Bimekizumab long-term efficacy in patients with plaque psoriasis from BE BRIGHT: Improvements in mean absolute clinical outcome scores over 4 years

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Objective

To evaluate the clinical efficacy of bimekizumab (BKZ), using mean absolute scores in commonly used clinical outcomes through 4 years of treatment, in patients who entered the BE BRIGHT open-label extension (OLE).

Synopsis

- BKZ has demonstrated rapid and superior efficacy in patients with moderate to severe plaque psoriasis vs ustekinumab, adalimumab, and secukinumab, with established long-term durability of response.[1–5]
- Measuring responses using absolute outcome scores may be clinically beneficial, as they are not influenced by baseline disease severity and provide a direct measure of current disease severity.[6]

Methods

- Data were pooled from the 52-week BE VIVID, the 56-week BE READY and BE SURE phase 3 trials, and their OLE BE BRIGHT.[2–5] Included patients received BKZ 320 mg every 4 weeks (Q4W) to Week 16, then Q4W or every 8 weeks (Q8W) into the OLE.
- Mean absolute Psoriasis Area and Severity Index (PASI; scored 0–72), Investigator's Global Assessment (IGA; scored 0–4), body surface area affected by psoriasis (BSA; scored 0–100%) and Dermatology Life Quality Index (DLQI; scored 0–30) scores are reported to Year 4 (OLE Week 144). For each, lower scores indicate improved clinical outcomes.
- Data are reported for all patients who received any continuous BKZ-treatment from baseline and entered the OLE (BKZ Total), and for the subset who received BKZ Q4W to Week 16 then Q8W continuously into the OLE (Q4W/Q8W; the approved dosing regimen for most patients with psoriasis).[7,8]
- A multiple imputation (MI) model was used to impute any missing data or data following the discontinuation of treatment due to lack of efficacy or treatment-related adverse events. Observed case (OC) data are also presented.

Results

- 771 patients who had been continuously treated with BKZ through to the end of the first year entered the OLE (BKZ Total). Of these, 197 patients received BKZ Q4W/Q8W.
- Baseline mean absolute scores for BKZ Total patients were: PASI 21.1, IGA 3.3, BSA 27.0%, and DLQI 10.5 (BKZ Q4W/Q8W subset scores were similar, as presented in **Table 1**).
- Following one dose of BKZ treatment, at Week 4, BKZ Total patients had mean scores of: PASI 3.6, IGA 1.4, BSA 9.7%, and DLQI 3.1.
- By Week 16 (end of initial treatment period), clinical outcomes had improved further, and these improvements were maintained in the long-term (**Figure 1A–D**).
- In BKZ Total patients, Year 4 mean absolute scores were: PASI 0.7, IGA 0.5, BSA 1.2%, and DLQI 0.9; similar results were reported in the Q4W/Q8W patient subset (**Figure 1A–D**).

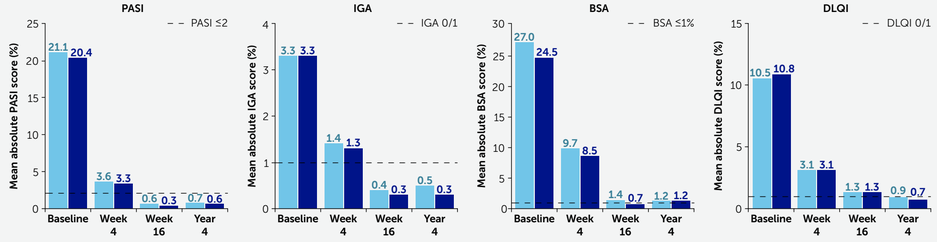
Conclusions

Mean absolute PASI, IGA, BSA, and DLQI scores were notably decreased by Week 4 and reached low and stable levels by Week 16, which were sustained through 4 years of continuous bimekizumab treatment, including in the subset who received the approved dosing regimen (Q4W/Q8W).

These results provide a direct measure of reduced disease severity following bimekizumab treatment and demonstrate a rapid, high level of response, maintained in the long-term.

Summary

Improvements in mean absolute clinical outcomes through 4 years (MI)



In BKZ-treated patients who enrolled in the OLE, **large improvements in mean absolute scores of commonly-used clinical outcomes** were achieved **rapidly** and were **highly durable** in the long-term through 4 years.

