Bimekizumab 4-year maintenance of responses in Week 16 responders with moderate to severe plaque psoriasis: Results from the BE BRIGHT open-label extension phase 3 trial

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Synopsis

- Psoriasis is a chronic disease where loss of response to biologic therapies over time is commonly observed;[1] thus, studying long-term efficacy of new treatments is important.
- Maintenance of high responses to bimekizumab (BKZ) have been reported previously through 3 years in patients with moderate to severe plaque psoriasis.[2]

Objective

To evaluate maintenance of clinical responses over 4 years among patients with psoriasis who achieved complete or near-complete skin clearance after 16 weeks of BKZ treatment.

Methods

- Data were pooled from the 52-week BE VIVID and 56-week BE SURE and BE READY phase 3 trials, and their open-label extension (OLE) BE BRIGHT.[2–5]
- Analyzed patients were randomized to BKZ 320 mg Q4W to Week 16, then received BKZ 320 mg Q4W or Q8W during the maintenance and OLE periods (BKZ Total) (**Figure 1**).
  - The subset of patients who received BKZ Q4W to Week 16 then Q8W thereafter (BKZ Q4W/Q8W), the dosing regimen that is approved for most patients, were also analyzed.[6]
- Maintenance of ≥90/100% improvement from baseline in Psoriasis Area and Severity Index (PASI 90/100), and body surface area (BSA) ≤1% to Year 4 were assessed in respective Week 16 responders. Dermatology Life Quality Index (DLQI) 0/1 responses were also assessed for patients who were PASI 100 responders at Week 16.
- Maintenance of responses are reported using modified non-responder imputation (mNRI).
  - Patients who discontinued due to lack of efficacy/treatment-related adverse events were considered non-responders; multiple imputation was used for other missing data. Observed case (OC) results are also presented.
  - Patients who entered the BE READY escape arm were also considered as non-responders from the date of escape until the end of BE READY, after which they were considered in the same way as all other non-escape patients during the BE BRIGHT OLE.

Results

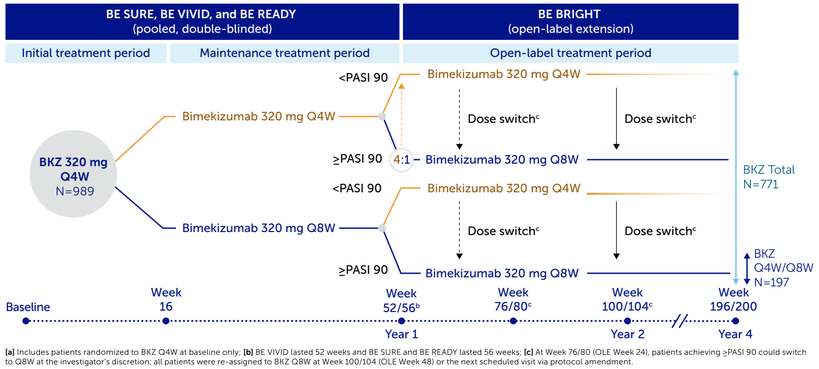
- Of 989 BKZ-randomized patients, 87.5% achieved PASI 90 and 62.7% achieved PASI 100 at Week 16 (non-responder imputation; NRI) (**Figure 2**).
  - Of patients who achieved PASI 90, PASI 100, and BSA ≤1% responses at Week 16, 693, 503, and 597 of them entered the OLE, respectively (BKZ Total); 186, 147, and 172 received BKZ Q4W/Q8W, respectively.
  - Baseline characteristics (BKZ Total) are presented in **Table 1**.
- OLE study discontinuation rates in Week 16 PASI 90, PASI 100, PASI ≤2, or BSA ≤1% responders (N=771) due to lack of efficacy (8 [1.0%]) or adverse events (42 [5.4%]) were low.
- Of Week 16 PASI 90, PASI 100, and BSA ≤1% responders, 88.5%, 73.0%, and 83.1% maintained their responses to Year 4, respectively (BKZ Total; **Figure 2A–C**). Among Week 16 PASI 100 responders, 84.1% maintained DLQI 0/1 responses to Year 4 (BKZ Total; **Figure 2D**).
  - In the BKZ Q4W/Q8W subset, 89.0%, 76.7%, 83.3%, and 85.4% maintained their PASI 90, PASI 100, BSA ≤1%, and DLQI 0/1 responses to Year 4, respectively (**Figure 2**).

