Bimekizumab efficacy from treatment initiation through 4 years in patients with plaque psoriasis: A comprehensive, long-term, pooled analysis from BE BRIGHT

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Objective

To provide the first disclosure of efficacy responses from treatment initiation of bimekizumab (BKZ) through 4 years in moderate to severe plaque psoriasis.

To provide a comprehensive view of efficacy in BKZ-treated patients over 4 years across clinical and health-related quality of life outcomes, using the largest available pool of 4-year global phase 3 clinical data at the time of this study.

Introduction

- Psoriasis is a chronic disease; assessing long-term treatment efficacy is imperative.[1]
- BKZ is a monoclonal immunoglobulin G1 (IgG1) antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A.[2,3]
- BKZ has demonstrated rapid and superior efficacy in the treatment of psoriasis versus ustekinumab, adalimumab, and secukinumab, with established long-term durability of response.[4–8]

Methods

- Data were pooled across the 52-week BE VIVID, 56-week BE SURE and BE READY trials, and their open-label extension (OLE) BE BRIGHT. Analyzed patients were randomized to BKZ 320 mg every 4 weeks (Q4W) to Week 16, received BKZ Q4W or every 8 weeks (Q8W) thereafter, and entered the OLE (**Figure 1**).[4–6,8]
- Proportions achieving ≥90%/100% improvement from baseline in Psoriasis Area and Severity Index (PASI 90/PASI 100), body surface area (BSA) ≤1%, and Dermatology Life Quality Index (DLQI) 0/1 are reported from initial study baseline through Year 4 (OLE Week 144).
- Missing data were imputed using modified non-responder imputation (mNRI). Patients who discontinued due to lack of efficacy/treatment-related adverse events were considered non-responders at subsequent timepoints; multiple imputation was used for other missing data.

Results

Baseline characteristics and patient disposition

- Baseline characteristics and patient disposition are presented in **Table 1** and **Figure 2**, respectively.

Treatment response

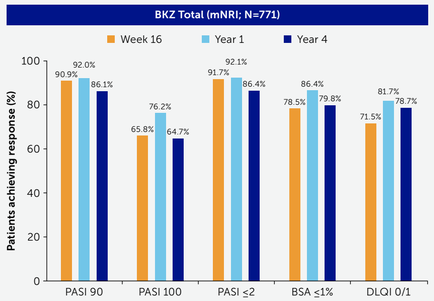
- BKZ treatment responses over 4 years are summarized in **Figure 3**.
- Among patients who received BKZ continuously from baseline and entered the OLE (N=771), 90.9%, 65.8%, 91.7%, 78.5%, and 71.5% of patients achieved PASI 90, PASI 100, PASI ≤2, BSA ≤1%, and DLQI 0/1, respectively, at Week 16. Responses were highly durable throughout 4 years of BKZ treatment, with 86.1%, 64.7%, 86.4%, 79.8%, and 78.7% of patients reporting PASI 90, PASI 100, PASI ≤2, BSA ≤1%, and DLQI 0/1, respectively, at Year 4.
- In the subset of patients who received BKZ Q4W/Q8W/Q8W (initial/maintenance/OLE; N=197), 88.0%, 72.6%, 89.2%, 83.2%, and 83.3% reported PASI 90, PASI 100, PASI ≤2, BSA ≤1%, and DLQI 0/1, respectively, at Year 4.

Conclusions

In patients who received bimekizumab and enrolled in the OLE, high rates of clinical and health-related quality of life responses were achieved rapidly and were highly durable in the long term through 4 years.

