Bimekizumab simultaneous skin and nail clearance in patients with psoriasis: Assessing comparative efficacy in four phase 3/3b studies

Joseph F. Merola,[1] Richard B. Warren,[2,3] Diamant Thaçi,[4] Kenneth B. Gordon,[5] Emi Nishida,[6] Bruce Strober,[7,8] Curdin Conrad,[9] Sarah Kavanagh,[10] José Manuel López Pinto,[11] Bengt Hoepken,[12] Paolo Gisondi[13]

Objective

To evaluate simultaneous complete skin and nail clearance in patients with moderate to severe plaque psoriasis treated with bimekizumab (BKZ) or active comparators.

Background

- 40–60% of patients with plaque psoriasis have simultaneous nail involvement and, due to their structure and growth rate, nails are often more difficult to treat than skin.[1,2] Nail psoriasis has been identified as a medium to long-term risk factor for psoriatic arthritis (PsA) development.[2–5]
- Psoriasis of the nails disproportionately impacts physical and emotional well-being,[6,7] and clearance of nails could improve patients' health-related quality of life.[2]
- Complete skin clearance (100% improvement from baseline in Psoriasis Area and Severity Index [PASI 100]) is becoming an achievable treatment goal with new biologics;[8–11] however, the PASI does not include assessment of nail clearance.[1]
- Complete clearance of nail psoriasis in addition to skin may result in lower rates of progression to PsA.[4]
- Therefore, it is important to evaluate simultaneous clearance of nail and skin psoriasis.

Methods

- Data were analysed from patients receiving BKZ 320 mg every 4 weeks (Q4W) or Q8W vs active comparators or placebo (PBO) in four phase 3/3b trials (BKZ Total represents BKZ Q4W and Q8W dose groups combined):
  - BE SURE: BKZ Total vs adalimumab (ADA) to Week 24;[10]
  - BE RADIANT: BKZ Total vs secukinumab (SEC) to Week 48;[11]
  - BE VIVID: BKZ Q4W vs ustekinumab (UST) to Week 52;[8]
  - Pooled BE VIVID/BE READY: BKZ Q4W vs PBO to Week 16.[8,9]
- Patients included in these analyses had fingernail involvement at baseline, defined as a modified Nail Psoriasis Severity Index (mNAPSI) >0.
- Proportions of patients who achieved simultaneous complete clearance of skin (PASI 100) and complete clearance of nails (mNAPSI 0) are reported.
- Data are reported using non-responder imputation (NRI) and as observed case (OC).