Conclusions

Pooled data from three trials and their open-label extension found that, among Week 16 responders, high clinical responses were maintained through 4 years of bimekizumab treatment.

High levels of response were also maintained in those who received bimekizumab Q4W/Q8W, the approved dosing regimen for most patients with psoriasis.

Figure 1 Study design[a]



[a] Includes patients randomized to BKZ Q4W at baseline only; [b] BE VIVID lasted 52 weeks and BE SURE and BE READY lasted 56 weeks; [c] At Week 76/80 (OLE Week 24), patients achieving ≥PASI 90 could switch to Q8W at the investigator's discretion; all patients were re-assigned to BKZ Q8W at Week 100/104 (OLE Week 48) or the next scheduled visit via protocol amendment.

Table 1 Baseline characteristics

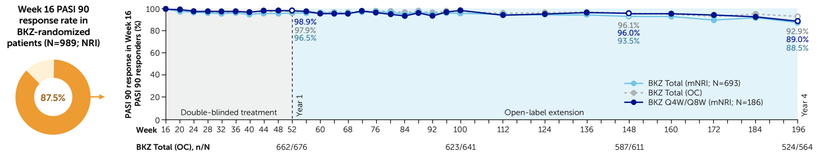
	BKZ Total[a]		
	Week 16 PASI 90 responders (N=693)	Week 16 PASI 100 responders (N=503)	Week 16 BSA ≤1% responders (N=597)
Age (years), mean ± SD	45.0 ± 13.3	44.8 ± 13.2	44.9 ± 13.3
Male, n (%)	494 (71.3)	352 (70.0)	420 (70.4)
White, n (%)	591 (85.3)	441 (87.7)	513 (85.9)
Weight (kg), mean ± SD	89.0 ± 20.9	87.8 ± 19.3	88.4 ± 20.3
Duration of psoriasis (years), mean ± SD	18.4 ± 12.5	18.0 ± 12.3	18.3 ± 12.6
PASI, mean ± SD	21.5 ± 7.7	21.3 ± 7.2	21.1 ± 7.4
BSA (%), mean ± SD	27.7 ± 15.9	26.7 ± 14.9	26.7 ± 15.2
IGA, n (%)			
3: moderate	456 (65.8)	331 (65.8)	400 (67.0)
4: severe	236 (34.1)	171 (34.0)	196 (32.8)
DLQI total, mean ± SD	10.6 ± 6.3	10.9 ± 6.4	10.7 ± 6.3
Any prior systemic therapy, n (%)	557 (80.4)	415 (82.5)	486 (81.4)
Any prior biologic therapy, n (%)	281 (40.5)	210 (41.7)	245 (41.0)

[a] Baseline characteristics shown for all patients who were randomized to BKZ at the start of the feeder studies, entered the OLE, and had been responders at Week 16 for the corresponding outcome.

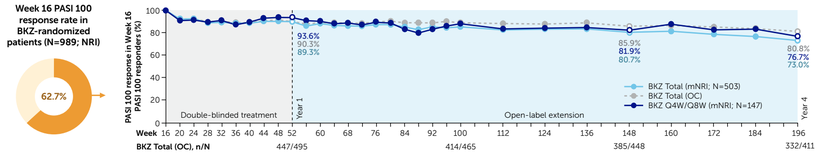
BKZ: bimekizumab; **BSA:** body surface area; **DLQI:** Dermatology Life Quality Index; **IGA:** Investigator's Global Assessment; **mNRI:** modified non-responder imputation; **NRI:** non-responder imputation; **OC:** observed case; **OLE:** open-label extension; **PASI:** Psoriasis Area and Severity Assessment; **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.