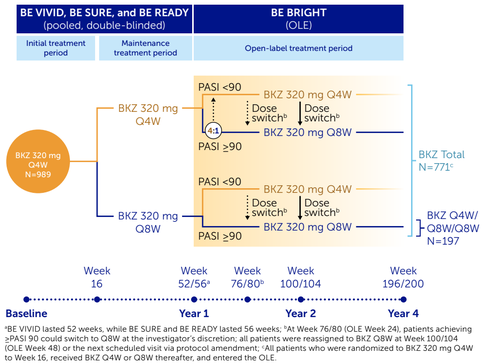
PASI 90, PASI 100, PASI ≤2, BSA ≤1%, and DLQI 0/1 response rates were consistent in the subset of patients enrolled in the OLE who received bimekizumab 320 mg Q4W to Week 16 then Q8W thereafter, the approved dosing regimen for the majority of patients with plaque psoriasis.[9,10]

Summary



BKZ provided **high** and **durable** clinical and health-related quality of life responses through 4 years in patients with moderate to severe plaque psoriasis.

Figure 1 Study design overview



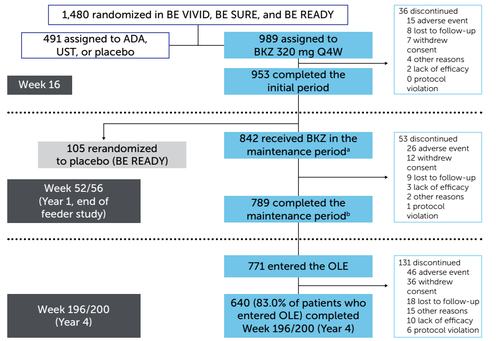
[a]BE VIVID lasted 52 weeks, while BE SURE and BE READY lasted 56 weeks; [b]At Week 76/80 (OLE Week 24), patients achieving ≥PASI 90 could switch to Q8W at the investigator's discretion; all patients were reassigned to BKZ Q8W at Week 100/104 (OLE Week 48) or the next scheduled visit via protocol amendment; [c]All patients who were randomized to BKZ 320 mg Q4W to Week 16, received BKZ Q4W or Q8W thereafter, and entered the OLE.

Table 1 Baseline characteristics

	BKZ Total N=771[a]	BKZ Q4W/Q8W/Q8W N=197
Age (years), mean ± SD	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), mean ± SD	89.7 ± 21.2	88.5 ± 20.8
BMI (kg/m²), mean ± SD	29.9 ± 6.6	29.3 ± 6.2
Duration of psoriasis (years), mean ± SD	18.6 ± 12.7	18.9 ± 12.0
PASI, mean ± SD	21.1 ± 7.6	20.4 ± 6.9
BSA (%), mean ± SD	27.0 ± 15.6	24.5 ± 12.2
IGA, n (%)		
3: moderate	508 (65.9)	142 (72.1)
4: severe	262 (34.0)	55 (27.9)
DLQI total score, mean ± SD	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)

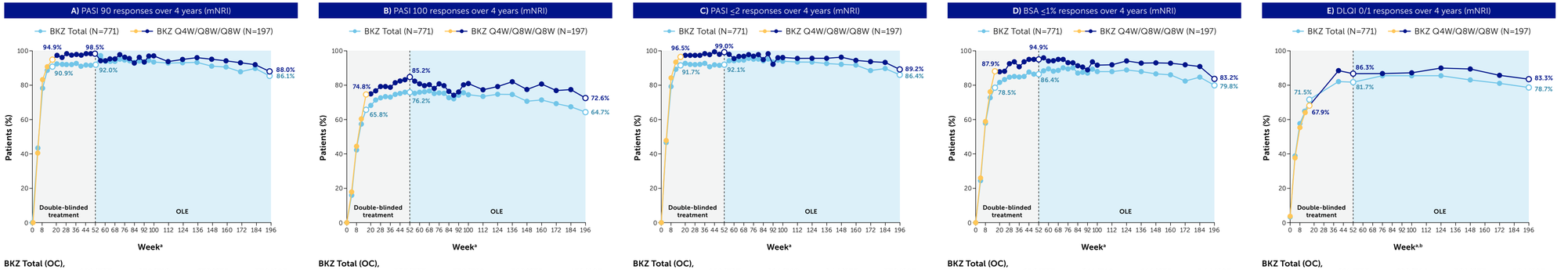
[a]Baseline characteristics shown for all patients who were randomized to BKZ 320 mg Q4W to Week 16, received BKZ Q4W or Q8W thereafter, and entered the OLE.

