# Bimekizumab efficacy through 3 years in patients with moderate to severe plaque psoriasis: Long-term pooled analysis from BE BRIGHT

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## Synopsis

- A key determinant of biologic discontinuation in plaque psoriasis is loss of response over time; considering long-term treatment efficacy is therefore important.[1]
- Bimekizumab (BKZ), a monoclonal IgG1 antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A,[2] has demonstrated rapid and superior efficacy in the treatment of patients with moderate to severe plaque psoriasis in head-to-head studies versus ustekinumab, adalimumab, and secukinumab, with established long-term durability of response.[3–7]

## Objective

**To report efficacy of BKZ from baseline through 3 years of treatment in patients with moderate to severe plaque psoriasis, pooled across three phase 3 clinical trials and their open-label extension (OLE).**

## Methods

- Data were pooled from the following trials: BE SURE, BE VIVID, BE READY, and their common OLE, BE BRIGHT (**Figure 1**).[3–5,7]
- Proportions of patients achieving PASI 75 (≥75% improvement in Psoriasis Area and Severity Index from baseline), PASI 90, PASI ≤2, PASI 100, body surface area (BSA) ≤1%, and Dermatology Life Quality Index (DLQI) 0/1 (no effect of skin disease on a patient's life)[8] are reported over 3 years.
- Data are reported for all patients who were treated continuously with BKZ through the initial and maintenance periods, and then entered the OLE (BKZ Total). Data are also presented for the subgroup that received BKZ Q4W/Q8W/Q8W (initial/maintenance/OLE).
- Data are reported using modified non-responder imputation (mNRI): patients who discontinued treatment due to lack of efficacy or treatment-related adverse events were considered non-responders at subsequent timepoints; multiple imputation was used for all other missing data. Data are also reported using non-responder imputation (NRI) and as observed case (OC) for all outcomes.

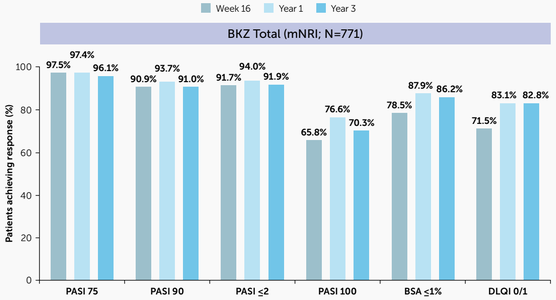
## Results

- 771 patients continuously treated with BKZ through to the end of the first year entered the OLE. 197 patients received BKZ Q4W/Q8W/Q8W.
- Baseline characteristics for included patients are presented in **Table 1**.
- At Week 16, patients in the BKZ Total group achieved high levels of PASI 75, PASI 90, and PASI ≤2 response (**Figure 2A–C**; **Table 2**).
  - These responses remained high through to Year 3 (Week 148) (**Figure 2A–C**; **Table 2**).
- PASI 100, BSA ≤1%, and DLQI 0/1 responses increased through the first year (**Figure 2D–F**; **Table 2**).
  - High levels of PASI 100, BSA ≤1%, and DLQI 0/1 response achieved at Year 1 were sustained through to Year 3 (**Figure 2D–F**; **Table 2**).
- Similar trends were observed in patients that received BKZ Q4W/Q8W/Q8W (**Figure 2A–F**; **Table 2**).

## Conclusions

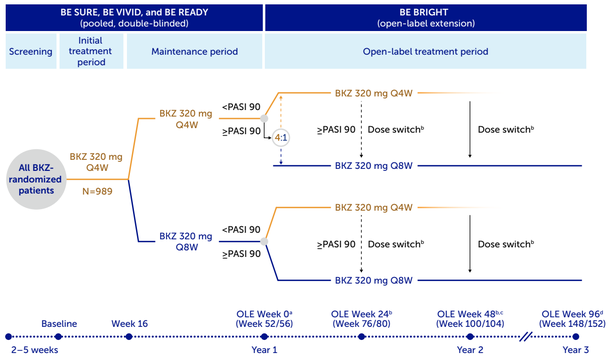
**High and durable clinical and health-related quality of life responses were observed over 3 years of BKZ treatment across three phase 3 trials and their OLE.**

