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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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Objective

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

Introduction

- Psoriasis affecting certain 'high-impact' areas, such as the scalp, nails, palms, and soles, can have a large impact on 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]

Methods

- Data were analysed 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 randomised to BKZ and 169 to PBO. In BE SURE, 319 were randomised to BKZ and 159 to ADA. In BE RADIANT, 373 were randomised to BKZ and 370 to SEC. In BE VIVID only, 321 were randomised 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-randomised 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-randomised patients at Week 4 vs comparators (**Figure 1**).
- These proportions increased through the end of comparator-controlled periods, remaining greater in BKZ-randomised 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-randomised 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-randomised 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-randomised 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

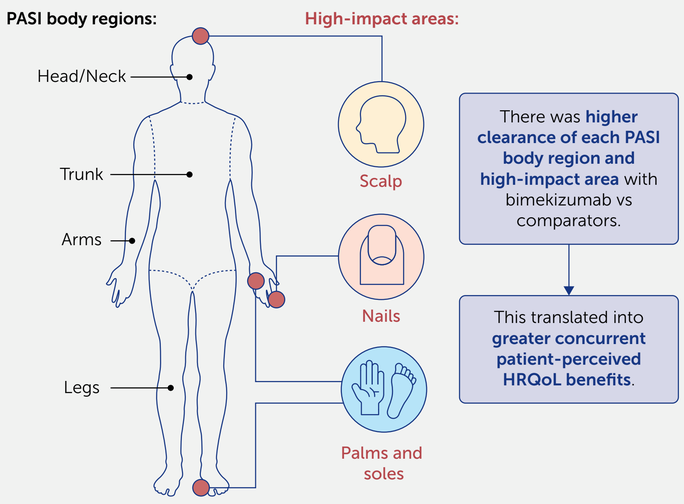
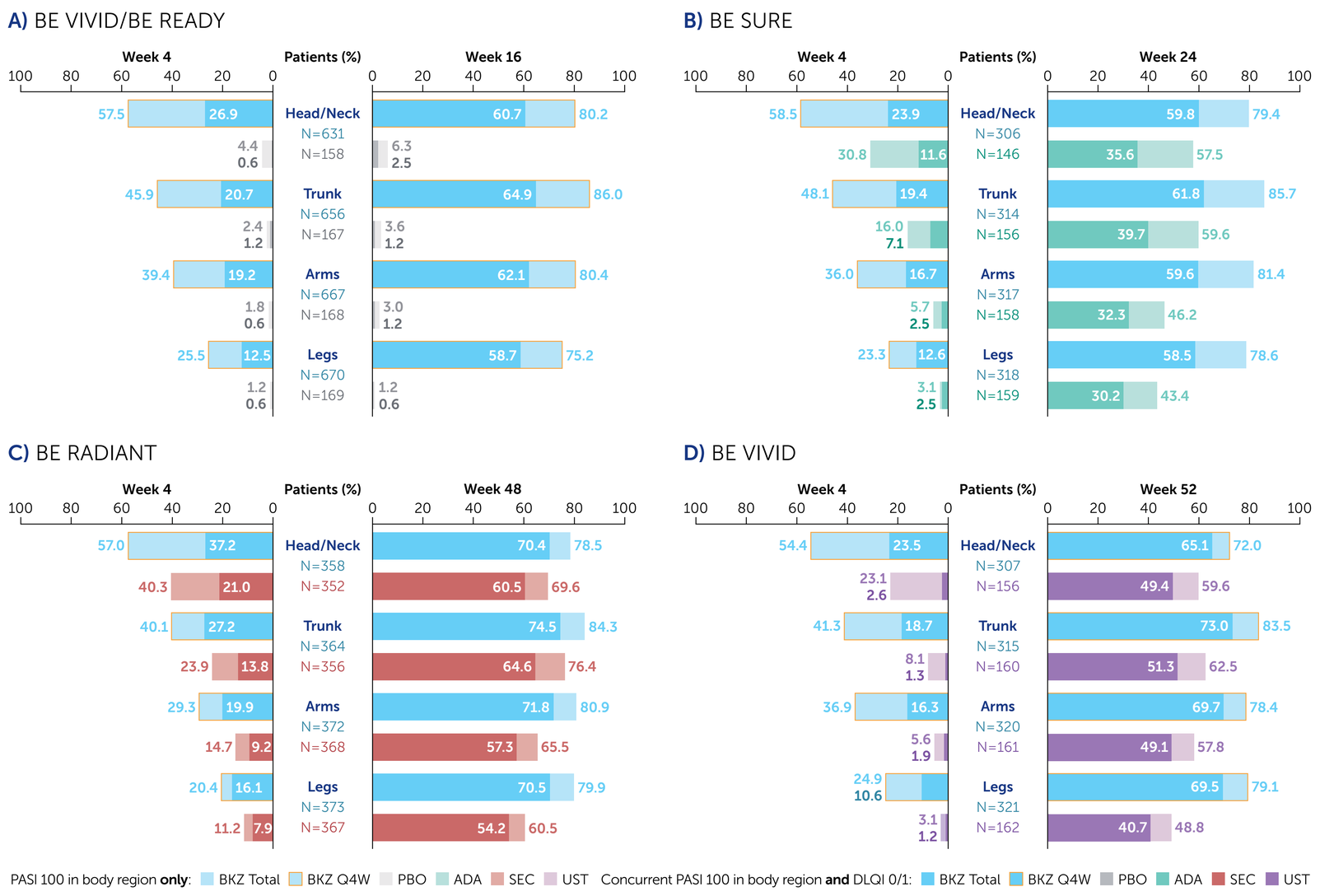


