Bimekizumab Remission and High Disease Control Over 4 years in Patients with Psoriasis Achieving Complete Skin Clearance at Week 16: Results from Four Phase 3 Trials

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Objective

To assess whether bimekizumab (BKZ)-treated patients who achieve complete skin clearance after 16 weeks maintain remission of psoriasis or high disease control over 4 years.

Synopsis

- With the emergence of newer biologics, achieving and maintaining completely clear skin in the long term is now an achievable goal for patients living with psoriasis.[1] Therefore, new concepts surrounding remission in psoriasis are increasingly being explored.[2]
- Given the loss of disease control often seen over time with biologics,[3] it is important to evaluate whether high efficacy levels with biologics such as BKZ are continuously maintained in the long term.
- Here, we report the proportions of patients continuously maintaining high efficacy levels at every visit over 4 years, allowing for up to 4 visits with lower, yet still favorable, responses (referred to here using exploratory definitions of remission and high disease control).

Methods

- Data were pooled from the BE SURE, BE VIVID, and BE READY phase 3 trials, and their open-label extension (OLE) BE BRIGHT (**Figure 1**).[4–7]
- Included patients received BKZ 320 mg every 4 weeks (Q4W) to Week 16, then BKZ Q4W or every 8 weeks (Q8W) into the OLE; all patients received BKZ Q8W from Week 100/104 (OLE Week 48) or the next scheduled visit.
- Data are reported for patients regardless of dosing regimen (BKZ Total), and for the subset who received BKZ Q4W to Week 16 then Q8W continuously into the OLE (Q4W/Q8W; the approved dosing regimen for the majority of patients with psoriasis).[8]
- Proportions of patients achieving remission or high disease control are explored among patients who achieved a Psoriasis Area and Severity Index (PASI) score of 0 (PASI 0) at Week 16. We assess maintenance of high efficacy levels at every subsequent study visit from Week 16–Year 4 (Week 196/200; 29/30 further visits [study-dependent]), and allowing for up to 1/2/3/4 visits (representing up to 1 visit per year on average) with lower, yet still favorable, responses.
- The following outcomes are reported among patients who achieved PASI 0 at Week 16:
  - Percentages who maintained PASI 0 at every study visit, and allowing for up to 1/2/3/4 visits with PASI >0–≤2 (remission);
  - Percentages who maintained PASI ≤2 or Body Surface Area (BSA) ≤1% at every study visit, and allowing for up to 1/2/3/4 visits with PASI >2–≤5 or BSA >1%–≤3%, respectively (high disease control; thresholds were chosen based on target outcomes defined in treatment guidelines).[9,10]
- Patients who discontinued treatment due to lack of efficacy or treatment-related adverse events were considered non-responders at subsequent timepoints; last observation carried forward (LOCF) was used for other missing data (modified non-responder imputation [mNRI]-LOCF).

Results

- Overall, 503 BKZ-randomized patients who achieved PASI 0 at Week 16 received continuous BKZ and entered the OLE (Q4W/Q8W: N=147).
- Among these Week 16 PASI 0 responders:
  - PASI 0 was maintained by 48.9% at every visit from Week 16–Year 4; 59.8%/65.0%/68.6%/72.0% maintained PASI 0 at every visit except up to 1/2/3/4 visits with PASI >0–≤2 (**Figure 2A**);
  - PASI ≤2 was maintained by 81.3% at every visit to Year 4; 87.9%/90.1%/91.5%/91.8% maintained PASI ≤2 at every visit except up to 1/2/3/4 visits with PASI >2–≤5 (**Figure 2B**);
  - BSA ≤1% was maintained by 69.4% at every visit to Year 4; 77.5%/80.3%/81.1%/81.7% maintained BSA ≤1% at every visit except up to 1/2/3/4 visits with BSA >1%–≤3% (**Figure 2C**);
  - Similar results were observed in the BKZ Q4W/Q8W group (**Figure 2A–C**).
- Baseline characteristics were generally similar across the overall groups and the groups who maintained remission (**Table 1**).

Conclusion

High percentages of patients who achieved PASI 0 (complete skin clearance) at Week 16 with bimekizumab maintained remission or high disease control through 4 years.