## Summary



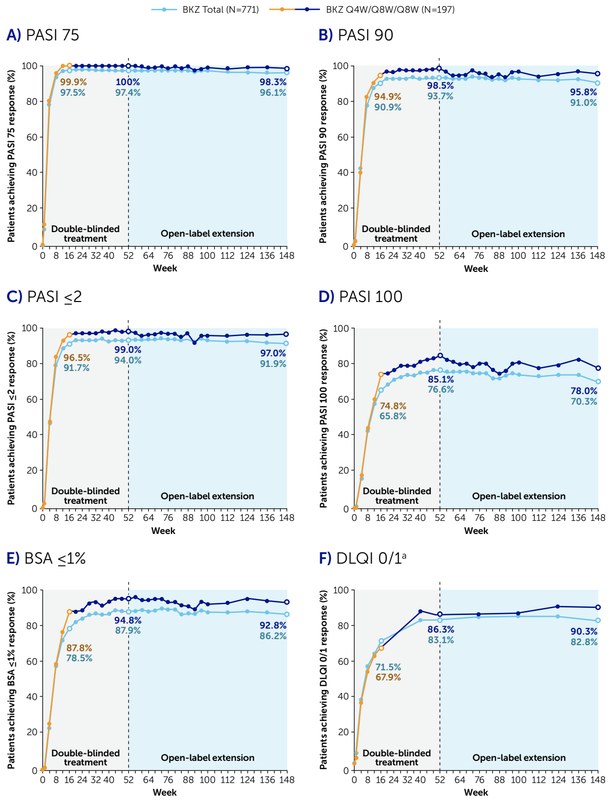

BKZ provided **high** and **durable** clinical and health-related quality of life responses over 3 years in patients with moderate to severe plaque psoriasis.

## Figure 1 Study design (included patients)




Included patients were randomized to BKZ in the initial treatment period and continued to receive BKZ in the maintenance period and OLE. Patients randomized to treatments other than BKZ, and those who did not receive BKZ continuously throughout the study period (including those who were re-randomized to placebo at Week 16 in BE READY [n=105]), were not included in this analysis. [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 achieving ≥PASI 90 could switch to Q8W at the investigator's discretion, and all patients were re-assigned to BKZ Q8W at OLE Week 48 or the next scheduled visit via protocol amendment; [c]OLE Week 48 (the end of Year 2) corresponds to BE VIVID/BE BRIGHT Week 100, and BE READY/BE BRIGHT and BE SURE/BE BRIGHT Week 104; [d]OLE Week 96 (the end of Year 3) corresponds to BE VIVID/BE BRIGHT Week 148, and BE READY/BE BRIGHT and BE SURE/BE BRIGHT Week 152.

## Figure 2 Efficacy responses with BKZ through 3 years (mNRI)




Data are reported using modified non-responder imputation (mNRI): patients who discontinued treatment due to lack of efficacy or treatment-related adverse events were considered non-responders at subsequent timepoints; multiple imputation was used for all other missing data. The BE SURE and BE READY feeder studies had a duration of 56 weeks, while BE VIVID had a duration of 52 weeks; to pool the data across all three studies, Week 56 data from the feeder studies were not included. Therefore, timepoints after Week 52 in this figure are from the BE BRIGHT OLE. [a]For DLQI 0/1 efficacy responses, Week 52 corresponds to the Week 48 assessment for BE SURE and BE READY, and Week 52 for BE VIVID, due to the lack of common visits at which DLQI 0/1 was assessed in these studies.

## Table 1 Baseline characteristics

| | BKZ Total (N=771) | 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 |
| **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-12/23 | 43 (5.6) | 13 (6.6) |
| Anti-IL-23 | 37 (4.8) | 13 (6.6) |

Data are reported for all patients who were treated continuously with BKZ through the initial and maintenance periods, and entered the OLE.

## Table 2 Summary of efficacy outcomes (NRI and OC)

| | BKZ Total (N=771) | | BKZ Q4W/Q8W/Q8W (N=197) | |
|---|---|---|---|---|
| | NRI, n (%)[b] | OC, n/Nsub (%)[c] | NRI, n (%)[b] | OC, n/Nsub (%)[c] |
| **PASI 75** | | | | |
| Week 16 | 746 (96.8) | 746/764 (97.6) | 194 (98.5) | 194/194 (100.0) |
| Year 1 | 719 (93.3) | 719/727 (98.9) | 195 (99.0) | 195/195 (100.0) |
| Year 3 | 668 (86.6) | 668/674 (99.1) | 170 (86.3) | 170/171 (99.4) |
| **PASI 90** | | | | |
| Week 16 | 696 (90.3) | 696/764 (91.1) | 185 (93.9) | 185/194 (95.4) |
| Year 1 | 699 (90.7) | 699/727 (96.1) | 192 (97.5) | 192/195 (98.5) |
| Year 3 | 638 (82.7) | 638/674 (94.7) | 168 (85.3) | 168/171 (98.2) |
| **PASI ≤2** | | | | |
| Week 16 | 702 (91.1) | 702/764 (91.9) | 188 (95.4) | 188/194 (96.9) |
| Year 1 | 699 (90.7) | 699/727 (96.1) | 193 (98.0) | 193/195 (99.0) |
| Year 3 | 643 (83.4) | 643/674 (95.4) | 170 (86.3) | 170/171 (99.4) |
| **PASI 100** | | | | |
| Week 16 | 505 (65.5) | 505/764 (66.1) | 146 (74.1) | 146/194 (75.3) |
| Year 1 | 583 (75.6) | 583/727 (80.2) | 167 (84.8) | 167/195 (85.6) |
| Year 3 | 518 (67.2) | 518/674 (76.9) | 143 (72.6) | 143/171 (83.6) |
| **BSA ≤1%** | | | | |
| Week 16 | 601 (78.0) | 601/763 (78.8) | 171 (86.8) | 171/194 (88.1) |
| Year 1 | 656 (85.1) | 656/727 (90.2) | 185 (93.9) | 185/195 (94.9) |
| Year 3 | 610 (79.1) | 610/674 (90.5) | 164 (83.2) | 164/171 (95.9) |
| **DLQI 0/1**[a] | | | | |
| Week 16 | 547 (70.9) | 547/765 (71.5) | 131 (66.5) | 131/194 (67.5) |
| Year 1 | 621 (80.5) | 621/725 (85.7) | 168 (85.3) | 168/195 (86.2) |
| Year 3 | 581 (75.4) | 581/673 (86.3) | 157 (79.7) | 157/171 (91.8) |