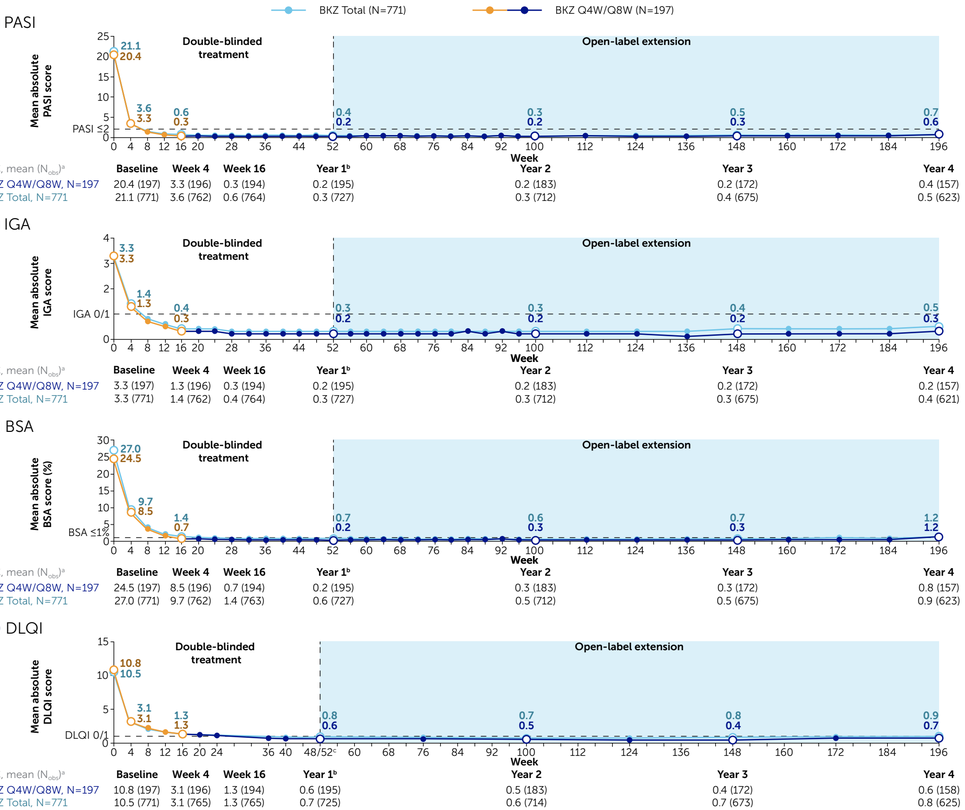
Table 1 Baseline characteristics

Mean (SD), unless otherwise specified	BKZ Total N=771	BKZ Q4W/Q8W N=197
Age (years)	45.4 (13.5)	45.0 (14.1)
Male, n (%)	550 (71.3)	141 (71.6)
White, n (%)	656 (85.1)	185 (93.9)
Weight (kg)	89.7 (21.2)	88.5 (20.8)
BMI (kg/m²)	29.9 (6.6)	29.3 (6.2)
Duration of psoriasis (years)	18.6 (12.7)	18.9 (12.0)
PASI	21.1 (7.6)	20.4 (6.9)
BSA (%)	27.0 (15.6)	24.5 (12.2)
IGA, n (%)[a]		
3: moderate	508 (65.9)	142 (72.1)
4: severe	262 (34.0)	55 (27.9)
DLQI	10.5 (6.3)	10.8 (6.0)
Any prior systemic therapy, n (%)	618 (80.2)	154 (78.2)
Any prior biologic therapy, n (%)	309 (40.1)	73 (37.1)
Anti-TNF	113 (14.7)	19 (9.6)
Anti-IL-17	193 (25.0)	48 (24.4)
Anti-IL-23	37 (4.8)	13 (6.6)
Anti-IL-12/23	43 (5.6)	13 (6.6)

Data are reported for all patients who were treated continuously with BKZ through the initial treatment and maintenance periods, and entered the OLE. **[a]** One patient had an IGA score of 2 (mild) in the BKZ Total group.

BKZ: bimekizumab; **BMI:** body mass index; **BSA:** body surface area; **DLQI:** Dermatology Life Quality Index; **IGA:** Investigator's Global Assessment; **IL:** interleukin; **MI:** multiple imputation; **OC:** observed case; **OLE:** open-label extension; **PASI:** Psoriasis Area and Severity Index; **PASI 90/100:** ≥90/100% improvement from baseline in Psoriasis Area and Severity Index; **Q4W:** every 4 weeks; **Q8W:** every 8 weeks; **SD:** standard deviation; **TNF:** tumour necrosis factor.