Table 1 Concurrent achievement of high-impact area clearance and DLQI 0/1 at Week 4 (NRI)

		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

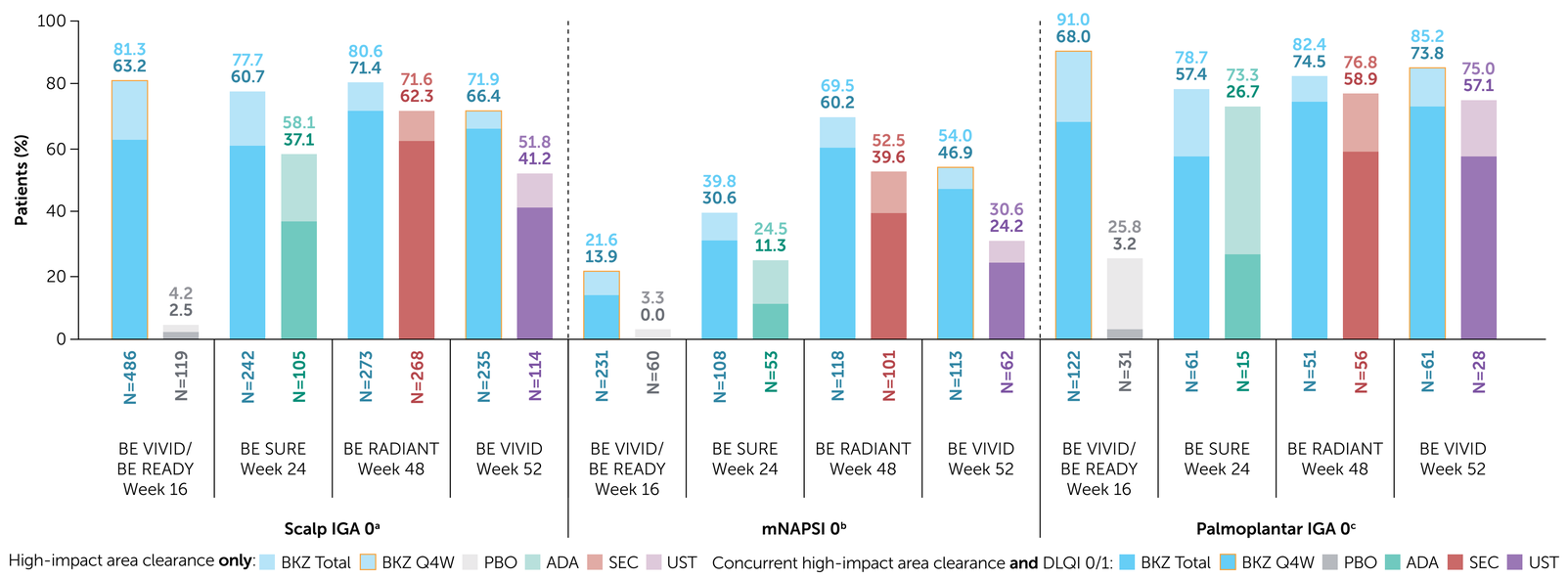
N numbers are shown in Figure 2. **[a]** Palmoplantar IGA data were not collected at Week 4 in the BE RADIANT trial.

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 were 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 were 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 were 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; **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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