Bimekizumab maintenance of response through three years in patients with moderate to severe plaque psoriasis who responded at Week 16: Results from the BE BRIGHT open-label extension trial

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Objectives

To evaluate maintenance of response over three years among patients with moderate to severe plaque psoriasis who had an initial efficacy response after 16 weeks' bimekizumab (BKZ) treatment and entered the BE BRIGHT open-label extension (OLE), including those who received continuous BKZ every 8 weeks (Q8W) dosing in the maintenance period and the OLE.

Introduction

- Loss of response to biologics over time is commonly observed in plaque psoriasis,[1] it is therefore important to understand long-term efficacy of new therapies.
- BE BRIGHT (NCT03598790) is an ongoing, multicentre, OLE study assessing long-term safety, tolerability, and efficacy of BKZ in patients with moderate to severe plaque psoriasis who completed one of three phase 3 feeder studies.[2–4]
- Data reported previously indicated that response to BKZ treatment is maintained over two years.[5]

Materials and Methods

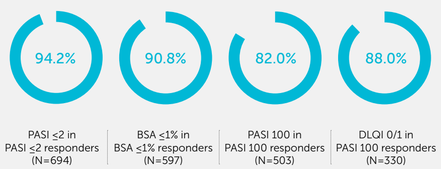
- All patients who completed one of the BE SURE (NCT03412747), BE VIVID (NCT03370133), and BE READY (NCT03410992) phase 3 studies were eligible to enrol in BE BRIGHT and were assigned to treatment as shown in **Figure 1**.[2–4]
- Here, maintenance of Psoriasis Area and Severity Index (PASI) ≤2 among Week 16 PASI ≤2 responders, maintenance of body surface area (BSA) ≤1% among Week 16 BSA ≤1% responders, and maintenance of PASI 100 (100% improvement from baseline in PASI) and Dermatology Life Quality Index (DLQI) 0/1 among Week 16 PASI 100 responders are reported through Year 3 (OLE Week 96).
- Data are presented for all BKZ-treated patients (BKZ Total) who entered the OLE, and in the subset of patients who received BKZ 320 mg every 4 weeks (Q4W) through Week 16 followed by continuous BKZ 320 mg Q8W (Q4W/Q8W).
- Data are reported using modified non-responder imputation (mNRI), NRI, and as the observed case (OC).
  - For mNRI, patients who discontinued due to lack of efficacy were considered non-responders at subsequent timepoints; multiple imputation was used for all other missing data.

Results

- 989 patients were randomized to BKZ Q4W at baseline in the feeder studies; 694 Week 16 PASI ≤2 responders, 597 BSA ≤1% responders, and 503 Week 16 PASI 100 responders entered the OLE. Baseline characteristics are presented in **Table 1**.
- 94.2%, 90.8%, and 82.0% of BKZ-treated patients who achieved PASI ≤2, BSA ≤1%, and PASI 100, respectively, at Week 16 maintained their response at Year 3 (OLE Week 96) (**Figure 2**; **Table 2**).
- DLQI 0/1 response rates in BKZ-treated Week 16 PASI 100 responders increased through the first year of BKZ treatment, and were maintained through to the end of Year 3 (OLE Week 96) in 88.0% of patients (**Figure 2**; **Table 2**).

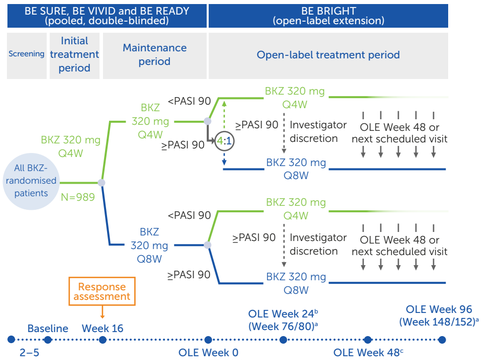
Summary

Maintenance of Week 16 responses at Year 3 (OLE Week 96)



BKZ provided long-term maintenance of efficacy and health-related quality of life benefit over three years in patients with moderate to severe plaque psoriasis who achieved an initial response at Week 16.