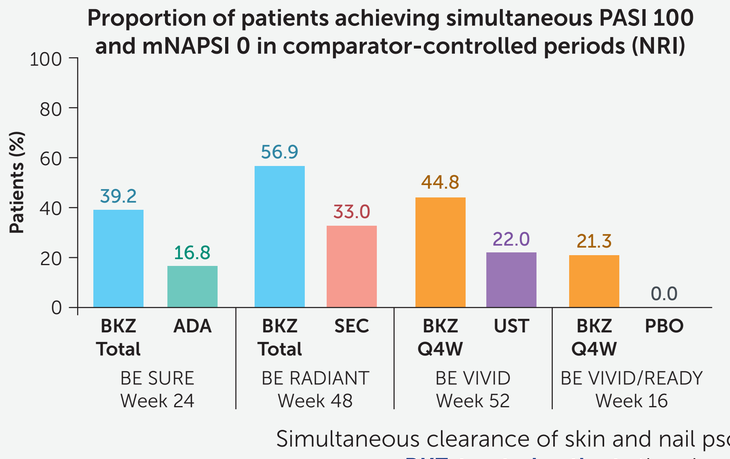
Results

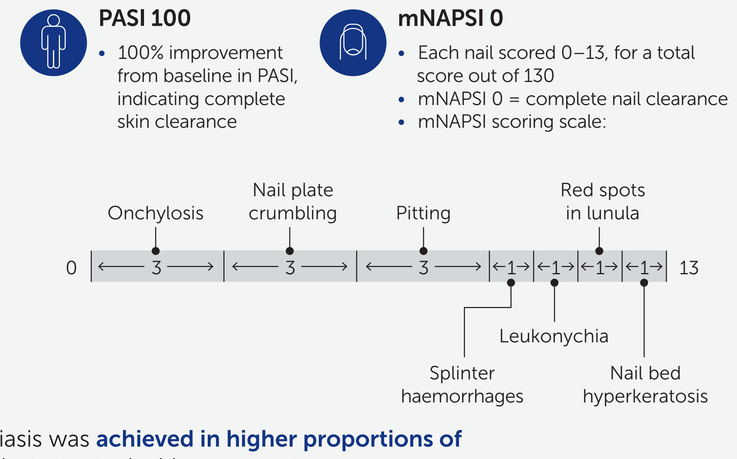
- Proportions of patients with mNAPSI >0 at baseline were:
  - BE SURE: 181/319 (56.7%) BKZ- and 95/159 (59.7%) ADA-randomised patients;
  - BE RADIANT: 204/373 (54.7%) BKZ- and 179/370 (48.4%) SEC-randomised patients;
  - BE VIVID: 194/321 (60.4%) BKZ- and 109/163 (66.9%) UST-randomised patients;
  - Pooled BE VIVID/BE READY: 404/670 (60.3%) BKZ- and 101/169 (59.8%) PBO-randomised patients.
- Baseline characteristics of patients with mNAPSI >0 are reported in **Table 1**.
- At Week 16, 20.4% BKZ vs 6.3% ADA patients (BE SURE), 28.4% BKZ vs 26.8% SEC patients (BE RADIANT), 16.5% BKZ vs 4.6% UST patients (BE VIVID), and 21.3% BKZ vs 0.0% PBO patients (BE VIVID/BE READY) achieved PASI 100 and mNAPSI 0 simultaneously (NRI; **Figure 1A–D**).
- At the end of comparator-controlled periods, 39.2% BKZ vs 16.8% ADA patients (BE SURE Week 24), 56.9% BKZ vs 33.0% SEC patients (BE RADIANT Week 48), and 44.8% BKZ vs 22.0% UST patients (BE VIVID Week 52) achieved PASI 100 and mNAPSI 0 simultaneously (NRI; **Figure 1A–C**).

Conclusions

Rates of simultaneous complete skin and nail clearance ranged 16.5–28.4% in BKZ-treated patients as early as Week 16, increased further to the end of controlled study periods, and were higher for BKZ-treated patients vs active comparators or PBO. This underscores the consistent and durable efficacy of BKZ across multiple domains of psoriatic disease, including nail involvement - one of the known risk factors for progression to PsA.[4]

Summary





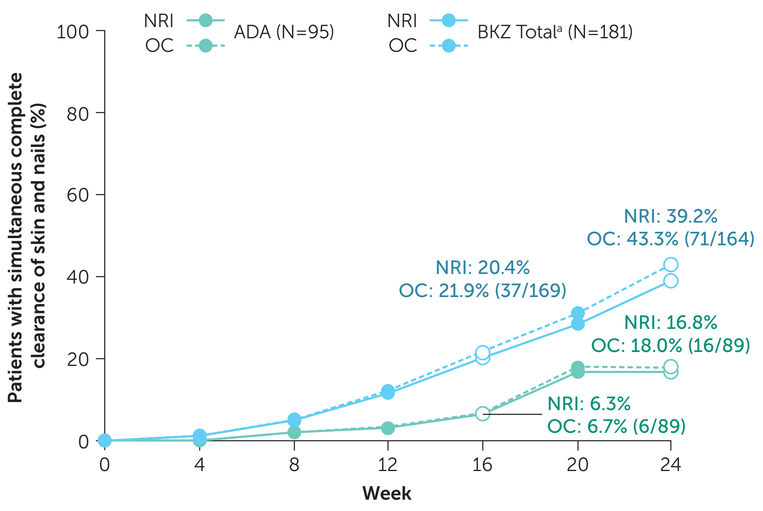
Simultaneous clearance of skin and nail psoriasis was **achieved in higher proportions of BKZ-treated patients** than in patients treated with comparators.