Summary

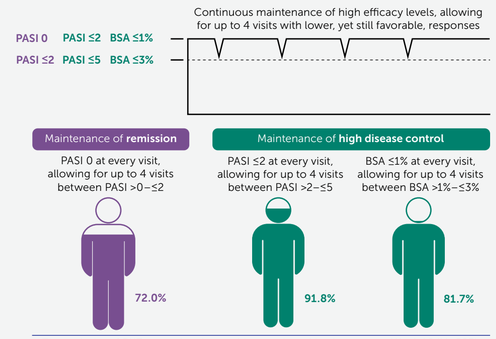
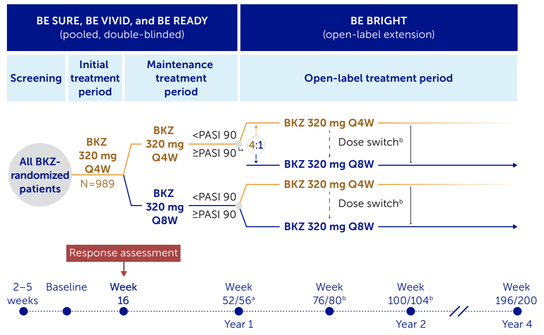
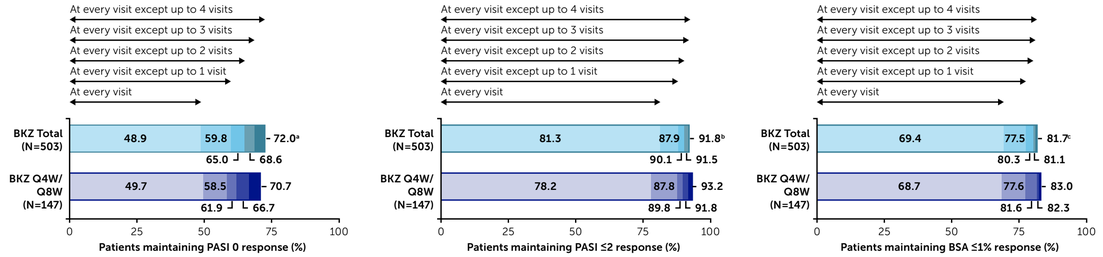


Figure 1 Study design



Included patients in these analyses (N=503) were randomized to BKZ in the initial treatment period and continued to receive BKZ in the maintenance period and OLE, and achieved PASI 0 at Week 16. BKZ-randomized patients who were re-randomized to placebo at Week 16 in BE READY were not included in these analyses. **[a]** BE VIVID had a duration of 52 weeks, and BE SURE and BE READY had a duration of 56 weeks; **[b]** At Week 76/80, patients achieving PASI 90 could switch to BKZ Q8W at the investigator's discretion, and all patients were re-assigned to BKZ Q8W at Week 100/104 or the next scheduled visit.

Figure 2 Week 16 PASI 0 responders who maintained remission/high disease control through 4 years (mNRI-LOCF)



Response levels were assessed at every study visit from Week 16 to Year 4 (29/30 further visits [study-dependent]). Continuous maintenance of PASI 0/PASI ≤2/BSA ≤1% was defined as having PASI 0/PASI ≤2/BSA ≤1% at every visit up to and including Week 196/200, and allowing for up to 1/2/3/4 visits where patients did not maintain PASI 0/PASI ≤2/BSA ≤1% but retained PASI ≤2/PASI ≤5/BSA ≤3%, respectively. To be included in the analysis, patients had to have an observed Week 16 PASI 0 response. One patient in the BE READY trial did not have a Week 16 PASI assessment; however, this patient had a PASI 0 response at Week 12 and Week 20 of BE READY, which was maintained through Week 56, and so they were included in the analysis. **[a]** Among 17 patients who lost PASI 0 at 4 visits but retained PASI ≤2, 1 patient lost their response at 4 consecutive visits; **[b]** Among 2 patients who lost PASI ≤2 at 4 visits but retained PASI ≤5, neither lost their response at 4 consecutive visits; **[c]** Among 3 patients who lost BSA ≤1% at 4 visits but retained BSA ≤3%, 1 patient lost their response at 4 consecutive visits.