Figure 1 Study design (included patients)



[a]BE SURE and BE READY had a duration of 56 weeks and BE VIVID had a duration of 52 weeks; [b]At OLE Week 24, patients receiving BKZ Q4W who achieved PASI 90 could switch to receive BKZ Q8W at the discretion of the investigator; [c]At OLE Week 48, or at the next scheduled clinic visit, all patients were re-assigned to BKZ Q8W, following protocol amendment.

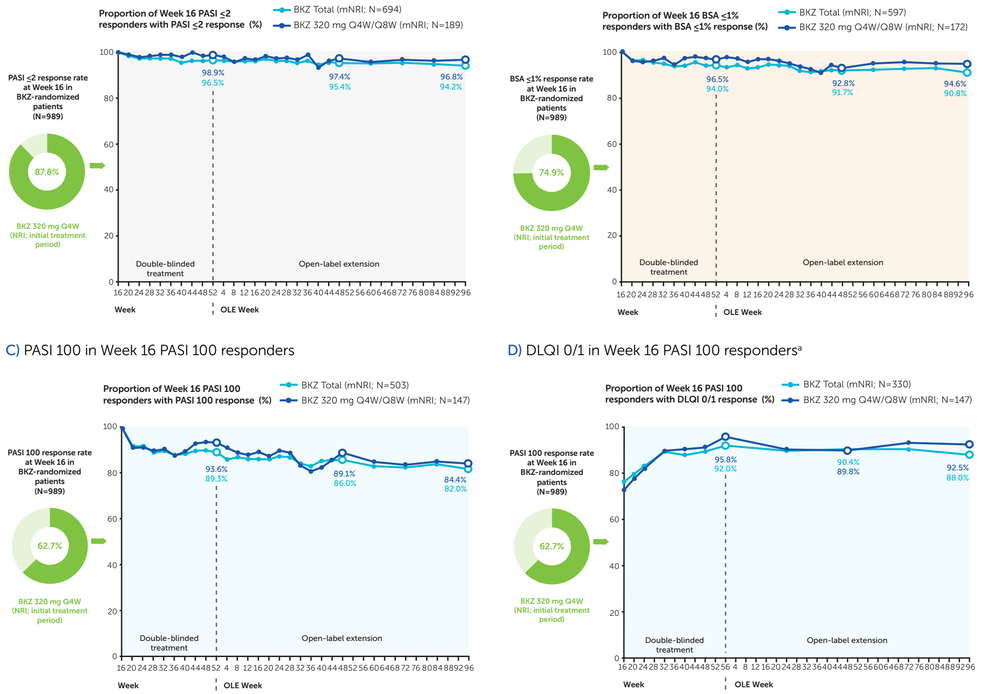
Figure 2 Maintenance of efficacy in patients with a Week 16 response who entered the OLE (mNRI)

A) PASI ≤2 in Week 16 PASI ≤2 responders

B) BSA ≤1% in Week 16 BSA ≤1% responders

C) PASI 100 in Week 16 PASI 100 responders

D) DLQI 0/1 in Week 16 PASI 100 responders[a]



Week 16 responses are shown for all patients randomized to BKZ 320 mg Q4W in the initial treatment period. Due to the differing lengths of feeder studies, Week 56 data for PASI ≤2, BSA ≤1% and PASI 100 responses in BE SURE and BE READY are not presented in these pooled analyzes. [a]DLQI was measured on a different schedule in BE VIVID compared with BE SURE and BE READY; DLQI 0/1 data for patients enrolled in BE VIVID are therefore not included, due to the lack of common visits at which DLQI was recorded.

BKZ: bimekizumab; **BSA:** body surface area; **DLQI:** Dermatology Quality of Life Index; **mNRI:** modified non-responder imputation; **NRI:** non-responder imputation; **OC:** observed case; **OLE:** open-label extension; **PASI:** Psoriasis Area and Severity Index; **PASI 100:** 100% improvement from baseline in PASI; **Q4W:** every 4 weeks; **Q8W:** every 8 weeks; **SD:** standard deviation.