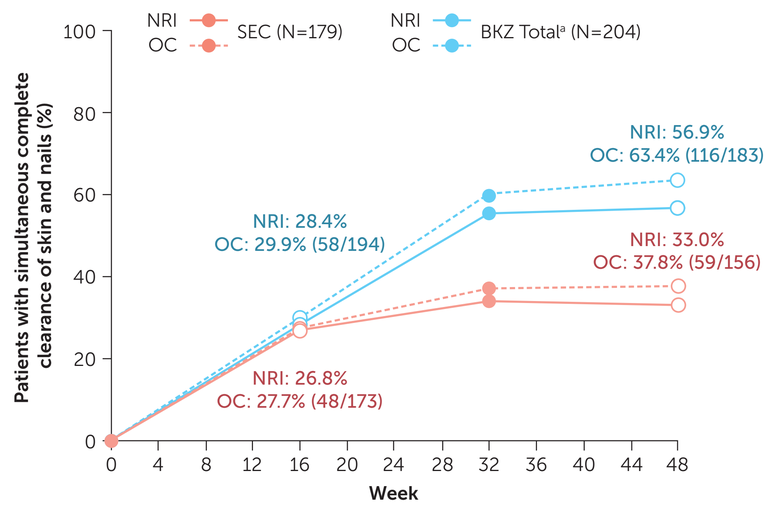
Table 1 Baseline characteristics of patients with mNAPSI >0 in BE SURE, BE RADIANT, BE VIVID, and pooled BE VIVID/BE READY

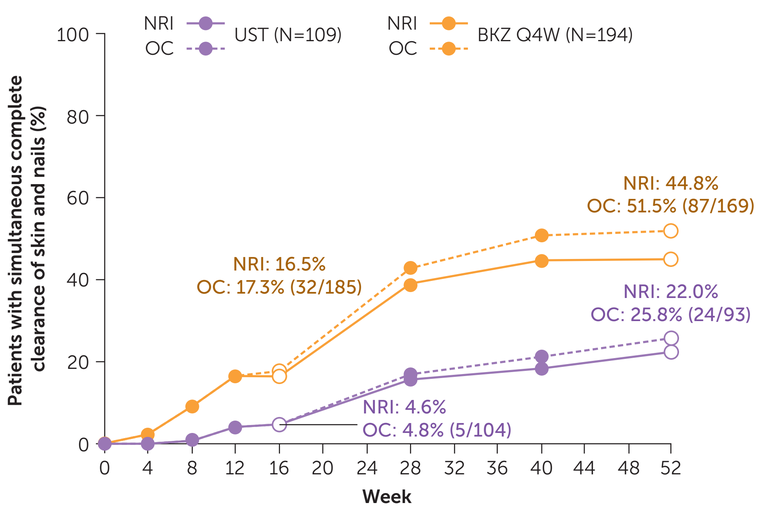
	BE SURE		BE RADIANT		BE VIVID		BE VIVID/BE READY	
	BKZ Total (N=181)	ADA (N=95)	BKZ Total (N=204)	SEC (N=179)	BKZ Q4W (N=194)	UST (N=109)	BKZ Q4W (N=404)	PBO (N=101)
Age (years), mean ± SD	45.2 ± 12.4	45.5 ± 13.9	46.4 ± 14.7	44.7 ± 13.0	45.3 ± 13.6	46.9 ± 12.9	45.7 ± 13.0	47.0 ± 12.7
Male, n (%)	138 (76.2)	72 (75.8)	151 (74.0)	142 (79.3)	162 (83.5)	86 (78.9)	328 (81.2)	81 (80.2)
White, n (%)	158 (87.3)	86 (90.5)	188 (92.2)	176 (98.3)	140 (72.2)	76 (69.7)	335 (82.9)	85 (84.2)
Weight (kg), mean ± SD	93.1 ± 22.2	90.2 ± 20.6	91.4 ± 20.4	91.4 ± 18.1	91.7 ± 23.9	88.6 ± 19.9	91.0 ± 21.9	93.9 ± 24.9
Duration of psoriasis (years), mean ± SD	19.5 ± 11.9	16.3 ± 10.7	19.1 ± 13.6	17.8 ± 11.6	16.6 ± 10.7	18.3 ± 11.0	18.3 ± 12.3	20.3 ± 13.3
mNAPSI, mean ± SD	22.0 ± 21.9	18.3 ± 18.1	18.2 ± 18.0	19.2 ± 20.1	20.5 ± 20.1	21.0 ± 21.0	20.5 ± 20.7	19.7 ± 20.6
PASI score, mean ± SD	20.8 ± 7.1	19.1 ± 6.0	21.0 ± 8.4	19.8 ± 6.5	23.0 ± 8.9	21.4 ± 8.5	22.3 ± 8.6	20.7 ± 7.5
BSA (%), mean ± SD	27.4 ± 15.3	25.3 ± 15.3	26.4 ± 17.1	23.0 ± 13.3	30.5 ± 18.3	26.9 ± 16.9	28.6 ± 17.5	26.9 ± 16.3
IGA, n (%)								
3: moderate	115 (63.5)	68 (71.6)	122 (59.8)[a]	128 (71.5)	115 (59.3)[a]	62 (56.9)	249 (61.6)[a]	63 (62.4)[a]
4: severe	66 (36.5)	27 (28.4)	81 (39.7)	51 (28.5)	78 (40.2)	47 (43.1)	154 (38.1)	37 (36.6)
Any prior systemic therapy, n (%)	121 (66.9)	71 (74.7)	152 (74.5)	137 (76.5)	163 (84.0)	93 (85.3)	336 (83.2)	77 (76.2)
Any prior biologic therapy, n (%)	55 (30.4)	32 (33.7)	73 (35.8)	67 (37.4)	76 (39.2)	42 (38.5)	161 (39.9)	38 (37.6)

