Bimekizumab 5-year maintenance of response in US and Canadian patients with psoriasis who responded at Week 16

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Objective

To report maintenance of response through 5 years in patients with moderate to severe plaque psoriasis from the US and Canada who received continuous bimekizumab (BKZ) treatment and achieved complete skin clearance after 16 weeks.

Introduction

- Psoriasis is a chronic disease in which loss of response to biologics over time is commonly observed;[1] therefore, assessing long-term maintenance of treatment efficacy in patients with an initial response is important for patients and their dermatologists.
- Treatment with BKZ, a monoclonal IgG1 antibody that inhibits interleukin (IL)-17F in addition to IL-17A,[2] has demonstrated maintenance of high response rates through 4 years in patients with moderate to severe plaque psoriasis who achieved complete skin clearance at Week 16.[3]

Methods

- Patients with moderate to severe plaque psoriasis from the US or Canada who completed the 52-week BE VIVID and 56-week BE SURE and BE READY phase 3 trials and their 144-week open-label extension (OLE), BE BRIGHT (4 years' total treatment), could enter a second 48-week extension (OLE2; **Figure 1**).[4–7]
  - Analysed patients were initially randomised to BKZ 320 mg every 4 weeks (Q4W) to Week 16, received BKZ Q4W or every 8 weeks (Q8W) through the maintenance period and OLE and entered OLE2 without a treatment interruption (BKZ Total).
  - All included patients were reassigned to BKZ Q8W at OLE Week 48, or the next scheduled visit, and continued to receive BKZ Q8W on OLE2 entry.
  - The subset who received BKZ Q4W to Week 16 then Q8W continuously into the OLE are also analysed (BKZ Q4W/Q8W; the approved dosing regimen for most patients with psoriasis).[8,9]
- Here, we assess the following outcomes to Year 5 (OLE2 Week 48; 244 or 248 weeks' total treatment) in those who had 100% improvement from baseline in Psoriasis Area and Severity Index (PASI 100) at Week 16:
  - PASI 100;
  - ≥90% improvement from baseline in PASI (PASI 90);
  - ≥75% improvement from baseline in PASI (PASI 75);
  - PASI ≤2;
  - Dermatology Life Quality Index score of 0 or 1 (DLQI 0/1; no impact of skin disease on patients' lives).[10]
- Responses are reported using modified non-responder imputation (mNRI) and observed case (OC).
  - For mNRI, patients discontinuing treatment due to lack of efficacy/treatment-related adverse events were considered non-responders at subsequent timepoints; multiple imputation was used for all other missing data.

