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 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

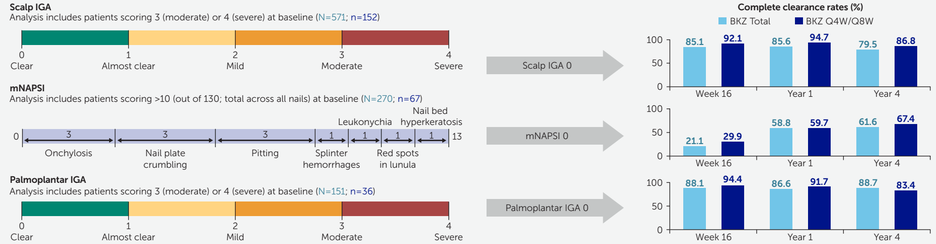
- Baseline characteristics are shown in **Table 1**.
- In total, 771 patients received BKZ from baseline into the OLE.
  - 571 (74.1%), 270 (35.0%), and 151 (19.6%) had baseline scalp IGA ≥3, mNAPSI >10, and palmoplantar IGA ≥3, respectively.
- Of those patients, 197 received BKZ Q4W/Q8W.
  - 152 (77.2%),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

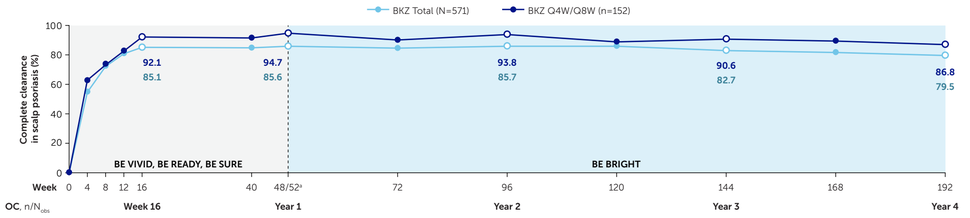
Table 1 Baseline characteristics

	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.

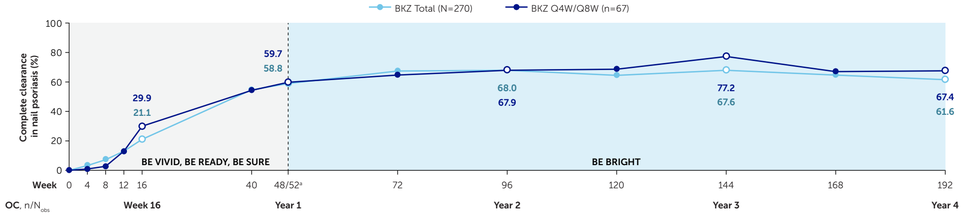
Figure 1 Complete clearance of scalp, nail, and palmoplantar psoriasis over 4 years (mNRI and OC)

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



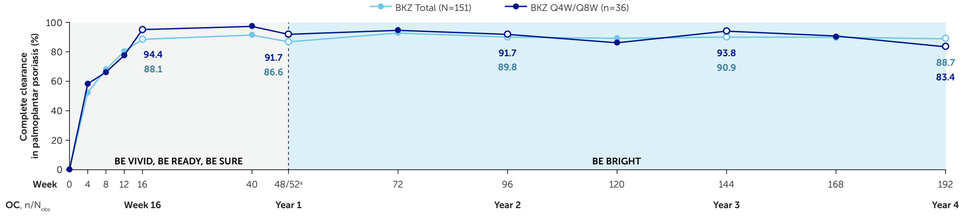
OC, n/N$_{obs}$	Week 16	Year 1	Year 2	Year 3	Year 4
Scalp IGA 0	482/565 139/150	478/535 141/149	445/508 131/139	431/499 123/132	388/453 110/119

