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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Synopsis

- Psoriasis is a chronic disease; assessing long-term treatment efficacy is imperative.[1]
- Bimekizumab (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]

Objective

To provide the first disclosure of efficacy responses from treatment initiation of 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.

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

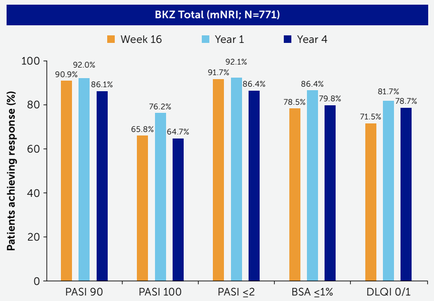
- BKZ treatment responses over 4 years are summarized in **Figure 3**.
- Among patients who received BKZ continuously from baseline and entered the OLE (N=771), 90.9%, 65.8%, 91.7%, 78.5%, and 71.5% of patients achieved PASI 90, PASI 100, PASI ≤2, BSA ≤1%, and DLQI 0/1, respectively, at Week 16. Responses 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.

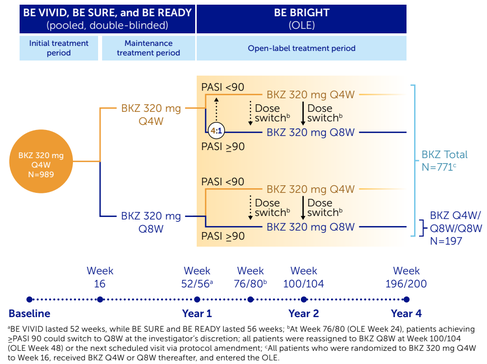
PASI 90, PASI 100, PASI ≤2, BSA ≤1%, and DLQI 0/1 response rates were consistent in the subset of patients enrolled in the OLE who received bimekizumab 320 mg Q4W to Week 16 then Q8W thereafter, the approved dosing regimen for the majority of patients with plaque psoriasis.[9,10]

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



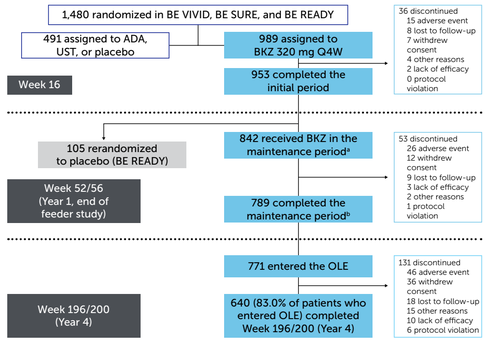
[a]BE VIVID lasted 52 weeks, while BE SURE and BE READY lasted 56 weeks; [b]At Week 76/80 (OLE Week 24), patients achieving ≥PASI 90 could switch to Q8W at the investigator's discretion; all patients were reassigned to BKZ Q8W at Week 100/104 (OLE Week 48) or the next scheduled visit via protocol amendment;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

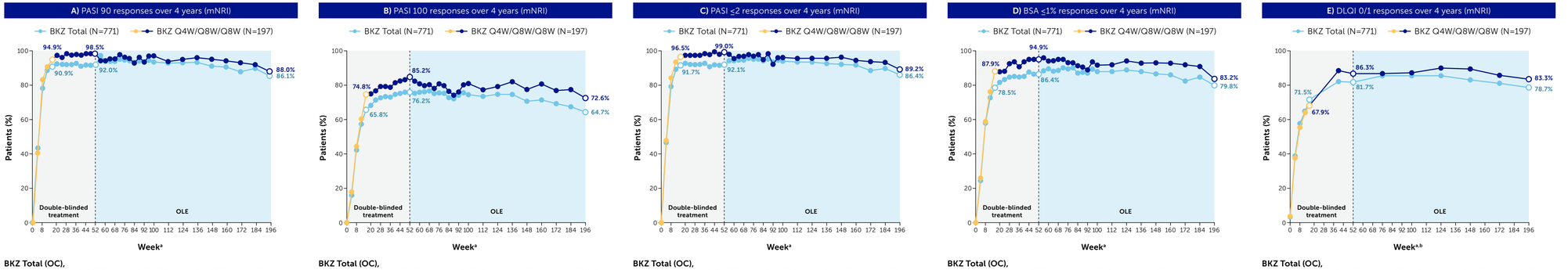
[a]Baseline characteristics shown for all patients who were randomized to BKZ 320 mg Q4W to Week 16, received BKZ Q4W or Q8W thereafter, and entered the OLE.

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]



BKZ Total (OC), n/N	A) PASI 90	B) PASI 100	C) PASI ≤2	D) BSA ≤1%	E) DLQI 0/1
Week 16	699/727	583/727	699/727	656/727	621/725
Week 52/56[a]	678/712	559/712	681/712	641/712	622/714
Week 76/80[b]	639/675	519/675	644/675	611/675	581/673
Week 100/104	572/623	452/623	572/623	544/623	524/625

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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References: [1]Mrowietz U et al. J Eur Acad Dermatol Venereol 2012;26(Suppl 2):12–20; [2]Adams R et al. Front Immunol 2020;11:1894; [3]Glatt S et al. Ann Rheum Dis 2018;77(4):523–532; [4]Reich K et al. Lancet 2021;397:487–498; NCT03370133; [5]Gordon K et al. Lancet 2021;397:475–486; NCT03410992; [6]Warren RB et al. N Engl J Med 2021;385:130–141, NCT03412747; [7]Reich K et al. N Engl J Med 2021;385:142–152, NCT03536884; [8]Strober B et al. Br J Dermatol 2023;188(6):749–759, NCT03598790; [9]Bimzelx® Summary of Product Characteristics. 2023. Available at: https://www.ema.europa.eu/en/medicines/human/EPAR/bimzelx [Accessed February 2024]; [10]Bimzelx® US Prescribing Information. 2023. 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; 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