Figure 2 PASI 90, PASI 100, BSA ≤1%, and DLQI 0/1 response maintenance in patients that entered the OLE

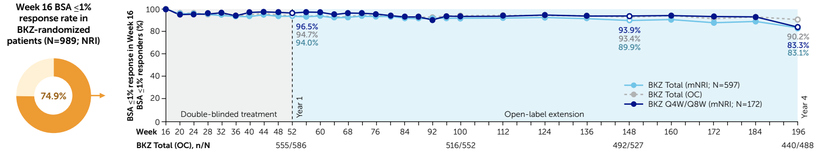
A) PASI 90 in Week 16 PASI 90 responders[a]



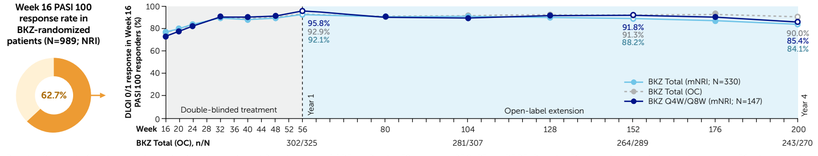
B) PASI 100 in Week 16 PASI 100 responders[a]



C) BSA ≤1% in Week 16 BSA ≤1% responders[a]



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



Results differ slightly from the accepted abstract due to updated mNRI methodology. [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 these figures, the period after Week 52 corresponds to the BE BRIGHT OLE; [b] DLQI 0/1 responses were performed on a different schedule to BE SURE and BE READY in BE VIVID; BE VIVID data are therefore not included in this analysis and Week 56 was used as the last common timepoint when pooling the studies.

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References: Warren RB. et al. J Invest Dermatol 2015;135:2632–40. [2]Strober B. et al. Br J Dermatol 2023;188:749–59. NCT03598790. [3]Reich K. et al. Lancet 2021;397:487–98. NCT03370133. [4]Warren B et al. N Engl J Med 2021;385:130–41. NCT03412747. [5]Gordon KB. et al. Lancet 2021;397:475–86. NCT03410992. [6]Food and Drugs Administration. Prescribing Information. 2023. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/761151s000lbl.pdf [Accessed September 2024]. **Author Contributions:** Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: **AB**, **PF**, **RGL**, **CC**, **DR**, **RR**, **MW**, **BS**, **BH**, **RBW**; Drafting of the publication, or reviewing it critically for important intellectual content: **AB**, **PF**, **RGL**, **CC**, **DR**, **RR**, **MW**, **BS**, **BH**, **RBW**; Final approval of the publication: **AB**, **PF**, **RGL**, **CC**, **DR**, **RR**, **MW**, **BS**, **BH**, **RBW**. **Author Disclosures: AB:** Speaker (received honoraria) for Eli Lilly and Company and UCB, served as a scientific adviser (received honoraria) for AbbVie, Abcentra, Aclaris, Affibody, Aligos, Almirall, Alumis, Amgen, Anaptysbio, Apogee, Arcutis, Arena, Aslan, Athenex, Bluefin Biomedicine, Boehringer Ingelheim, Bristol Myers Squibb, Cara Therapeutics, Celldex, CTI BioPharma, Dermavant Sciences, EcoR1, Eli Lilly and Company, Escient, Evelo, Evommune, Forte, Galderma, HighlightIl Pharma, Incyte, InnoventBio, Janssen, Landos, LEO Pharma, Lipidio, Merck, Microbion, Monte Rosa Therapeutics, Nektar, Novartis, Oruka, Overtone Therapeutics, Paragon, Pfizer, Q32 Bio, Rani, Rapt, Regeneron, Sanofi, Spherix Global Insights, Sun Pharma, Takeda, TLL Pharmaceutical, TrialSpark, UCB, Union, Ventyx, Viliolome, and Xencor, and has acted as a clinical study investigator (institution has received clinical study funds) for AbbVie, Aceleyrin, Allakos, Almirall, Alumis, Amgen, Arcutis, Athenex, Boehringer Ingelheim, Bristol Myers Squibb, Concert, Dermavant Sciences, DermBiont, Eli Lilly and Company, Evelo, Evommune, Galderma, Incyte, Janssen, LEO Pharma, Merck, Novartis, Pfizer, Regeneron, Sanofi, Sun Pharma, UCB, and Ventyx, and owns stock in Lipidio and Oruka. **PF:** Grant support from AbbVie, Amgen, Bristol Myers Squibb, Celgene, Eli Lilly and Company, Janssen, LEO Pharma, Merck, Novartis, Pfizer, Sanofi, and Sun Pharma; 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