Bimekizumab efficacy by body region in plaque psoriasis: Comparative analyses from four phase 3/3b studies

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Objective

To compare achievement of 100%/≥90% improvement from baseline in each body region of the Psoriasis Area and Severity Index (PASI 100/90) for bimekizumab (BKZ) versus comparators over the placebo (PBO)- and active comparator-controlled periods of four studies.

Background

- Plaque psoriasis can negatively impact patients' quality of life to varying degrees, depending on the body regions affected.[1]
- Psoriasis severity and treatment responsiveness can vary by body region;[1] for example, the lower limbs have been shown to be the most difficult-to-treat body region.[2] Patients may benefit from reassurance that new therapies provide uniform improvement.
- The PASI assesses the size and severity of psoriatic lesions in four body regions: head and neck, trunk, upper limbs, and lower limbs.
- BKZ, a monoclonal IgG1 antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A,[3] has demonstrated rapid and superior efficacy in the treatment of moderate to severe plaque psoriasis in head-to-head studies vs adalimumab (ADA), secukinumab (SEC), and ustekinumab (UST), with established long-term durability of response.[4–8]

Methods

- Data were included from four phase 3/3b studies which assessed patients who received BKZ 320 mg every 4 weeks (Q4W) or every 8 weeks (Q8W) vs active comparators or PBO:
  - BE SURE: BKZ Total vs ADA to Week 24;[4]
  - BE RADIANT: BKZ Total vs SEC to Week 48;[5]
  - BE VIVID: BKZ Q4W vs UST to Week 52;[6]
  - Pooled BE VIVID/BE READY: BKZ Q4W vs PBO to Week 16.[6,7]
- BKZ Total includes all BKZ-randomised patients who entered the studies, regardless of dosing regimen.
- PASI 100 and PASI 90 responses for each PASI body region are reported using non-responder imputation (NRI). Analysis was restricted to patients with baseline PASI >0 in the relevant body region.
- Throughout all included studies, patients could continue to use mild and low potency topical steroids on the face, axillae, and/or genitalia, as needed; these were not to be used within 24 hours of study visits at which PASI was measured.

Results

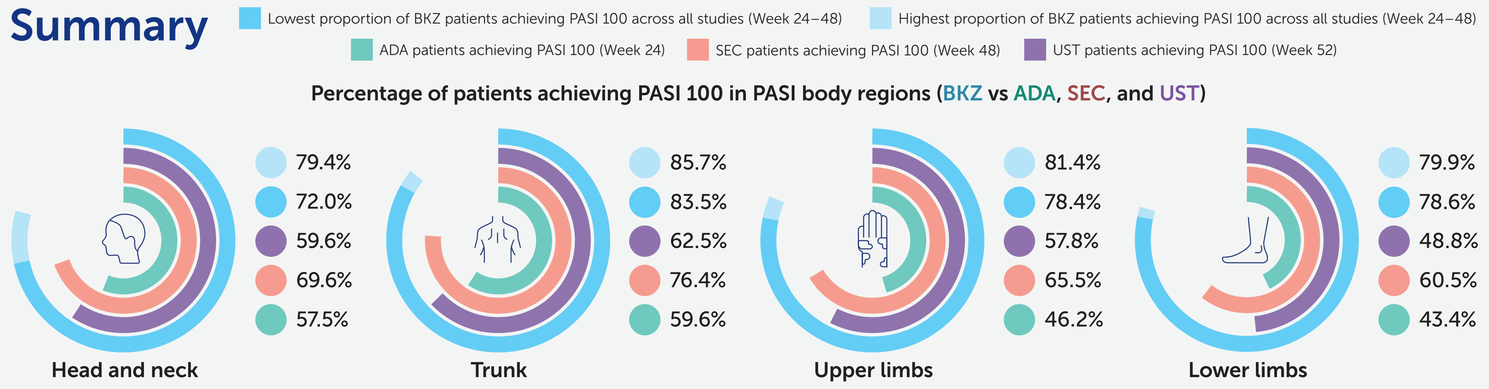
- Baseline characteristics for each study have been reported previously; baseline mean PASI scores in patients with PASI >0 were comparable across studies (**Table 1**).[4–7]
- Numbers of patients randomised to each treatment across studies were as follows:
  - BE SURE: 319 patients to BKZ, 159 to ADA;
  - BE RADIANT: 373 patients to BKZ, 370 to SEC;
  - BE VIVID: 321 patients to BKZ, 163 to UST;
  - Pooled BE VIVID/BE READY: 670 patients to BKZ, 169 to PBO.
- By Week 4 in each study, greater proportions of BKZ-randomised patients achieved PASI 100 and PASI 90 than their respective comparators in each body region (**Table 2**); the greatest Week 4 responses were observed in the head and neck.
- In each study, greater proportions of BKZ-randomised patients achieved PASI 100 and PASI 90 (**Figure 1**) across each PASI body region vs the respective comparator at the final visit of each comparator-controlled period.
- Across studies, the proportions of BKZ-randomised patients who achieved PASI 100 in different PASI body regions were:
  - Head and neck: 72.0–80.2%;
  - Trunk: 83.5–86.0%;
  - Upper limbs: 78.4–81.4%;
  - Lower limbs: 75.2–79.9%.
- The proportions of BKZ-randomised patients who achieved PASI 90 in different PASI body regions were:
  - Head and neck: 74.9–84.8%;
  - Trunk: 84.8–90.7%;
  - Upper limbs: 80.0–86.7%;
  - Lower limbs: 82.0–85.8%.
- The greatest differences in treatment effect for BKZ vs an active comparator for PASI 100 and PASI 90 were observed in BE SURE; 20.1–36.2% more BKZ-randomised patients achieved these PASI outcomes than ADA-randomised patients. BKZ vs SEC and UST showed differences of 6.8–19.4% and 10.2–30.3%, respectively.