Year 1 refers to Week 52 for all outcome measures except DLQI 0/1. Year 3 refers to OLE Week 96. [a]For DLQI 0/1 efficacy responses, Year 1 corresponds to the Week 48 assessment for BE SURE and BE READY, and Week 52 for BE VIVID, due to the lack of common visits at which DLQI 0/1 was assessed in these studies; [b]Patients with missing data at a given week are counted as non-responders; [c]Nsub represents the number of subjects with a non-missing measurement, and percentages are calculated accordingly.

**BKZ:** bimekizumab; **BSA:** body surface area; **DLQI:** Dermatology Life Quality Index; **IGA:** Investigator's Global Assessment; **IL:** interleukin; **mNRI:** modified non-responder imputation; **NRI:** non-responder imputation; **OC:** observed case; **OLE:** open-label extension; **PASI:** Psoriasis Area and Severity Index; **PASI 75/90/100:** ≥75/≥90/100% improvement from baseline in PASI; **Q4W:** every 4 weeks; **Q8W:** every 8 weeks; **SD:** standard deviation.

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**References:** [1]Warren RB et al. J Invest Dermatol 2015;135:2632–40; [2]Adams R et al. Front Immunol 2020;11:1894; [3]Warren RB et al. N Engl J Med 2021;385:130–41. NCT03412747; [4]Reich K et al. Lancet 2021;397:487–98. NCT03370133; [5]Gordon KB et al. Lancet 2021;397:475–86. NCT03536884; [6]Strober B et al. Br J Dermatol 2023;188:749–59. NCT03598790; [7]Hongbo Y et al. J Invest Dermatol 2005;125:659–64.

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He has 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, Evelo, Galderma, Genentech, Geneseq, GenesisCare, GSK, Hexima, Janssen, Kymab, LEO Pharma, Medimmune, Merck, Novartis, Pfizer, Regeneron, Reistone, Roche, Sanofi, Sun Pharma, Teva, UCB Pharma, and Valeant. He has served on advisory boards for AbbVie, Amgen, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Eli Lilly, Galderma, GSK, Janssen, LEO Pharma, Mayne Pharma, Merck, Novartis, Pfizer, Sanofi, Sun Pharma, UCB Pharma, and Valeant. He has served as a consultant for Allan, Bristol Myers Squibb, Eli Lilly, Galderma, GenesisCare, Janssen, LEO Pharma, Mayne Pharma, Medimmune, Novartis, Pfizer, Roche, UCB Pharma, and Wintermute. He has received travel grants from AbbVie, Eli Lilly, Galderma, Janssen, LEO Pharma, Merck, Novartis, Pfizer, Roche, Sanofi, and Sun Pharma, and has served as a speaker for or received honoraria from AbbVie, Amgen, Celgene, Eli Lilly, Galderma, GSK, Janssen, LEO Pharma, Merck, Novartis, Pfizer, Roche, Sanofi, Sun Pharma, and Valeant. **RGL:** Principal investigator for AbbVie, Amgen, Boehringer Ingelheim, Celgene, Eli Lilly, LEO Pharma, Merck, Novartis, Pfizer, and UCB Pharma; served on scientific advisory boards for AbbVie, Amgen, Boehringer Ingelheim, Celgene, Eli Lilly, LEO Pharma, Merck, Novartis, and Pfizer. **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, Torii Pharmaceutical, and UCB Pharma. **PH:** Received educational grants and advisory board fees from AbbVie, Eli Lilly, LEO Pharma, and UCB Pharma; received unrestricted development grant for mobile medical app development from UCB Pharma. **LD**, **SW**, **BH**, **JL:** Employees and shareholders of UCB Pharma. **GK:** Received travel grants or honoraria, or has been a consultant member of advisory boards and speaker bureaus or has served as investigator for AbbVie, Actelion, Almirall, Amgen, Basilea, Biogen, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Eli Lilly, Hexal-Sandoz, Janssen-Cilag, LEO Pharma, MSD, Novartis, Pfizer, Sanofi, Stada, and UCB Pharma. **Acknowledgments:** This study was funded by UCB Pharma. We thank the patients and their caregivers in addition to the investigators and their teams who contributed to this study. The authors acknowledge Joe Dixon, PhD, UCB Pharma, Slough, UK for publication coordination, Jack Wardle, MSc, Costello Medical, Cambridge, UK, for medical writing and editorial assistance and the Creative team at Costello Medical for graphic design assistance. All costs associated with development of this poster were funded by UCB Pharma.

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Poster ID: FC23_1

Link expiration: November 5, 2023