Figure 2 Patient disposition



[a]Of these patients, 34 entered the escape treatment period (23 who did not achieve PASI 90 at Week 16, and 11 who did, were rerandomized to BKZ, and relapsed); [b]Includes patients who completed the escape treatment period.

Figure 3 Response to BKZ over 4 years measured by (A) PASI 90, (B) PASI 100, (C) PASI ≤2, (D) BSA ≤1%, and (E) DLQI 0/1 [mNRI; OC]



Yellow line coloring signifies BKZ Q4W dosing. For OC, data from the point of escape and through Week 56 of BE READY for these patients were considered missing, and from the point of entry into BE BRIGHT, their data are presented as observed. [a]BE VIVID lasted 52 weeks, and BE SURE and BE READY lasted 56 weeks; to pool data across studies, Week 56 data were not included. In this figure panel, the period after Week 52 corresponds to the BE BRIGHT OLE; [b]For DLQI 0/1, Week 52 corresponds to the Week 48 assessment for BE VIVID and BE SURE, and Week 52 for BE READY, because DLQI was assessed on a different schedule in these studies.

ADA: adalimumab; **BKZ:** bimekizumab; **BMI:** body mass index; **BSA:** body surface area; **DLQI:** Dermatology Life Quality Index; **IGA:** Investigator's Global Assessment; **IL:** interleukin; **mNRI:** modified non-responder imputation; **OC:** observed cases; **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:** tumor necrosis factor; **UST:** ustekinumab.