Conclusions

BKZ-randomised patients achieved more rapid and greater clinical responses in all PASI body regions vs comparators during PBO- and active comparator-controlled study periods.

While comparators had differing responses across body regions, performing better on the head and neck compared to the upper and lower limbs, BKZ had higher, more uniform responses across body regions.

Summary



BKZ-treated patients achieved **greater clinical responses** in all PASI body regions versus comparators across all comparative studies

Table 1 Baseline mean PASI scores in each body region for BKZ vs comparators

Baseline PASI score, mean (SD) [n]	BE SURE		BE RADIANT		BE VIVID		BE VIVID/BE READY	
	BKZ Total N=319	ADA N=159	BKZ Total N=373	SEC N=370	BKZ 320 mg Q4W N=321	UST N=163	BKZ 320 mg Q4W N=670	PBO N=169
Head and neck	19.5 (11.5) [306]	17.4 (10.2) [146]	20.3 (13.3) [358]	20.0 (13.2) [352]	19.1 (12.1) [307]	18.0 (11.9) [156]	18.7 (11.6) [631]	18.4 (12.0) [158]
Trunk	18.7 (9.3) [314]	18.4 (8.7) [156]	19.1 (10.2) [364]	18.5 (9.3) [356]	21.2 (11.0) [315]	19.6 (9.6) [160]	19.7 (10.7) [656]	18.3 (9.5) [167]
Upper limbs	19.6 (8.3) [317]	19.0 (8.3) [158]	19.5 (8.8) [372]	19.1 (7.9) [368]	20.9 (9.6) [320]	20.1 (9.0) [161]	20.9 (9.4) [667]	19.4 (8.7) [168]
Lower limbs	22.3 (9.3) [318]	20.7 (7.8) [159]	22.0 (9.3) [373]	21.7 (9.0) [367]	24.5 (11.0) [321]	24.5 (11.9) [162]	23.7 (10.5) [670]	22.8 (9.3) [169]

