Bimekizumab clinical efficacy in important body regions and health-related quality of life in patients with plaque psoriasis: Data from four phase 3/3b comparator-controlled trial periods

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Synopsis

- Psoriasis affecting certain 'high-impact' areas, such as the scalp, nails, palms, and soles, can have a large impact on health-related quality of life (HRQoL).[1,2]
- In addition, psoriasis can have a different impact on patient HRQoL depending on the body regions it affects (head/neck, trunk, arms, legs).[1–3]

Objective

To examine how achievement of complete skin clearance in various body regions and high-impact areas translates into HRQoL benefits perceived by patients treated with bimekizumab (BKZ) vs comparators.

Methods

- Data were analyzed from patients with moderate to severe plaque psoriasis who received BKZ 320 mg every 4 weeks (Q4W), or BKZ Q4W to Week 16 followed by every 8 weeks (Q8W), vs those who received comparators during controlled periods of four phase 3/3b trials: pooled BE VIVID/BE READY (BKZ vs placebo [PBO] to Week 16),[4,5] BE SURE (BKZ vs adalimumab [ADA] to Week 24),[6] BE RADIANT (BKZ vs secukinumab [SEC] to Week 48),[7] and BE VIVID (BKZ vs ustekinumab [UST] to Week 52).[4]
- Proportions of patients who achieved the following outcomes concurrently with Dermatology Life Quality Index (DLQI) 0/1 (no effect of skin disease on patient's life) are reported: body region-specific PASI 100 (100% improvement from baseline in Psoriasis Area and Severity Index [PASI] for head/neck, trunk, arms, and legs), and scalp Investigator's Global Assessment (IGA) 0, modified Nail Psoriasis Severity Index (mNAPSI) 0, and palmoplantar IGA 0 (complete scalp/nail/palmoplantar clearance).
- Included patients had PASI >0 for the relevant PASI body region, scalp IGA ≥3, mNAPSI >10, or palmoplantar IGA ≥3 at baseline. Data are reported using non-responder imputation (NRI).

Results

- Pooled across BE VIVID/BE READY, 670 patients were randomized to BKZ and 169 to PBO. In BE SURE, 319 were randomized to BKZ and 159 to ADA. In BE RADIANT, 373 were randomized to BKZ and 370 to SEC. In BE VIVID only, 321 were randomized to BKZ and 163 to UST.

PASI body region clearance and DLQI 0/1

- In each study at Week 4 (after a single dose of BKZ), a greater proportion of BKZ-randomized patients achieved PASI 100 across each body region vs all comparators (**Figure 1**).
- Concurrent PASI 100 and DLQI 0/1 achievement for each body region was greater in BKZ-randomized patients at Week 4 vs comparators (**Figure 1**).
- These proportions increased through the end of comparator-controlled periods, remaining greater in BKZ-randomized patients vs comparators for each body region (**Figure 1**). Proportions were similar across body regions with BKZ by the end of controlled periods.

High-impact area clearance and DLQI 0/1

- A greater proportion of BKZ-randomized patients achieved palmoplantar IGA 0 and scalp IGA 0 vs comparators at each time point (**Table 1**, **Figure 2**; although some patient groups with palmoplantar involvement were small).
- While few patients in any study achieved mNAPSI 0 at Week 4, reflecting the longer time taken for nails to grow, greater proportions of BKZ- vs comparator-treated patients achieved mNAPSI 0 at the end of controlled periods (**Figure 2**).
- Similarly, across studies, greater proportions of BKZ-randomized patients achieved concurrent scalp IGA 0/palmoplantar IGA 0 and DLQI 0/1 at Week 4 vs comparators (**Table 1**). At the end of comparator-controlled periods, for each high-impact area, greater proportions of BKZ-randomized patients achieved concurrent clearance and DLQI 0/1 vs comparators (**Figure 2**).

Conclusions

Bimekizumab-treated patients experienced higher clinical responses in the scalp, nails, palms and soles, and each PASI body region compared to placebo, adalimumab, secukinumab, and ustekinumab in comparator-controlled studies, which translated concurrently into numerically greater patient-perceived HRQoL benefits.