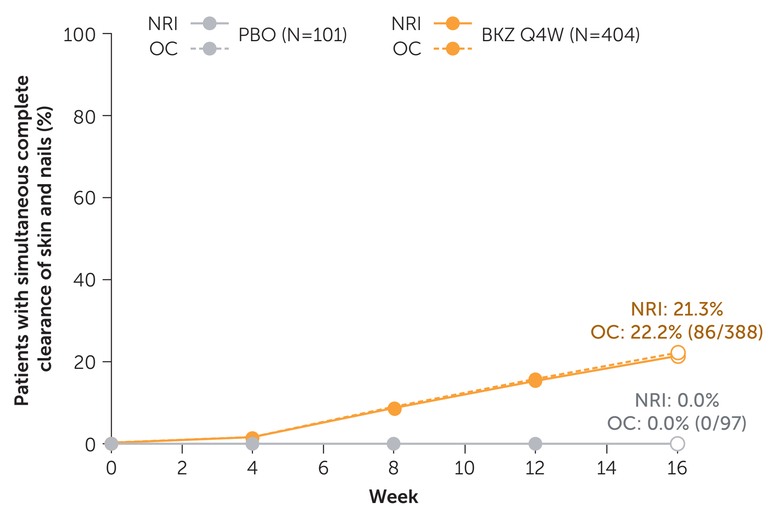
BKZ Total represents BKZ 320 mg Q4W and Q8W dose groups combined. [a] One additional patient had mild IGA.

Figure 1 Simultaneous achievement of PASI 100 and mNAPSI 0 in comparator- or placebo-controlled periods (NRI, OC)









Data shown are NRI (%) or OC (% [n/N_{obs}]), as indicated. All patients randomised to each treatment regimen, with mNAPSI >0 at baseline, are included. [a] BKZ Total represents BKZ 320 mg Q4W and Q8W dose groups combined.