Table 1 Baseline characteristics

	BKZ Total Week 16 PASI 0 responders (N=503)[a]	BKZ Q4W/Q8W Week 16 PASI 0 responders (N=147)	Remission: BKZ Total Week 16 PASI 0 responders who maintained PASI 0 at every visit (N=362)[b]	Remission: BKZ Q4W/Q8W Week 16 PASI 0 responders who maintained PASI 0 at every visit (N=104)[b]
Age (years), mean (SD)	44.8 (13.2)	44.4 (13.5)	44.2 (13.3)	43.7 (13.7)
Sex, **male**, n (%)	352 (70.0)	102 (69.4)	254 (70.2)	70 (67.3)
Racial group, **white**, n (%)	441 (87.7)	139 (94.6)	325 (89.8)	97 (93.3)
Weight (kg), mean (SD)	87.8 (19.3)	87.4 (18.9)	87.2 (18.8)	85.9 (18.2)
Duration of psoriasis (years)				
Mean (SD)	18.0 (12.3)	19.6 (12.4)	17.2 (11.8)	18.8 (11.7)
Q1	8.4	9.5	7.6	9.4
Median	15.6	18.4	14.7	17.5
Q3	25.4	27.4	23.9	24.7
≤2 years, n (%)	23 (4.6)	5 (3.4)	15 (4.1)	2 (1.9)
PASI, mean (SD)	21.3 (7.2)	20.7 (7.0)	21.0 (7.1)	20.7 (6.9)
BSA (%), mean (SD)	26.7 (14.9)	24.3 (11.9)	26.2 (14.5)	23.9 (11.7)
IGA, n (%)				
3: moderate	331 (65.8)[c]	102 (69.4)	244 (67.4)	74 (71.2)
4: severe	171 (34.0)	45 (30.6)	118 (32.6)	30 (28.8)
DLQI, mean (SD)	10.9 (6.4)	11.0 (6.2)	10.7 (6.4)	10.8 (6.2)
Any prior systemic therapy, n (%)	415 (82.5)	122 (83.0)	299 (82.6)	85 (81.7)
Any prior biologic therapy, n (%)	210 (41.7)	58 (39.5)	145 (40.1)	38 (36.5)
Anti-TNF	74 (14.7)	16 (10.9)	47 (13.0)	8 (7.7)
Anti-IL-17	126 (25.0)	34 (23.1)	89 (24.6)	23 (22.1)
Anti-IL-23	29 (5.8)	13 (8.8)	23 (6.4)	9 (8.7)
Anti-IL-12/23	28 (5.6)	10 (6.8)	20 (5.5)	10 (9.6)

Only patients who entered the OLE were included in these analyses. **[a]** Baseline characteristics for BKZ Total Week 16 PASI 0 responders (N=503) were published previously;[11] **[b]** Allowing for up to 4 visits with PASI >0–≤2; **[c]** One additional patient had an IGA of 2 (mild) at baseline.

BKZ: bimekizumab; **BSA:** body surface area; **DLQI:** Dermatology Life Quality Index; **IGA:** Investigator's Global Assessment; **IL:** interleukin; **LOCF:** last observation carried forward; **mNRI-LOCF:** modified non-responder imputation-last observation carried forward; **OLE:** open-label extension; **PASI:** Psoriasis Area and Severity Index; **Q1:** first quartile; **Q3:** third quartile; **Q4W:** every 4 weeks; **Q8W:** every 8 weeks; **SD:** standard deviation; **TNF:** tumor necrosis factor.