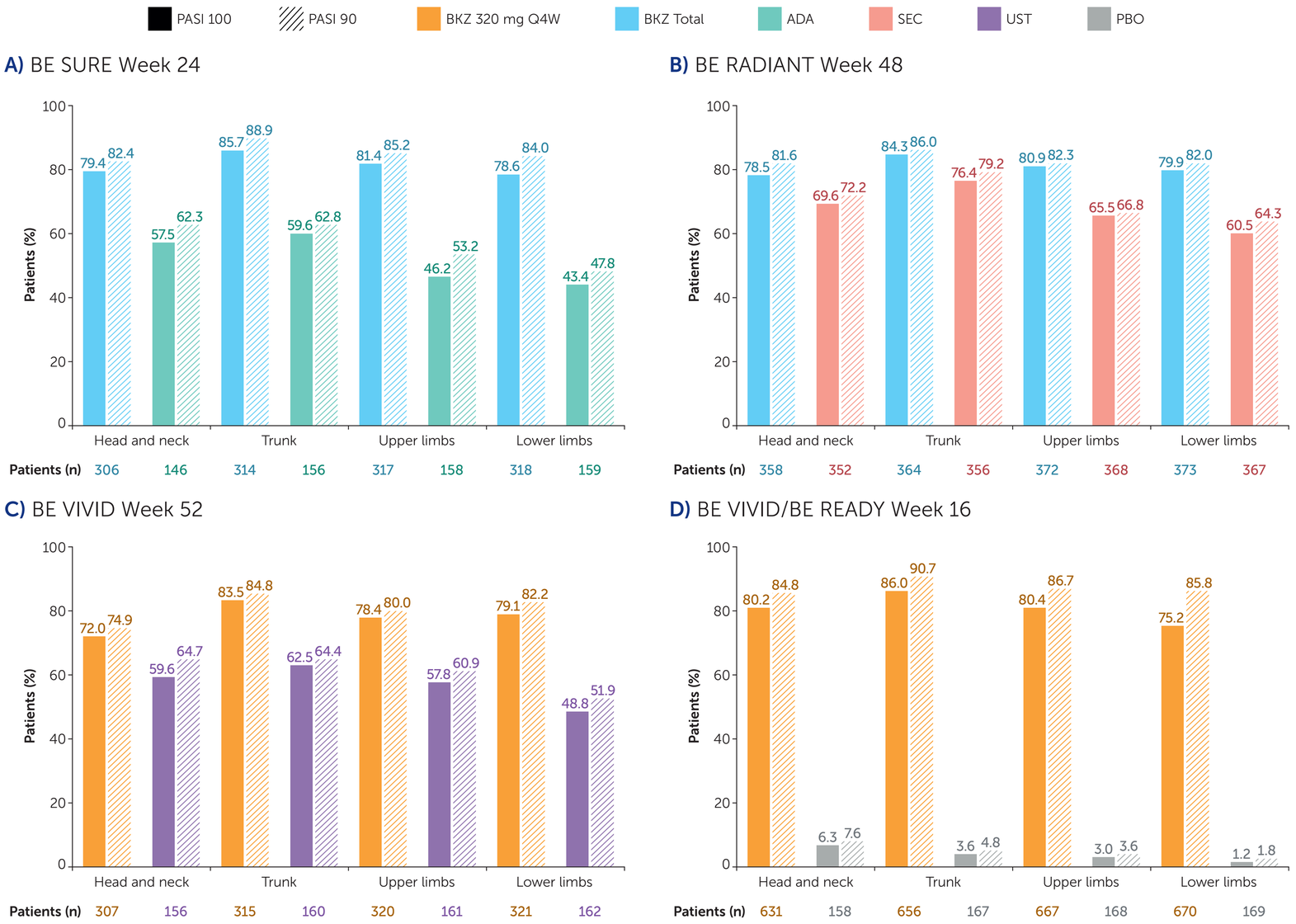
Only patients with PASI >0 for each given body region are included. BKZ Total represents BKZ 320 mg Q4W and Q8W dose groups combined.

Table 2 Week 4 PASI 100/90 responses in each body region with BKZ vs comparators (NRI)

Week 4 PASI responses, % (n)	BE SURE		BE RADIANT		BE VIVID		BE VIVID/BE READY	
	BKZ Total N=319	ADA N=159	BKZ Total N=373	SEC N=370	BKZ 320 mg Q4W N=321	UST N=163	BKZ 320 mg Q4W N=670	PBO N=169
PASI 100								
Head and neck	58.5 (306)	30.8 (146)	57.0 (358)	40.3 (352)	54.4 (307)	23.1 (156)	57.5 (631)	4.4 (158)
Trunk	48.1 (314)	16.0 (156)	40.1 (364)	23.9 (356)	41.3 (315)	8.1 (160)	45.9 (656)	2.4 (167)
Upper limbs	36.0 (317)	5.7 (158)	29.3 (372)	14.7 (368)	36.9 (320)	5.6 (161)	39.4 (667)	1.8 (168)
Lower limbs	23.3 (318)	3.1 (159)	20.4 (373)	11.2 (367)	24.9 (321)	3.1 (162)	25.5 (670)	1.2 (169)
PASI 90								
Head and neck	68.3 (306)	36.3 (146)	66.2 (358)	50.9 (352)	65.5 (307)	26.3 (156)	66.9 (631)	5.7 (158)
Trunk	59.9 (314)	21.8 (156)	54.1 (364)	33.4 (356)	59.4 (315)	10.0 (160)	60.2 (656)	2.4 (167)
Upper limbs	47.3 (317)	8.9 (158)	40.6 (372)	20.7 (368)	48.4 (320)	9.3 (161)	52.0 (667)	2.4 (168)
Lower limbs	33.3 (318)	3.1 (159)	29.5 (373)	15.0 (367)	39.3 (321)	4.9 (162)	38.7 (670)	1.2 (169)

n represents the number of patients with PASI >0 in each body region at baseline. BKZ Total represents BKZ 320 mg Q4W and Q8W dose groups combined.