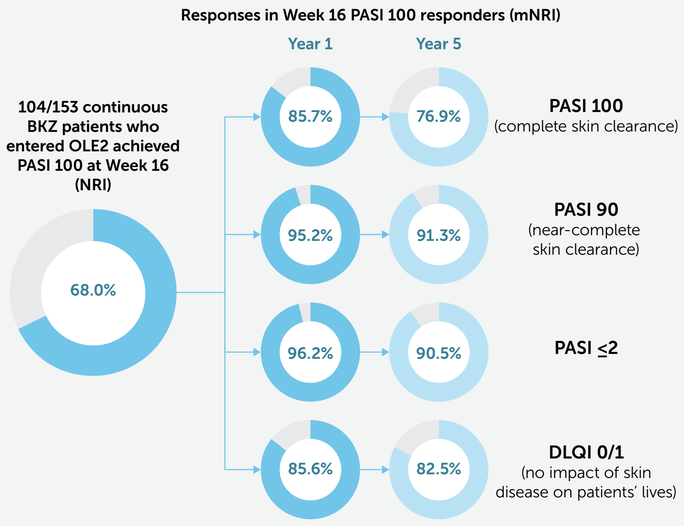
Results

- Overall, 68.0% of the BKZ Total patients analysed (N=153), and 76.9% among the BKZ Q4W/Q8W subset (N=52), achieved PASI 100 at Week 16 (non-responder imputation; NRI).
- Of the Week 16 PASI 100 responders who entered OLE2 (N=104), 96.2% completed Year 5; 97.5% in the BKZ Q4W/Q8W subset of PASI 100 responders who entered OLE2 (N=40).
  - Two BKZ Total patients discontinued due to lack of efficacy/adverse events, one of whom received BKZ Q4W/Q8W.
- Among BKZ Total Week 16 PASI 100 responders, 85.7% maintained PASI 100 at Year 1 (Week 52) and 76.9% sustained this response to Year 5 (**Figure 2A**):
  - PASI 90 was maintained by 95.2% at Year 1 and 91.3% at Year 5;
  - PASI 75 was maintained by 98.1% at Year 1 and 95.2% at Year 5;
  - PASI ≤2 was maintained by 96.2% at Year 1 and 90.5% at Year 5 (**Figure 2C**);
  - DLQI 0/1 was achieved by 69.0% at Week 16, 85.6% at Year 1 (Week 48/52) and 82.5% at Year 5 (**Figure 2D**).
- In the BKZ Q4W/Q8W subset, 90.0% of Week 16 PASI 100 responders maintained PASI 100 at Year 1 and 85.0% sustained this response to Year 5 (**Figure 2B**):
  - PASI 90 was maintained by 97.5% at Year 1 and 92.5% at Year 5;
  - PASI 75 was maintained by 100% at Year 1 and 97.5% at Year 5;
  - PASI ≤2 was maintained by 97.5% at Year 1 and 95.0% at Year 5
  - DLQI 0/1 was achieved by 62.3% at Week 16, 82.5% at Year 1 and 93.3% at Year 5 (**Figure 2D**).

Conclusions

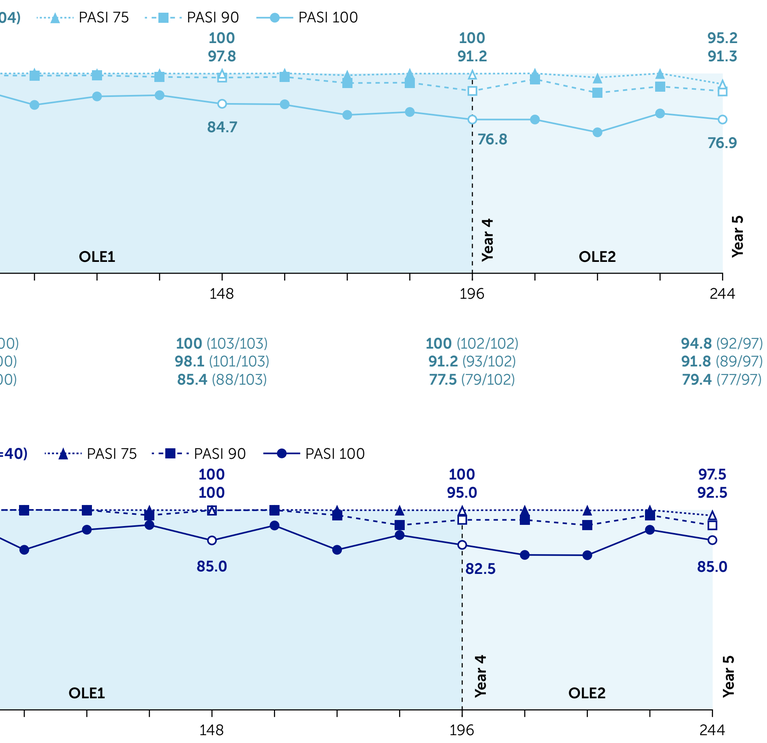
High proportions of bimekizumab-treated patients with psoriasis from the US and Canada who achieved complete skin clearance after 16 weeks maintained this response through 5 years; of those who did not, most sustained PASI 90/PASI ≤2. High rates of DLQI 0/1 were also maintained in the long term.

Summary



High proportions of bimekizumab-treated patients with moderate to severe psoriasis from the US and Canada who achieved complete skin clearance after 16 weeks maintained **high rates of clinical and health-related quality of life responses through 5 years**.

Figure 1 Study design



[a] BE VIVID did not include an option for Q8W dosing of BKZ during the maintenance period. Patients instead received BKZ Q4W up to Week 52; **[b]** BE VIVID lasted 52 weeks and BE SURE and BE READY lasted 56 weeks; **[c]** All patients were re-assigned to BKZ Q8W at Week 100/104 (OLE Week 48) or the next scheduled visit via protocol amendment; **[d]** The BE BRIGHT study was extended, only in the US and Canada, for an additional 48 weeks; 46 patients had completed the study before it was extended, so their treatment was interrupted.