References: [1]Blauvelt A et al. J Drugs Dermatol 2020;19:487–92; [2]Balak DMW et al. J Eur Acad Dermatol Venereol 2022;36:2291–300; [3]Elberdin L et al. Dermatol Ther (Heidelb) 2022;12:761–70; [4]Warren RB et al. N Engl J Med 2021;385:130–41 (NCT03412747); [5]Reich K et al. Lancet 2021;397:487–98 (NCT03370133); [6]Gordon KB et al. Lancet 2021;397:475–86 (NCT03410992); [7]Blauvelt A et al. J Am Acad Dermatol 2025 93:3:644–53; [8]Bimzelx® Summary of Product Characteristics. 2025. Available at: https://www.ema.europa.eu/en/medicines/human/EPAR/bimzelx [Accessed June 2025]; [9]Armstrong AW et al. J Am Acad Dermatol 2017;76:290–8; [10]Nast A et al. J Eur Acad Dermatol Venereol 2020;34:2461–98; [11]Strober B et al. Br J Dermatol 2023;188:749–59. **Author Contributions:** Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: **RBW**, **BSt**, **DJ**, **ML**, **KE**, **RGL**, **BSz**, **RW**, **AA**; Drafting of the publication, or reviewing it critically for important intellectual content: **RBW**, **BSt**, **DJ**, **ML**, **KE**, **RGL**, **BSz**, **RW**, **AA**; Final approval of the publication: **RBW**, **BSt**, **DJ**, **ML**, **KE**, **RGL**, **BSz**, **RW**, **AA**. **Author Disclosures: RBW:** Consulting fees from AbbVie, Almirall, Amgen, Arena, Astellas, Avillion, Biogen, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, DICE Therapeutics, Eli Lilly, Galderma, GSK, immunocore, Janssen, LEO Pharma, Meiji Pharma, Nektar Therapeutics, Novartis, Pfizer, RAPT Therapeutics, Sanofi, Sun Pharma, UCB, and Union; research grants to his institution from AbbVie, Almirall, Amgen, Celgene, Eli Lilly and Company, Janssen, LEO Pharma, Novartis, Pfizer, and UCB; honoraria from AbbVie, Almirall, Bristol Myers Squibb, Eli Lilly and Company, Galderma, Janssen, and Novartis. **BSt:** Consultant (honorarial for AbbVie, Almirall, Alumis, Amgen, Arcutis, Boehringer Ingelheim, Bristol Myers Squibb, Capital One, PPD CorEvitas, Dermavant, Eli Lilly and Company, Janssen, LEO Pharma, Maruho, Meiji Seika Pharma, Novartis, Oruka, Pfizer, Protagonist, Rapt, Regeneron, Sanofi-Genzyme, Takeda, UCB, and Union Therapeutics; stock options from Connect Biopharma and Mindera Health; speaker for AbbVie, Arcutis, Dermavant, Eli Lilly and Company, Incyte, Johnson & Johnson, Regeneron, and Sanofi-Genzyme; Scientific Co-Director (consulting fee) for CorEvitas Psoriasis Registry; investigator for CorEvitas Psoriasis Registry; editor-in-chief (honorarium): Journal of Psoriasis and Psoriatic Arthritis. **DJ:** Served as a board member and/or consultant for AbbVie, Almirall, Amgen, Biogen, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Eli Lilly and Company, Fresenius Kabi, Janssen-Cilag, Leo, MEDAC, MSD, Novartis, Pfizer, Sanofi, and UCB; received payment for development of educational presentations including service on speakers' bureaus from AbbVie, Celgene, Eli Lilly and Company, Janssen-Cilag, LEO Pharma, MEDAC, Novartis, and Pfizer; had travel/accommodation expenses covered or reimbursed by AbbVie, Amgen, Biogen, Celgene, Eli Lilly and Company, Fresenius Kabi, Janssen-Cilag, LEO Pharma, MEDAC, MSD, Novartis, Pfizer, Sanofi, and UCB. **ML:** Employee of Mount Sinai and receives research funds from AbbVie, Arcutis, Avotres, Boehringer Ingelheim, Cara Therapeutics, Clexio, Dermavant Sciences, Eli Lilly and Company, Incyte, Inozyme, Johnson & Johnson, Pfizer, Sanofi-Regeneron, and UCB; consultant for Aikium, Almirall, AltruBio Inc., Amgen, Apogee, Arcutis Inc., AstraZeneca, Atomwise, Avotres Therapeutics, Boehringer Ingelheim, Bristol Myers Squibb, Castle Biosciences, Celltrion, CorEvitas, Dermavant Sciences, Dermsquared, Evommune Inc., Facilitation of International Dermatology Education, Forte Biosciences, Galderma, Genentech, Incyte, LEO Pharma, Mayne Pharmaceuticals, Meiji Seika Pharma, Mindera, Mirium Pharmaceuticals, Oruka, Pfizer, Revolo, Sanofi-Regeneron, Seanergy, Strata, Sun Pharma, Takeda, Trevi, and Verrica. **KE:** Speaker and/or advisor for AbbVie, Almirall, Boehringer Ingelheim, Bristol Myers Squibb, Eli Lilly and Company, Janssen, LEO Pharma, Novartis, Pfizer, Sanofi, and UCB. **RGL:** Has been a 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. **BSz:** Employee and shareholder of UCB. **RW:** Veramed statistical consultant for UCB. **AA:** Has served as a research investigator and/or scientific advisor to AbbVie, Almirall, Arcutis, ASLAN, Boehringer Ingelheim, Bristol Myers Squibb, Dermavant, Dermira, Eli Lilly and Company, EPI, Incyte, Johnson & Johnson, LEO Pharma, Nimbus, Novartis, Ortho Dermatologics, Pfizer, Regeneron, Sun Pharma, Sanofi, and UCB. **Acknowledgements:** These studies were funded by UCB. 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