Figure 1 Improvements in mean absolute clinical outcome scores with BKZ through 4 years (MI, OC)



OC, mean (N_{obs})[a]

	Baseline	Week 4	Week 16	Year 1[b]	Year 2	Year 3	Year 4
BKZ Q4W/Q8W, N=197	20.4 (197)	3.3 (196)	0.3 (194)	0.2 (195)	0.2 (183)	0.2 (172)	0.4 (157)
BKZ Total, N=771	21.1 (771)	3.6 (762)	0.6 (764)	0.3 (727)	0.3 (712)	0.4 (675)	0.5 (623)

OC, mean (N_{obs})[a]

	Baseline	Week 4	Week 16	Year 1[b]	Year 2	Year 3	Year 4
BKZ Q4W/Q8W, N=197	3.3 (197)	1.3 (196)	0.3 (194)	0.2 (195)	0.2 (183)	0.2 (172)	0.2 (157)
BKZ Total, N=771	3.3 (771)	1.4 (762)	0.4 (764)	0.3 (727)	0.3 (712)	0.3 (675)	0.4 (621)

OC, mean (N_{obs})[a]

	Baseline	Week 4	Week 16	Year 1[b]	Year 2	Year 3	Year 4
BKZ Q4W/Q8W, N=197	24.5 (197)	8.5 (196)	0.7 (194)	0.2 (195)	0.3 (183)	0.3 (172)	0.8 (157)
BKZ Total, N=771	27.0 (771)	9.7 (762)	1.4 (763)	0.6 (727)	0.5 (712)	0.5 (675)	0.9 (623)

OC, mean (N_{obs})[a]

	Baseline	Week 4	Week 16	Year 1[b]	Year 2	Year 3	Year 4
BKZ Q4W/Q8W, N=197	10.8 (197)	3.1 (196)	1.3 (194)	0.6 (195)	0.5 (183)	0.4 (172)	0.6 (158)
BKZ Total, N=771	10.5 (771)	3.1 (765)	1.3 (765)	0.7 (725)	0.6 (714)	0.7 (673)	0.8 (625)

Data are reported for patients who entered the OLE only. Horizontal dotted lines demonstrate key target treatment thresholds (PASI ≤2, IGA 0/1, BSA ≤1%, DLQI 0/1).9,10 A reduction in score indicates improvement for all outcomes; score ranges are PASI: 0–72, IGA: 0–4, BSA: 0–100%, DLQI: 0–30. For OC, data from patients who entered the BE READY escape arm were considered missing from the date of escape until the end of BE READY, after which their data are presented as observed. **[a]** N_{obs} represents the number of patients with observed data at a given timepoint; **[b]** BE VIVID lasted 52 weeks and BE SURE and BE READY lasted 56 weeks; to pool data across studies, Week 52 was considered as the last common timepoint before OLE entry (Year 1); **[c]** Due to lack of common timepoints at which the DLQI was assessed, Week 48 (BE SURE and BE READY)/52 (BE VIVID) was used as a composite last timepoint before OLE entry (Year 1) when pooling the studies.