Table 1 Baseline characteristics

	Week 16 PASI ≤2 responders BKZ Total (N=694)	Week 16 BSA ≤1% responders BKZ Total (N=597)	Week 16 PASI 100 responders BKZ Total (N=503)
Age (years), mean ± SD	45.0 ± 13.3	44.9 ± 13.3	44.8 ± 13.2
Male, n (%)	490 (70.6)	420 (70.4)	352 (70.0)
Weight (kg), mean ± SD	88.7 ± 20.5	88.4 ± 20.3	87.8 ± 19.3
Duration of psoriasis (years), mean ± SD	18.4 ± 12.5	18.3 ± 12.6	18.0 ± 12.3
PASI, mean ± SD	21.2 ± 7.5	21.1 ± 7.4	21.3 ± 7.2
BSA (%), mean ± SD	27.0 ± 15.4	26.7 ± 15.2	26.7 ± 14.9
DLQI, mean ± SD	10.6 ± 6.3	10.7 ± 6.3	10.9 ± 6.4
Any prior systemic therapy, n (%)	556 (80.1)	486 (81.4)	415 (82.5)
Prior biologic therapy, n(%)	278 (40.1)	245 (41.0)	210 (41.7)

Data are reported for all patients who were treated continuously with BKZ through the initial and maintenance periods, achieved the efficacy response of interest at Week 16 and entered the OLE.

Table 2 Summary of efficacy outcomes (NRI and OC)

	Week 16 PASI ≤2 Responders			
	NRI, n (%)	OC, n/N (%)[a]	NRI, n (%)	OC, n/N (%)[a]
	BKZ Total N=694		BKZ 320 mg Q4W/Q8W[b] N=189	
PASI ≤2 Response				
Year 1 (Week 52)	663 (95.5)	663/678 (97.8)	186 (98.4)	186/188 (98.9)
Year 2 (OLE Week 48)	617 (88.9)	622/642 (96.9)	173 (91.5)	173/176 (98.3)
Year 3 (OLE Week 96)	586 (84.4)	592/612 (96.7)	165 (87.3)	165/166 (99.4)
	Week 16 BSA ≤1% Responders			
	BKZ Total N=597		BKZ 320 mg Q4W/Q8W[b] N=172	
BSA ≤1% Response				
Year 1 (Week 52)	555 (93.0)	555/586 (94.7)	165 (95.9)	165/171 (96.5)
Year 2 (OLE Week 48)	514 (86.1)	516/552 (93.5)	151 (87.8)	151/160 (94.4)
Year 3 (OLE Week 96)	490 (82.1)	491/526 (93.3)	146 (84.9)	146/151 (96.7)
	Week 16 PASI 100 Responders			
	BKZ Total N=503		BKZ 320 mg Q4W/Q8W[b] N=147	
PASI 100 Response				
Year 1 (Week 52)	447 (88.9)	447/495 (90.3)	137 (93.2)	137/146 (93.8)
Year 2 (OLE Week 48)	413 (82.1)	414/465 (89.0)	125 (85.0)	125/137 (91.2)
Year 3 (OLE Week 96)	383 (76.1)	384/447 (85.9)	113 (76.9)	113/130 (86.9)
	Week 16 PASI 100 Responders			
	BKZ Total N=330		BKZ 320 mg Q4W/Q8W[b] N=147	
DLQI 0/1 Response[c]				
Year 1 (Week 56)	302 (91.5)	302/325 (92.9)	140 (95.2)	140/146 (95.9)
Year 2 (OLE Week 48)	280 (84.8)	281/307 (91.5)	123 (83.7)	123/137 (89.8)
Year 3 (OLE Week 96)	263 (79.7)	263/288 (91.3)	121 (82.3)	121/130 (93.1)

[a]For NRI, patients in BE READY who escaped to open-label BKZ during the randomized withdrawal period are counted as non-responders from the point of escape and throughout all of BE BRIGHT. For OC, data from the point of escape and through Week 56 of BE READY for these patients are considered as missing, and from the point of entry into BE BRIGHT their data are presented as observed. As a result, the number of responders for OC may be higher than the number of responders for NRI for the OLE time points; [b]Continuous Q8W dosing in the maintenance period and the OLE was only possible for patients who entered BE BRIGHT from BE SURE or BE READY; [c]DLQI was measured on a different schedule in BE VIVID compared with BE SURE and BE READY; DLQI 0/1 data for patients enrolled in BE VIVID are therefore not included here, due to the lack of common visits at which DLQI was recorded.