ADA: adalimumab; **BKZ:** bimekizumab; **BMI:** body mass index; **BSA:** body surface area; **IGA:** investigator's global assessment; **mNAPSI:** modified Nail Psoriasis Severity Index; **N_{obs}:** N observed; **NRI:** non-responder imputation; **OC:** observed case; **PASI 100:** 100% improvement from baseline in Psoriasis Area and Severity Index; **PBO:** placebo; **PsA:** psoriatic arthritis; **Q4W:** every 4 weeks; **Q8W:** every 8 weeks; **SEC:** secukinumab; **UST:** ustekinumab.

Institutions: [1]Department of Dermatology and Department of Medicine, Division of Rheumatology, UT Southwestern Medical Center, Dallas, Texas, USA; [2]Dermatology Centre, Northern Care Alliance NHS Foundation Trust, Manchester, UK; [3]NIHR Manchester Biomedical Research Centre, Manchester University NHS Foundation Trust, Manchester Academic Health Science Centre, Manchester, UK; [4]Institute and Comprehensive Center for Inflammation Medicine, University of Lübeck, Lübeck, Germany; [5]Department of Dermatology, Medical College of Wisconsin, Milwaukee, Wisconsin, USA; [6]Nagoya City University West Medical Center, Nagoya, Japan; [7]Department of Dermatology, Yale University, New Haven, Connecticut, USA; [8]Central Connecticut Dermatology Research, Cromwell, Connecticut, USA; [9]Department of Dermatology, University Hospital Lausanne, Lausanne, Switzerland; [10]UCB Pharma, Morrisville, North Carolina, USA; [11]UCB Pharma, Madrid, Spain; [12]UCB Pharma, Monheim am Rhein, Germany; [13]Section of Dermatology and Venereology, Department of Medicine, University of Verona, Verona, Italy.