Figure 1 Proportion of patients achieving PASI 100 and PASI 90 in each body region with BKZ vs comparators at the end of each comparator-controlled period (NRI)



Only patients with PASI >0 for each given body region are included. BKZ Total represents BKZ 320 mg Q4W and Q8W dose groups combined.

ADA: adalimumab; **BKZ:** bimekizumab; **IL:** interleukin; **NRI:** non-responder imputation; **PASI:** Psoriasis Area and Severity Index; **PASI 90/100:** ≥90%/100% improvement from baseline in PASI; **PBO:** placebo; **Q4W:** every 4 weeks; **Q8W:** every 8 weeks; **SD:** standard deviation; **SEC:** secukinumab; **UST:** ustekinumab.

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References: [1]Timotijević ZS et al. Acta Dermatovenerol Croat 2017;25:215–22; [2]Alpalhão M et al. BioDrugs 2022;36:781–9; [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. N Engl J Med 2021;385:142–152, NCT03536884; [6]Reich K et al. Lancet 2021;397: 487–98, NCT03370133; [7]Gordon K et al. Lancet 2021;397:475–86, NCT03410992; [8]Strober B et al. Br J Dermatol 2023; 188:749–59, NCT03598790. **Author Contributions:** Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: **LJS**, **AP**, **JC**, **PvdK**, **AA**, **SK**, **SW**, **BH**, **RBW**; Drafting of the publication, or reviewing it critically for important intellectual content: **LJS**, **AP**, **JC**, **PvdK**, **AA**, **SK**, **SW**, **BH**, **RBW**; Final approval of the publication: **LJS**, **AP**, **JC**, **PvdK**, **AA**, **SK**, **SW**, **BH**, **RBW**. **Author disclosures: LJS:** Received grant/research support from Janssen and Pfizer; consultant for AbbVie, Almirall, Biogen, Boehringer Ingelheim, Bristol Myers Squibb, Janssen, LEO Pharma, Eli Lilly and Company, Novartis, and UCB Pharma; speaker for AbbVie, Almirall, Amgen, Aspire Pharma, Biogen, Boehringer Ingelheim, Celgene, Celltrion, Galderma, Janssen, LEO Pharma, Eli Lilly and Company, Novartis, Pfizer, Sanofi Genzyme, and UCB Pharma. **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 Pharma. **JC:** Research/grant support from AbbVie, Amgen, Boehringer Ingelheim, Eli Lilly and Company, Janssen, MC2 Therapeutics, Merck, Novartis, Pfizer, Regeneron, Sandoz, Sanofi, Sun Pharma, UCB Pharma, and Verrica Pharmaceuticals; consultant for AbbVie, Amgen, Celgene, Dermira, Eli Lilly and Company, Novartis, Sun Pharma, and UCB Pharma; speakers bureau for AbbVie, Eli Lilly and Company, Janssen, Novartis, Regeneron, Sanofi, and UCB Pharma. **PvdK:** Received fees for consultancy service or lectureships from Abbott, Almirall, Amgen, Bristol Myers Squibb, Celgene, Centocor, Dermavant, Eli Lilly and Company, Galderma, Janssen, LEO Pharma, Novartis, Pfizer, Philips, and Sandoz. **AA:** Research investigator and/or scientific advisor to AbbVie, Almirall, Arcutis, ASLAN, Boehringer Ingelheim, Bristol Myers Squibb, Dermavant, Dermira, Eli Lilly and Company, EPI, Incyte, Janssen, LEO Pharma, Nimbus, Novartis, Ortho Dermatologics, Pfizer, Regeneron, Sun Pharma, Sanofi, and UCB Pharma. **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, Tonix, Tornado Therapeutics, UCB Pharma, Whitsell Innovations, Worldwide Clinical Trials, and Zosano. **SW**, **BH:** Employees and shareholders of 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, UCB Pharma, and Union Therapeutics; 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. **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 Inés Dueñas Pousa, PhD, UCB Pharma, Madrid, Spain for publication coordination, Isabel Raynaud, MBBS iBSc, Costello Medical, Cambridge, UK 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.

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