Conclusions

Among Week 16 responders, efficacy and health-related quality of life response rates were maintained through to three years' BKZ treatment, including among those who received BKZ 320 mg Q4W/Q8W.

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References: [1]Yiu ZZN et al. Br J Dermatol 2020;183:294–302; [2]Warren RB et al. N Engl J Med 2021;385:130–41; [3]Reich K et al. Lancet 2021;397:487–98; [4]Gordon KB et al. Lancet 2021;397:475–86; [5]Strober B et al. Presented at EADV 2021; P1317. **Author Contributions:** Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: **BSt, YT, UM, ML, PF, RGL, JB, MW, VV, BSz, VC, CP;** Drafting of the publication, or revising it critically for important intellectual content: **BSt, YT, UM, ML, PF, RGL, JB, MW, VV, BSz, VC, CP;** Final approval of the publication: **BSt, YT, UM, ML, PF, RGL, JB, MW, VV, BSz, VC, CP.** **Author Disclosures: BSt:** Consultant (honoraria): AbbVie, Almirall, Amgen, Arcutis, Arena, Aristea Therapeutics, Asana, Boehringer Ingelheim, Bristol Myers Squibb, Connect Biopharma, Dermavant, Eli Lilly, EPI Health, Evelo Biosciences, Immunic Therapeutics, Janssen, LEO Pharma, Eli Lilly, Maruho, Meiji Seika Pharma, Mindera Health, Novartis, Ono, Pfizer, Regeneron, Sanofi-Genzyme, Sun Pharma, UCB Pharma, Union Therapeutics, Ventyxbio, and vTv Therapeutics; Stock options: Connect Biopharma, Mindera Health; Speaker: AbbVie, Eli Lilly, Janssen, Regeneron, and Sanofi-Genzyme; Scientific Co-Director (consulting fee): CorEvitas (formerly Corronal Psoriasis Registry; Investigator: AbbVie, Cara Therapeutics, CorEvitas Psoriasis Registry, Dermavant, and Novartis; Editor-in-Chief (honorarium): Journal of Psoriasis and Psoriatic Arthritis. **YT:** Honoraria and/or grants from AbbVie, Boehringer Ingelheim, Bristol Myers Squibb, Eisai, Eli Lilly, Janssen, Kyowa Hakko Kirin, LEO Pharma, Maruho, Mitsubishi Tanabe Pharma, Sun Pharma, Taiho Pharmaceutical, and UCB Pharma. **UM:** Served as advisor and/or clinical study investigator for, and/or received honoraria and/or grants from AbbVie, Almirall, Aristea Therapeutics, Boehringer Ingelheim, Celgene, Dr. Reddy's Laboratories, Eli Lilly, Foamix, Formycon, Forward Pharma, Janssen, LEO Pharma, Medac, Novartis, Phi-Stone, Pierre Fabre, Sanofi, and UCB Pharma. **ML:** Employee of Mount Sinai and receives research funds from AbbVie, Amgen, Arcutis, Avotres Therapeutics, Boehringer Ingelheim, Dermavant, Eli Lilly, Incyte, Janssen, Ortho Dermatologics, Regeneron, and UCB Pharma and is a consultant for Aditum Bio, Almirall, AltruBio, AnaptysBio, Arcutis, Aristea Therapeutics, Arrive Technologies, Avotres Therapeutics, BiomX, Boehringer Ingelheim, Bristol Myers Squibb, Cara Therapeutics, Castle Biosciences, CorEvitas, Dermavant Sciences, Dr. Reddy's Laboratories, Evelo Biosciences, Evommune, Facilitation of International Dermatology Education, Forte Biosciences, Foundation for Research and Education in Dermatology, Helsinn Therapeutics, Hexima, LEO Pharma, Meiji Seika Pharma, Mindera Health, Pfizer, Seanergy, and Verrica. **PF:** Grant support from AbbVie, Amgen, Bristol Myers Squibb, Celgene, Eli Lilly, Janssen, LEO Pharma, Merck, Novartis, Pfizer, Sanofi, and Sun Pharma. 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