References: [1]Reich K et al. N Engl J Med 2021;385:142–52 (NCT03536884); [2]Gordon KB et al. Lancet 2021;397:475–86 (NCT03410992); [3]Warren RB et al. N Engl J Med 2021;385:130–41 (NCT03412747); [4]Reich K et al. Lancet 2021;397:487–98 (NCT03370133); [5]Strober B et al. Br J Dermatol 2023;188:749–59 (NCT03598790); [6]Gerdes S et al. J Dermatol Treat 2020;31:470–5; [7]Bimzelx® Summary of Product Characteristics. 2023. Available at: https://www.ema.europa.eu/en/medicines/human/EPAR/bimzelx [Accessed March 2025]; [8]Bimzelx® US Prescribing Information. 2023. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/761151s000lbl.pdf [Accessed June 2025]; [9]Mahil SK et al. Br J Dermatol 2020;182:1158–66; [10]Armstrong AW et al. J Am Acad Dermatol 2017;76:290–8. **Author Contributions:** Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: **SG**, **AC**, **PFP**, **KA**, **AB**, **AGC**, **SK**, **JMLP**, **BH**, **GH**; Drafting of the publication, or reviewing it critically for important intellectual content: **SG**, **AC**, **PFP**, **KA**, **AB**, **AGC**, **SK**, **JMLP**, **BH**, **GH**; Final approval of the publication: **SG**, **AC**, **PFP**, **KA**, **AB**, **AGC**, **SK**, **JMLP**, **BH**, **GH**. **Author Disclosures: SG:** Advisor and/or received speakers' honoraria and/or received grants and/or participated in clinical trials of the following companies: AbbVie, Acelyrin Inc., Admune, Inc., Affibody AB, Akari Therapeutics Plc, Almirall-Hermal, Amgen, Apogee Therapeutics, Argenx BV, Aristea Therapeutics, Bristol Myers Squibb, Boehringer Ingelheim, Celgene, Dermira, Eli Lilly & Company, Galderma, Hexal AG, Incyte Inc., Janssen-Cilag, Klinge Pharma, Kynab, LEO Pharma, Medac, MoonLake Immunotherapeutics AG, MSD, Neubourg Skin Care GmbH, Novartis, Pfizer, Pierre Fabre, Principia Biopharma, Regeneron Pharmaceutical, Sandoz Biopharmaceuticals, Sanofi-Aventis, and UCB. **AC:** Investigator and/or speaker and/or advisor for AbbVie, Almirall, Amgen, Boehringer Ingelheim, Celgene, Eli Lilly and Company, Galderma, Johnson & Johnson, LEO Pharma, Novartis, Pfizer, Regeneron Therapeutics, Sandoz, Sanofi, and UCB. **PFP:** Served on advisory boards for: AbbVie; Amgen, Boehringer Ingelheim, Bristol Myers Squibb, Eli Lilly and Company, Janssen, L'Oréal, LEO Pharma, Merck, Merck Sharp & Dohme, Novartis, Pfizer, Sanofi, and UCB; has given educational lectures for AbbVie, Amgen, Bristol Myers Squibb, Eli Lilly and Company, Galderma, Janssen, L'Oréal, LEO Pharma, Merck, Merck Sharp & Dohme, Novartis, Pfizer, Sanofi, and UCB; has given educational lectures for AbbVie, Amgen, Bristol Myers Squibb, Eli Lilly and Company, Galderma, GlaxoSmithKline, Immunovant, Incyte, IQVIA, Janssen, LEO Pharma, Lipidio, Merck, Novartis, Oruka, Paragon, Pfizer, Rani Therapeutics, Regeneron, Sanofi, Spherix Global Insights, Sun Pharma, Syncona, Takeda, UCB, Union, and Zai Lab; acted as a clinical study investigator (institution has received clinical study funds) for AbbVie, Acelyrin, Almirall, Alumis, Amgen, Arcutis, Boehringer Ingelheim, Bristol-Myers Squibb, Dermavant, Eli Lilly and Company, Galderma, Incyte, Janssen, LEO Pharma, Merck, Novartis, Pfizer, Regeneron, Sanofi, Sun Pharma, Takeda, and UCB; and owns stock in Lipidio and Oruka. **AGC:** Consultancy, honoraria and/or research funding from AbbVie, Almirall, Amgen, Celgene, Eli Lilly and Company, Johnson & Johnson, LEO Pharma, Novartis, and UCB. **SK:** Consultant for Aclipse Therapeutics, Aliada Therapeutics, Allay Therapeutics, Autobahn Therapeutics, Biolacuna, Cognition Therapeutics, Colorado Prevention Center, Karuna Therapeutics, Kisbee Therapeutics, LB Pharmaceuticals, Nesos, Novartis, Onward Medical, PharPoint Research, Summit Analytical, Therini Bio, Tonix Pharmaceuticals, Tornado Therapeutics, UCB, Whitsell Innovations, Worldwide Clinical Trials, and Zosano Pharma. **JMLP** and **BH:** Employees and shareholders of UCB. **GH:** Investigator, consultant, advisor, or speaker for AbbVie, Amgen, Athenex, Boehringer Ingelheim, Bond Avillion, Bristol Myers Squibb, Castle Biosciences, Celgene, Dermavant, Dermtech, Eli Lilly and Company, Incyte, Johnson & Johnson, LEO Pharma, MC2, Ortho Dermatologics, Pfizer, Regeneron, Sanofi Genzyme, Sun Pharma, and UCB. **Acknowledgements:** This study was funded by UCB. We would like to 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, Oscar Jenkyn-Jones, MSc, 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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