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Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/761151s000lbl.pdf [Accessed February 2024]. **Author Contributions:** Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: **BSt**, **ML**, **PF**, **RGL**, **AM**, **SP**, **JT**, **BSz**, **BH**, **JL**, **DT**; Drafting of the publication, or reviewing it critically for important intellectual content: **BSt**, **ML**, **PF**, **RGL**, **AM**, **SP**, **JT**, **BSz**, **BH**, **JL**, **DT**; Final approval of the publication: **BSt**, **ML**, **PF**, **RGL**, **AM**, **SP**, **JT**, **BSz**, **BH**, **JL**, **DT**. **Author Disclosures: BSt:** Consultant (honoraria): 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, Kanggu Pharmaceuticals, LEO Pharma, Maruho, Meiji Seika Pharma, Monte Carlo, Novartis, Pfizer, Protagonist, Rapt, Regeneron, Sanofi Genzyme, SG Cowen, Sun Pharma, Takeda, UCB Pharma, Union Therapeutics, Ventyxbio, and vTv Therapeutics; stock options from Connect Biopharma and Mindera Health; speaker for AbbVie, Arcutis, Dermavant, Eli Lilly and Company, Incyte, Janssen, Regeneron, and Sanofi Genzyme; scientific codirector (consulting fee) for CorEvitas Psoriasis Registry; investigator for CorEvitas Psoriasis Registry; Editor-in-Chief (honorarium) for Journal of Psoriasis and Psoriatic Arthritis. **ML:** Employee of Mount Sinai and receives research funds from AbbVie, Amgen, Arcutis, Avotres, Boehringer Ingelheim, Cara Therapeutics, Dermavant Sciences, Eli Lilly and Company, Incyte, Inozyme, Janssen Research & Development, LLC, Ortho Dermatologics, Pfizer, Sanofi–Regeneron, and UCB Pharma; consultant for Almirall, AltruBio Inc., AnaptysBio, Apogee, Arcutis Inc., AstraZeneca, Atomwise, Avotres Therapeutics, Brickell Biotech, Boehringer Ingelheim, Bristol Myers Squibb, Castle Biosciences, Celltrion, CorEvitas, Dermavant Sciences, EPI, Evommune Inc., Facilitation of International Dermatology Education, Forte Biosciences, Foundation for Research and Education in Dermatology, Galderma, Genentech, Incyte, LEO Pharma, Meiji Seika Pharma, Mindera, Pfizer, Sanofi–Regeneron, Seanergy, Strata, Takeda, Trevi, and Verrica. **PF:** Grant support from AbbVie, Amgen, Bristol Myers Squibb, Celgene, Eli Lilly and Company, Janssen, LEO Pharma, Merck, Novartis, Pfizer, Sanofi, and Sun Pharma; served as an investigator for AbbVie, Akaal, Amgen, Arcutis, Argenx, Aslan, AstraZeneca, Boehringer Ingelheim, Botanix, Bristol Myers Squibb, Celgene, Celtaxsys, CSL, Cutanea, Dermira, Eli Lilly and Company, Evelo, Galderma, Genentech, Geneseq, GenesisCare, GSK, Hexima, Incyte, Janssen, Kymab, LEO Pharma, MedImmune, Merck, Novartis, Pfizer, Regeneron, Reistone, Roche, Sanofi, Sun Pharma, Takeda, Teva, UCB Pharma, and Valeant; served on advisory boards for AbbVie, Amgen, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Eli Lilly and Company, Galderma, GSK, Janssen, LEO Pharma, Mayne Pharma, Merck, Novartis, Pfizer, Sanofi, Sun Pharma, UCB Pharma, and Valeant; served as a consultant for Aslan, Bristol Myers Squibb, Eli Lilly and Company, Galderma, GenesisCare, Janssen, LEO Pharma, Mayne Pharma, MedImmune, Novartis, Pfizer, Roche, UCB Pharma, and Wintermute; received travel grants from AbbVie, Eli Lilly and Company, Galderma, Janssen, LEO Pharma, Merck, Novartis, Pfizer, Roche, Sun Pharma, and Sanofi; served as a speaker for or received honoraria from AbbVie, Almirall, Amgen, Celgene, Eli Lilly and Company, Galderma, GSK, Janssen, LEO Pharma, Merck, Novartis, Pfizer, Roche, Sanofi, Sun Pharma, UCB Pharma, and Valeant. **RGL:** Principal investigator for AbbVie, Amgen, Boehringer Ingelheim, Celgene, Eli Lilly and Company, LEO Pharma, Merck, Novartis, Pfizer, and UCB Pharma; served on scientific advisory boards for AbbVie, Amgen, Boehringer Ingelheim, Celgene, Eli Lilly and Company, LEO Pharma, Merck, Novartis, Pfizer, and UCB Pharma; provided lectures for AbbVie, Amgen, Celgene, Eli Lilly and Company, LEO Pharma, Merck, Novartis, and Pfizer. **AM:** Research grants, consulting fees, and/or speaker's fees from AbbVie, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Eisai, Eli Lilly and Company, Janssen, Kyowa Hakko Kirin, LEO Pharma, Maruho, Mitsubishi Tanabe Pharma, Nichi-Iko, Nippon Kayaku, Novartis, Pfizer, Sun Pharma, Taiho Pharmaceutical, Torii Pharmaceutical, UCB Pharma, and Ushio. **SP:** Served as consultant and/or speaker for AbbVie, Almirall, Celgene, Janssen, LEO Pharma, Eli Lilly and Company, Merck, Novartis, Pfizer, Sandoz, and UCB Pharma. **JT:** Allegis Group statistical consultant for UCB Pharma. **BSz, BH, JL:** Employees and shareholders of UCB Pharma. **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. **Acknowledgments:** These studies were funded by UCB Pharma. We would like to thank the patients and their caregivers in addition to the investigators and their teams who contributed to these studies. The authors acknowledge Susanne Wiegratz, MSc, UCB Pharma, Monheim am Rhein, Germany, for publication coordination, Michael Haycox, PhD, Costello Medical, Manchester, UK, for medical writing support and editorial assistance, and Danielle Hart of the Creative team at Costello Medical, London, UK, for graphic design assistance. All costs associated with development of this poster were funded by UCB Pharma.

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