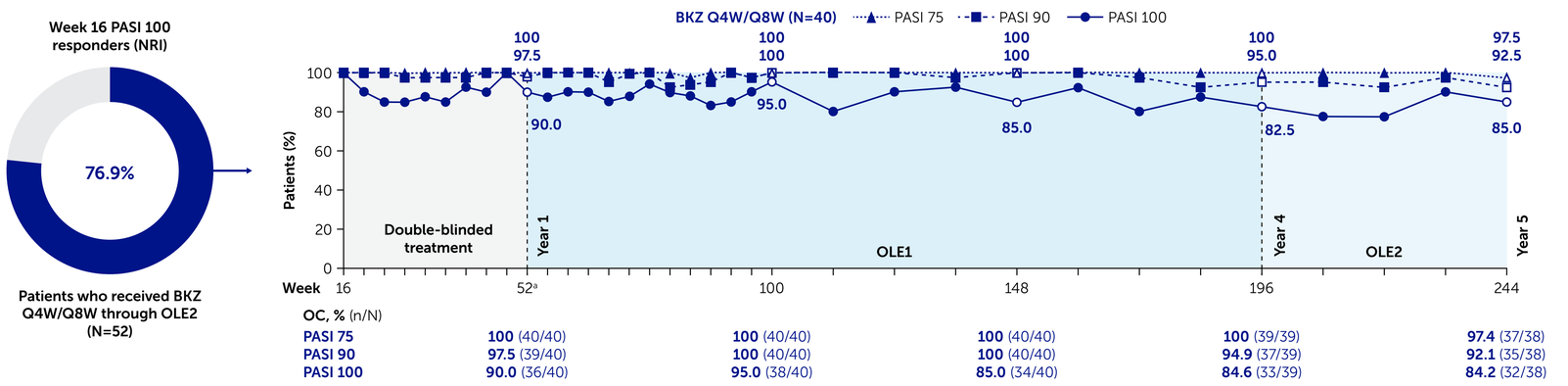
Figure 2 PASI 100/90/75, PASI ≤2 and DLQI 0/1 responses through Year 5 in patients who achieved PASI 100 at Week 16 (mNRI, OC)

A) PASI 100/90/75 – BKZ Total

OC, % (n/N)

	Week 52[a]	Week 100	Week 148	Week 196	Week 244
PASI 75	**99.0** (101/102)	**100** (100/100)	**100** (103/103)	**100** (102/102)	**94.8** (92/97)
PASI 90	**96.1** (98/102)	**99.0** (99/100)	**98.1** (101/103)	**91.2** (93/102)	**91.8** (89/97)
PASI 100	**87.3** (89/102)	**95.0** (95/100)	**85.4** (88/103)	**77.5** (79/102)	**79.4** (77/97)

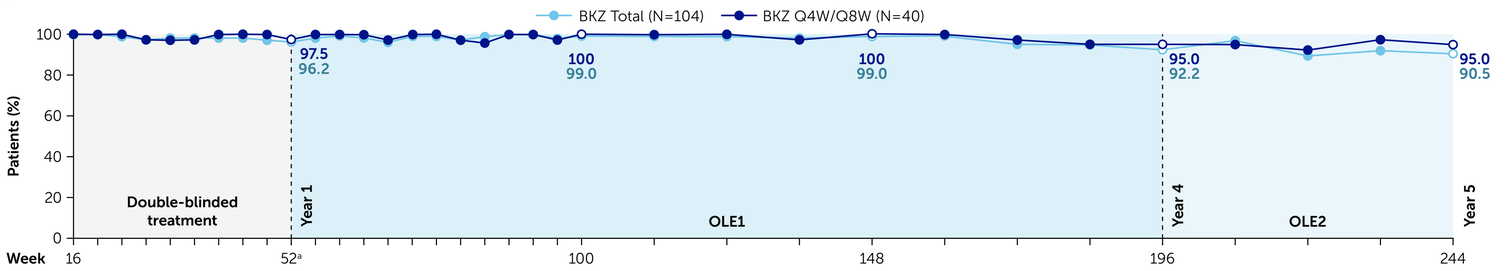
B) PASI 100/90/75 – BKZ Q4W/Q8W



OC, % (n/N)