References: [1]Kirkham BW et al. Rheumatol Ther 2023;10:1127–46; [2]Blauvelt A et al. Br J Dermatol 2021;184:1047–58; [3]Gottlieb A & Merola JF. J Dermatolog Treat 2020;31:662–79; [4]Zabotti A et al. ARD 2023;82:1162–70; [5]Langenbruch A et al. Br J Dermatol 2014;171:1123–28; [6]Augustin M et al. Br J Dermatol 2019;181:358–65; [7]Mrowietz U and Augustin M. Br J Dermatol 2022;187:1007–8; [8]Reich K et al. Lancet 2021;397:487–98, NCT03370133; [9]Gordon KB et al. Lancet 2021;397:475–86, NCT03410992; [10]Warren RB et al. N Engl J Med 2021;385:130–41, NCT03412747; [11]Reich K et al. N Engl J Med 2021;385:142–52, NCT03536884. **Author Contributions:** Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: **JFM**, **RBW**, **DT**, **KBG**, **EN**, **BS**, **CC**, **SK**, **JMLP**, **BH**, **PG**; Drafting of the publication, or reviewing it critically for important intellectual content: **JFM**, **RBW**, **DT**, **KBG**, **EN**, **BS**, **CC**, **SK**, **JMLP**, **BH**, **PG**; Final approval of the publication: **JFM**, **RBW**, **DT**, **KBG**, **EN**, **BS**, **CC**, **SK**, **JMLP**, **BH**, **PG**. **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 Pharma. **RBW:** Consulting fees from AbbVie, Almirall, Amgen, Arena, Astellas, Avillion, Biogen, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, DICE Therapeutics, Eli Lilly and Company, GSK, Janssen, LEO Pharma, Meiji Pharma, Novartis, Pfizer, RAPT Therapeutics, Sanofi, Sun Pharma, and UCB Pharma, and Union; research grants to his institution from AbbVie, Almirall, Amgen, Celgene, Eli Lilly and Company, Janssen, LEO Pharma, Novartis, Pfizer, and UCB Pharma; honoraria from AbbVie, Almirall, Bristol Myers Squibb, Eli Lilly and Company, Galderma, Janssen, and Novartis. **DT:** Investigator and/or consultant/advisor for AbbVie, Almirall, Amgen, Boehringer Ingelheim, Bristol Myers Squibb, Celltrion, Eli Lilly and Company, Galderma, Janssen-Cilag, Kyowa Kirin, LEO Pharma, L'Oreal, New Bridge, Novartis, Pfizer, Regeneron, Samsung, Sanofi, Target-RWE, UCB Pharma, and Vichy; received grants from AbbVie, LEO Pharma, and Novartis. **KBG:** Consulting fees from AbbVie, Almirall, Amgen, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Dermira, Eli Lilly and Company, Janssen, Novartis, Pfizer, Sun Pharma and UCB Pharma; research support from AbbVie, Bristol Myers Squibb, Celgene, Eli Lilly and Company, Janssen, Novartis and UCB Pharma. **EN:** Abbvie, Amgen, Boehringer Ingelheim, Bristol Myers Squibb, Daiichi Sankyo, Eli Lilly and Company, Janssen, Kyowa Kirin, LEO pharma, Maruho, Novartis, Pfizer, Regeneron, Sanofi, Sun Pharma, Taiho, Torii, and UCB Pharma. **BS:** Consultant (honoraria) for AbbVie, Acelyrin, Alamar, Almirall, Alumis, Amgen, Arcutis, Arena, Aristea, Asana, Boehringer Ingelheim, Bristol Myers Squibb, Capital One, Celltrion, CorEvitas, Dermavant, Eli Lilly and Company, Imagenebio, Janssen, Kangpu Pharmaceuticals, LEO Pharma, Maruho, Meiji Seika Pharma, Protagonist, Monte Carlo, Novartis, Pfizer, Rapt, Regeneron, Sanofi Genzyme, SG Cowen, Sun Pharma, Takeda, UCB Pharma, Union Therapeutics, Ventyxbio, and vTv Therapeutics; stock options from Connect Biopharma, Mindera Health; speaker for AbbVie, Arcutis, Dermavant, Eli Lilly and Company, Incyte, Janssen, Regeneron, and Sanofi Genzyme; Scientific Co-Director (consulting fee) for CorEvitas Psoriasis Registry; investigator for CorEvitas Psoriasis Registry; editor-in-chief (honorarium) for Journal of Psoriasis and Psoriatic Arthritis. **CC:** Consultant and/or principal investigator in clinical trials for AbbVie, Actelion, Almirall, Amgen, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Eli Lilly and Company, Incyte, Janssen, LEO Pharma, MSD, Novartis, Pfizer, Samsung, Sanofi, and UCB. **SK:** Statistical consultant for Aclipse Therapeutics, Aliada Therapeutics, Allay Therapeutics, Cognition Therapeutics, Colorado Prevention Center, Karuna Therapeutics, Kisbee Therapeutics, LB Pharma, Nesos, Novartis, Onward, PharPoint Research, Tonix, Tornado Therapeutics, UCB Pharma, Whitsell Innovations, Worldwide Clinical Trials, and Zosano. **JMLP, BH:** Employees and shareholders of UCB Pharma. **PG:** Consultant for AbbVie, Abiogen, Almirall, Celgene, Eli Lilly and Company, Janssen, LEO Pharma, Merck, MSD, Novartis, Otsuka, Pfizer, Pierre Fabre, Sanofi and UCB Pharma. **Acknowledgements:** These studies were funded by UCB Pharma. We thank the patients and their caregivers in addition to the investigators and their teams who contributed to these studies. The authors acknowledge Ines Dueñas Pousa, PhD, UCB Pharma, Spain and Susanne Wiegratz, MSc, UCB Pharma, Monheim, Germany for publication coordination, Michael Haycox, PhD, Costello Medical, Manchester, United Kingdom for medical writing and editorial assistance, and the Costello Medical Creative team for design support. All costs associated with development of this poster were funded by UCB Pharma.

To receive a copy of this poster, scan the QR code or visit:
UCBposters.com/IFPA2024
Poster ID: 99
Link expiration: 13 July 2024

Presented at the 7th World Psoriasis & Psoriatic Arthritis Conference | 27–29 June 2024 | Stockholm, Sweden