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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References: [1]Merola JF et al. Dermatol Ther 2018;31:e12589; [2]Cashman MW et al. Clin Dermatol 2010;28:420–5; [3]Adams R et al. Front Immunol 2020;11:1894; [4]Warren RB et al. N Engl J Med 2021;385:130–41, NCT03412747; [5]Reich K et al. Lancet 2021;397:487–98, NCT03370133; [6]Reich K et al. N Engl J Med 2021;385:142–52, NCT03536884; [7]Gordon KB et al. Lancet 2021;397:475–86, NCT03410992; [8]Merola JF et al. Presented at EADV 2023; P2547; [9]Strober B et al. Br J Dermatol 2023;188:749–59, NCT03598790; [10]European Medicines Agency. Bimekizumab Summary of Product Characteristics. 2023. Available at: https://www.ema.europa.eu/en/documents/product-information/bimzelx-epar-productinformation_en.pdf [Accessed September 2024]. **Author Contributions:** Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: **JFM**, **ABG**, **JS**, **PH**, **AP**, **MG**, **AM**, **SK**, **NC**, **SW**, **CP**; Drafting of the publication, or reviewing it critically for important intellectual content: **JFM**, **ABG**, **JS**, **PH**, **AP**, **MG**, **AM**, **SK**, **NC**, **SW**, **CP**. Final approval of the publication: **JFM**, **ABG**, **JS**, **PH**, **AP**, **MG**, **AM**, **SK**, **NC**, **SW**, **CP**. **Author Disclosures: JFM:** Consultant and/or investigator for AbbVie, Amgen, AstraZeneca, Biogen, Bristol Myers Squibb, Boehringer Ingelheim, Dermavant, Eli Lilly and Company, Incyte, Janssen, LEO Pharma, MoonLake Immunotherapeutics, Novartis, Pfizer, Sanofi-Regeneron, Sun Pharma, and UCB. **ABG:** Research grants, consulting and/or speaker fees from Amgen, AnaptysBio, Avotres Therapeutics, Boehringer Ingelheim, Bristol Myers Squibb, Dice Therapeutics, Eli Lilly and Company, Highlights Therapeutics, Janssen, Novartis, Sanofi, Teva, UCB, and Xbiotech (stock options for RA). **JS:** Honoraria and/or consulting fees from Amgen, Celgene, Dermavant, National Psoriasis Foundation, Ortho Dermatologics, and Regeneron; grants and consulting fees from AbbVie, Actelion, Boeringher Ingelheim, Dermira, Eli Lilly and Company, Janssen, LEO Pharma, Novartis, and UCB; research grants from Cassiopeia, Galderma, and Pfizer. **PH:** Received educational grants and advisory board fees from AbbVie, Eli Lilly and Company, LEO Pharma, and UCB; received unrestricted development grant for mobile medical app development from UCB. **AP:** Investigator, speaker, and/or advisor for AbbVie, Almirall, Amgen, Biogen, Boehringer Ingelheim, Celgene, Eli Lilly and Company, Galderma, GSK, Hexal, Janssen, LEO Pharma, MC2 Therapeutics, Medac, Merck Serono, Mitsubishi Pharma, MSD, MoonLake Immunotherapeutics, Novartis, Pfizer, Regeneron, Roche, Sandoz, Schering-Plough, Tigercat Pharma, and UCB. **MG:** Investigator, speaker, consultant or advisory board member for AbbVie, Acelyrin, Akros, Amgen, AnaptysBio, Arcutis, Aristea, Aslan, Bausch Health, Boehringer Ingelheim, Bristol Myers Squibb, Dermavant, Dermira, Eli Lilly and Company, Galderma, GSK, Incyte, Janssen, JAMP Pharma, Kyowa Kirin, L'Oreal, MedImmune, Meiji, Merck, MoonLake Immunotherapeutics, Nektar Therapeutics, Nimbus, Novartis, Pfizer, Regeneron, Reistone, Sanofi-Genzyme, Sun Pharma, Takeda, Tarsus, UCB, Union, and Ventyx. **AM:** Research grants, consulting fees, and/or speaker's fees from AbbVie, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Eisai, Eli Lilly and Company, Janssen, Kyowa Hakko Kirin, LEO Pharma, Maruho, Mitsubishi Tanabe Pharma, Nichi-Iko, Nippon Kayaku, Novartis, Pfizer, Sun Pharma, Taiho Pharmaceutical, Torii Pharmaceutical, UCB, and Ushio. **SK:** Consultant for Aclipse Therapeutics, Aliada Therapeutics, Allay Therapeutics, Cognition Therapeutics, Colorado Prevention Center, Karuna Therapeutics, Kisbee Therapeutics, LB Pharma, Nesos, Novartis, Onward, PharPoint Research, Summit Analytical, Tonix, Tornado Therapeutics, UCB, Whitsell Innovations, Worldwide Clinical Trials, and Zosano. **NC**, **SW:** Employees and shareholders of UCB. **CP:** Consulting fees and/or grants from AbbVie, Almirall, Amgen, Boehringer Ingelheim, Celgene, Eli Lilly and Company, GSK, Janssen-Cilag, LEO Pharma, Novartis, Pierre Fabre, Pfizer, Sanofi-Regeneron, and UCB. **Acknowledgments:** This study was funded by UCB. We thank the patients and their caregivers in addition to the investigators and their teams who contributed to this study. The authors acknowledge Inés Dueñas Pousa, PhD, UCB, Madrid, Spain for publication coordination, Esme Nias, BSc, Costello Medical, London, UK, for medical writing and editorial assistance, and the Costello Medical Creative team for graphic design assistance. All costs associated with development of this poster were funded by UCB.

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