	Week 52[a]	Week 100	Week 148	Week 196	Week 244
PASI 75	**100** (40/40)	**100** (40/40)	**100** (40/40)	**100** (39/39)	**97.4** (37/38)
PASI 90	**97.5** (39/40)	**100** (40/40)	**100** (40/40)	**94.9** (37/39)	**92.1** (35/38)
PASI 100	**90.0** (36/40)	**95.0** (38/40)	**85.0** (34/40)	**84.6** (33/39)	**84.2** (32/38)

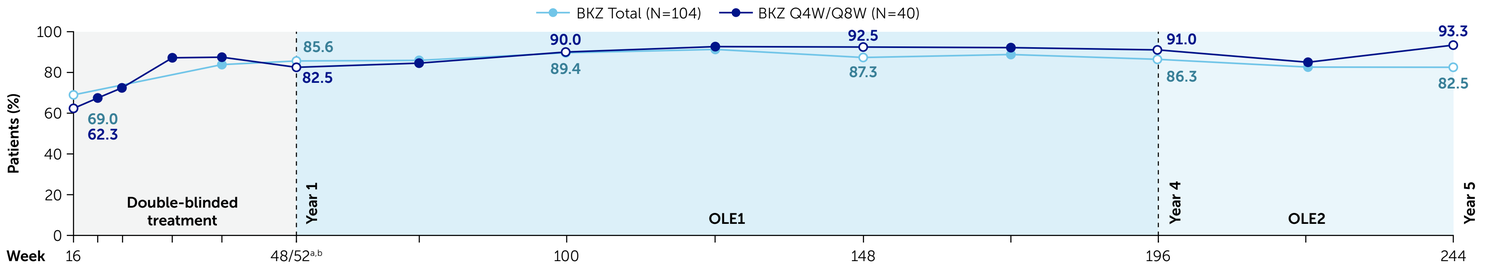
C) PASI ≤2



OC, % (n/N)

	Week 52[a]	Week 100	Week 148	Week 196	Week 244
BKZ Total	**97.1** (99/102)	**99.0** (99/100)	**99.0** (102/103)	**92.2** (94/102)	**90.7** (88/97)
BKZ Q4W/Q8W	**97.5** (39/40)	**100** (40/40)	**100** (40/40)	**94.9** (37/39)	**94.7** (36/38)

D) DLQI 0/1



OC, % (n/N)

	Week 48/52[a,b]	Week 100	Week 148	Week 196	Week 244
BKZ Total	**68.6** (70/102)	**87.3** (89/102)	**90.2** (92/102)	**87.4** (90/103)	**86.4** (89/103)	**83.5** (81/97)
BKZ Q4W/Q8W	**61.5** (24/39)	**82.5** (33/40)	**90.0** (36/40)	**92.5** (37/40)	**92.3** (36/39)	**94.7** (36/38)

Patients who entered the BE READY escape arm were 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. One BKZ-randomised patient in the BE READY trial did not have a Week 16 PASI assessment; however, this patient had a PASI 100 response at Week 12 and Week 20 of BE READY, which was maintained through Week 56. This patient was included in the analysis and assigned as a PASI 100 responder at Week 16. **[a]** Phase 3 trials lasted 52/56 weeks. To pool data, Week 56 data were not included; **[b]** Due to a lack of common timepoints at which DLQI was assessed, Week 48/52 represents Week 48 in BE SURE and BE READY and Week 52 in BE VIVID.

BKZ: bimekizumab; **DLQI 0/1:** Dermatology Life Quality Index score of 0 or 1; **IL:** interleukin; **mNRI:** modified non-responder imputation; **NRI:** non-responder imputation; **OC:** observed case; **OLE:** open-label extension; **PASI 100/90/75:** 100%/≥90%/≥75% improvement from baseline in Psoriasis Area and Severity Index; **Q4W:** every 4 weeks; **Q8W:** every 8 weeks.