Summary

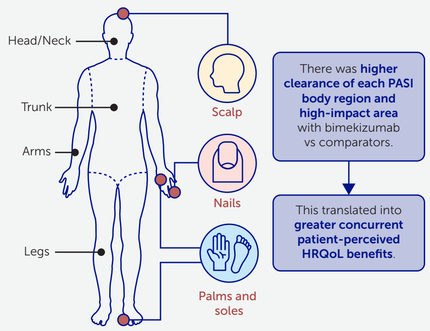
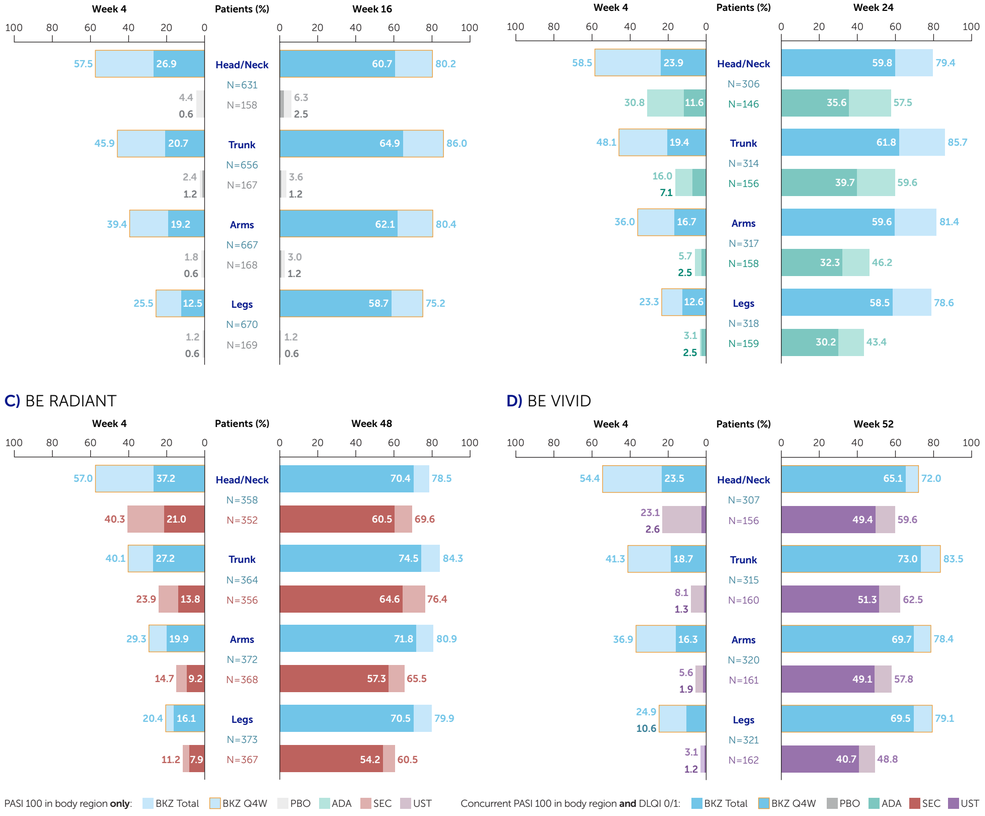


Table 1 Concurrent achievement of high-impact area clearance and DLQI 0/1 at Week 4 (NRI)

		Palmoplantar IGA 0 only (%)	Concurrent palmoplantar IGA 0 and DLQI 0/1 (%)	Scalp IGA 0 only (%)	Concurrent scalp IGA 0 and DLQI 0/1 (%)
BE VIVID/ BE READY	BKZ Q4W	77.0	31.1	56.2	27.8
	PBO	19.4	3.2	2.5	0.8
BE SURE	BKZ Q4W	57.4	21.3	53.3	22.7
	ADA	40.0	0.0	24.8	10.5
BE RADIANT	BKZ Q4W	N/A[a]	N/A[a]	50.9	34.8
	SEC	N/A[a]	N/A[a]	36.6	23.1
BE VIVID	BKZ Q4W	75.4	26.2	53.2	25.1
	UST	42.9	3.6	14.0	0.0

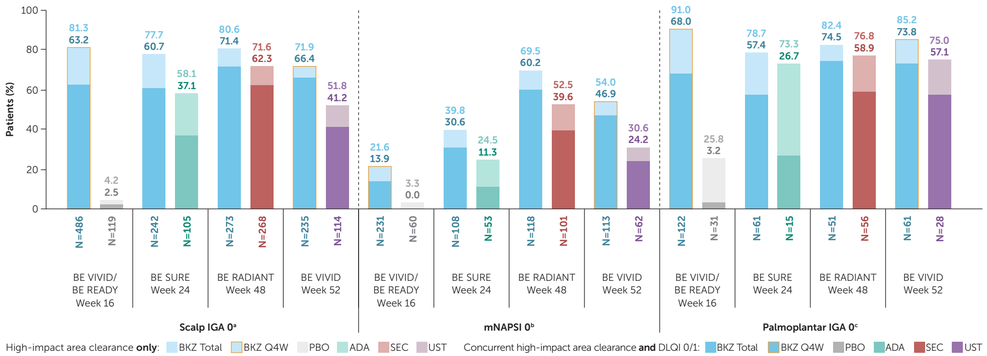
N numbers are shown in Figure 2; **[a]** Palmoplantar IGA data were not collected at Week 4 in the BE RADIANT trial.

Figure 1 Concurrent achievement of complete skin clearance (PASI 100) in PASI body regions and DLQI 0/1 (NRI)



Only patients with a PASI >0 for each given body region at baseline are included. BKZ Total represents BKZ 320 mg Q4W and Q8W dose groups combined. BKZ Q8W dosing was not possible in the comparator-controlled periods of BE VIVID or BE READY.

