6 ± 20.6	89.9 ± 19.8	85.2 ± 19.3	85.9 ± 16.8
Duration of psoriasis (years), mean ± SD	18.2 ± 12.6	19.1 ± 12.5	18.5 ± 11.5	18.2 ± 10.1	17.1 ± 11.5	18.8 ± 10.0
PASI, mean ± SD	21.6 ± 7.9	20.7 ± 7.0	22.6 ± 8.3	21.1 ± 6.9	23.8 ± 8.3	26.3 ± 8.7
BSA (%), mean ± SD	27.2 ± 15.9	24.6 ± 11.8	29.5 ± 17.1	25.1 ± 11.3	29.8 ± 16.1	31.4 ± 12.2
DLQI total, mean ± SD	10.7 ± 6.4	10.9 ± 6.3	10.7 ± 6.6	11.8 ± 5.5	10.9 ± 6.7	10.6 ± 5.8
Scalp IGA, mean ± SD	3.2 ± 0.4	3.2 ± 0.4	2.8 ± 1.0	2.8 ± 0.8	2.9 ± 0.9	3.0 ± 0.8
mNAPSI, mean ± SD	12.1 ± 18.2	11.1 ± 15.2	32.1 ± 21.3	29.2 ± 17.2	22.4 ± 28.6	20.7 ± 22.4
Palmoplantar IGA, mean ± SD	1.0 ± 1.3	0.9 ± 1.3	1.4 ± 1.4	1.3 ± 1.4	3.2 ± 0.4	3.2 ± 0.4
IGA,[a] 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)

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

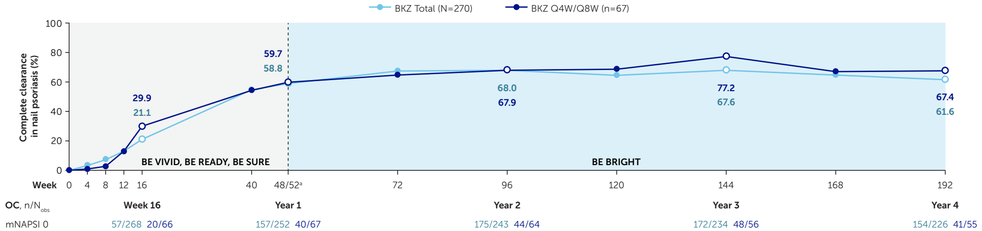
Figure 1 Complete clearance of scalp, nail, and palmoplantar psoriasis over 4 years (mNRI and OC)

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



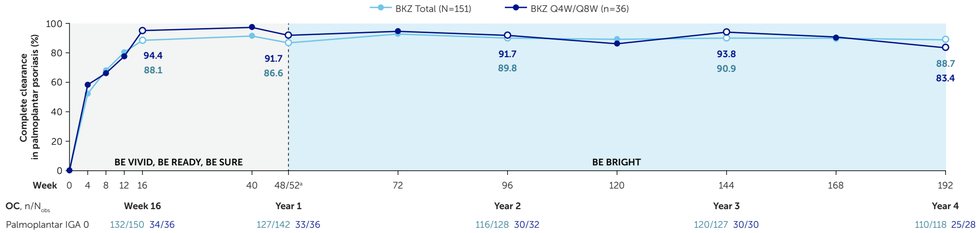
OC, n/N$_{obs}$	Week 16	Year 1	Year 2	Year 3	Year 4
Scalp IGA 0	482/565 139/150	478/535 141/149	445/508 131/139	431/499 123/132	388/453 110/119

B) mNAPSI 0 in patients with baseline mNAPSI >10



OC, n/N$_{obs}$	Week 16	Year 1	Year 2	Year 3	Year 4
mNAPSI 0	57/268 20/66	157/252 40/67	175/243 44/64	172/234 48/56	154/226 41/55

C) Palmoplantar IGA 0 in patients with baseline palmoplantar IGA ≥3



OC, n/N$_{obs}$	Week 16	Year 1	Year 2	Year 3	Year 4
Palmoplantar IGA 0	132/150 34/36	127/142 33/36	116/128 30/32	120/127 30/30	110/118 25/28

[a] 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:** tumor necrosis factor.

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