References: [1]Elberdín L et al. Dermatol Ther (Heidelb) 2022;12:761–70; [2]Adams R et al. Front Immunol 2020;11:1894; [3]Thaçi D et al. Presented EADV 2024, P3281; [4]Reich K et al. Lancet 2021;397:487–98 (NCT03370133); [5]Warren RB et al. N Engl J Med 2021;385:130–41 (NCT03412747); 6Gordon KB et al. Lancet 2021;397:475–86 (NCT03410992); [7]Strober B et al. Br J Dermatol 2023;188:749–59 (NCT03598790); [8]Bimekizumab Summary of Product Characteristics. 2023. Available at: https://www.ema.europa.eu/en/medicines/human/EPAR/bimzelx [Accessed February 2025]; [9]US Food and Drug Administration, Bimekizumab Prescribing Information, 2023. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/761151s000lbl.pdf [Accessed February 2025]; [10]Hongbo Y et al. J Invest Dermatol 2005;125:659–64. **Author Contributions:** Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: **RGL**, **PR**, **RV**, **KBG**, **JEH**, **BS**, **BK**, **RW**, **ML**; Drafting of the publication, or reviewing it critically for important intellectual content: **RGL**, **PR**, **RV**, **KBG**, **JEH**, **BS**, **BK**, **RW**, **ML**; Final approval of the publication: **RGL**, **PR**, **RV**, **KBG**, **JEH**, **BS**, **BK**, **RW**, **ML**. **Author Disclosures:** **RGL:** Principal investigator for AbbVie, Amgen, Boehringer Ingelheim, Celgene, Eli Lilly and Company, LEO Pharma, Merck, Novartis, Pfizer and UCB; served on scientific advisory boards for AbbVie, Amgen, Boehringer Ingelheim, Celgene, Eli Lilly and Company, LEO Pharma, Merck, Novartis, Pfizer and UCB; provided lectures for AbbVie, Amgen, Celgene, Eli Lilly and Company, LEO Pharma, Merck, Novartis and Pfizer. **PR:** Principal investigator/clinical trials for AbbVie, Amgen, Arcutis, Bristol Myers Squibb, Dermavant, Eli Lilly and Company, Janssen, Sun Pharma and UCB; consultant for Bristol Myers Squibb. **RV:** Grants/research support and/or speakers bureau/honoraria: AbbVie, Alumis, Amgen, Arcutis, Bausch Health/Valeant, Boehringer Ingelheim, Bristol Myers Squibb, Celltrion, Dermavant, Dermira, DiCE Pharmaceuticals, DiCE Therapeutics, Eli Lilly and Company, Galderma, Incyte, Janssen, LEO Pharma, Meiji Seika Pharma, Nimbus Therapeutics, Novartis, Pfizer, Sandoz, Sanofi-Aventis/Genzyme, Sun Pharma, Takeda, UCB and Zai Lab. **KBG:** Received consulting fees from AbbVie, Almirall, Amgen, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Dermira, Eli Lilly and Company, Janssen, Novartis, Pfizer, Sun Pharma and UCB; research support from AbbVie, Bristol Myers Squibb, Celgene, Eli Lilly and Company, Janssen, Novartis and UCB. **JEH:** Advisor/consultant for Apogee, Arcutis, Boehringer Ingelheim, Blueprint Medicines, Bristol Myers Squibb, Boxer Capital, Cogent Biosciences, Dermavant, Galderma, Institute for Systems Biology, Janssen, LEO Pharma, Novartis, Regeneron, Sanofi, Sun Pharma, Takeda and UCB; speaker for Bristol Myers Squibb, Boehringer Ingelheim, Galderma, Regeneron, Sanofi and UCB. **BS**, **BK:** Employees and shareholders of UCB. **RW:** Veramed statistical consultant for UCB. **ML:** Employee of Mount Sinai and receives research funds from AbbVie, Amgen, Arcutis, Avotres, Boehringer Ingelheim, Cara Therapeutics, Dermavant, Eli Lilly and Company, Incyte, Inozyme, Janssen Research & Development, Ortho Dermatologics, Pfizer, Sanofi-Regeneron and UCB; consultant for Almirall, AltruBio Inc., AnaptysBio, Apogee, Arcutis Inc., AstraZeneca, Atomwise, Avotres Therapeutics, Boehringer Ingelheim, Brickell Biotech, Bristol Myers Squibb, Castle Biosciences, Celltrion, CorEvitas, Dermavant, EPI, Evommune, 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. **Acknowledgements:** This study was funded by UCB. We 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, Ria Gill, BSc, Costello Medical, Manchester, 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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