Figure 2 Concurrent achievement of high-impact area clearance and DLQI 0/1 at the end of comparator-controlled periods (NRI)



BKZ Total represents BKZ 320 mg Q4W and Q8W dose groups combined. BKZ Q8W dosing was not possible in the comparator-controlled periods of BE VIVID or BE READY. **[a]** Only patients with scalp IGA ≥3 at baseline are included (N). Scalp IGA response is defined as clear (0) with at least a two-category improvement from baseline, representing complete scalp clearance; **[b]** Only patients with mNAPSI >10 at baseline are included (N). mNAPSI 0 represents complete nail clearance; **[c]** Only patients with palmoplantar IGA ≥3 at baseline were included (N). Palmoplantar IGA response is defined as clear (0) with at least a two-category improvement from baseline, representing complete palmoplantar clearance.

ADA: adalimumab; **BKZ:** bimekizumab; **DLQI:** Dermatology Life Quality Index; **HRQoL:** health-related quality of life; **IGA:** Investigator's Global Assessment; **mNAPSI:** modified Nail Psoriasis Severity Index; **NRI:** non-responder imputation; **N/A:** not available; **PASI 100:** 100% improvement from baseline in Psoriasis Area and Severity Index; **PBO:** placebo; **Q4W:** every 4 weeks; **Q8W:** every 8 weeks; **SEC:** secukinumab; **UST:** ustekinumab.

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References: [1]Timotijević ZS et al. Acta Dermatovenerol Croat 2017;25:215–22; [2]Strober B et al. J Dermatolog Treat 2024;35:2287401; [3]Augustin M & Radtke MA. Expert Rev Pharmacoecon Outcomes Res 2014;14:559–68; [4]Reich K et al. Lancet 2021;397:487–98. NCT03370133; [5]Gordon KB et al. Lancet 2021;397:475–86. NCT03410992; [6]Warren RB et al. N Engl J Med 2021;385:130–41. NCT03412747; [7]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: **AA**, **BE**, **PR**, **MA**, **JMC**, **RV**, **JL**, **JMLP**, **BH**, **SK**, **LP**. Drafting of the publication, or reviewing it critically for important intellectual content: **AA**, **BE**, **PR**, **MA**, **JMC**, **RV**, **JL**, **JMLP**, **BH**, **SK**, **LP**. Final approval of the publication: **AA**, **BE**, **PR**, **MA**, **JMC**, **RV**, **JL**, **JMLP**, **BH**, **SK**, **LP**. **Author Disclosures: AA:** Has served as a research investigator and/or scientific advisor to AbbVie, Almirall, Arcutis, ASLAN, Boehringer Ingelheim, Bristol Myers Squibb, Dermavant, Dermira, Eli Lilly, EPI, Incyte, Janssen, LEO Pharma, Nimbus, Novartis, Ortho Dermatologics, Pfizer, Regeneron, Sun Pharma, Sanofi, and UCB. **BE:** Received research support as funding to Case Western Reserve University from AbbVie, AnaptysBio, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Eli Lilly, Incyte, LEO Pharma, Menlo, Merck, Novartis, Pfizer, Regeneron, Sun Pharma, Valeant, and Vanda; Consultant (honoraria) from Arcutis, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Eli Lilly, LEO Pharma, Menlo, Novartis, Pfizer, Sun Pharma, UCB, Valeant, and Verrica. **PR:** Principal investigator/clinical trials for AbbVie, Amgen, Arcutis, Bristol Myers Squibb, Dermavant, Eli Lilly, Janssen, Sun Pharma, and UCB; Consultant for Bristol Myers Squibb. **MA:** Consulting fees from AbbVie, Almirall, Amgen, Biogen, Boehringer Ingelheim, Celgene, Centocor, Eli Lilly, GSK, Hexal, Janssen, LEO Pharma, Medac, Merck, MSD, Mundipharma, Novartis, Pfizer, Sandoz, UCB, and Xenoport. **JMC:** Principal/senior investigator and/or consultant and/or advisor for AbbVie, Amgen, Biogen, Bristol Myers Squibb, Celgene, Eli Lilly, Janssen, LEO Pharma, Novartis, Sandoz, and UCB. **RV:** Grants/research support and/or speakers bureau/honoraria: AbbVie, Alumis, Amgen, Arcutis, Bausch Health/Valeant, Boehringer Ingelheim, Bristol Myers Squibb, Celltrion, Dermavant, Dermira, DiCE Pharmaceuticals, DiCE Therapeutics, Eli Lilly, Galderma, Incyte, Janssen, LEO Pharma, Meiji Seika Pharma, Nimbus Therapeutics, Novartis, Pfizer, Sanofi-Aventis/Genzyme, Sandoz, Sun Pharma, Takeda, UCB, and Zai Lab. **JL**, **JMLP**, **BH:** Employees and shareholders of UCB. **SK:** Consultant for Eclipse 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. **LP:** Received consultancy/speaker's honoraria from and/or participated in trials sponsored by AbbVie, Almirall, Amgen, Biogen, Boehringer Ingelheim, Bristol Myers Squibb, Eli Lilly, Fresenius Kabi, Horizon, Janssen, LEO Pharma, Novartis, Pfizer, Sandoz, STADA, Sun Pharma, and UCB. **Acknowledgements:** 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, Michael Haycox-Ferguson, PhD, Costello Medical, Manchester, 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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