Bimekizumab maintenance of response at every visit over 4 years in patients with psoriasis achieving clear skin at Week 16: Results from four phase 3 trials

Mark Lebwohl,[1] Richard B. Warren,[2,3] Peter Foley,[4] Georgios Kokolakis,[5] Naiem T. Issa,[6–8] Richard G. Langley,[9] Balint Szilagyi,[10] Bengt Hoepken,[10] Heather Herr,[11] Rhys Warham,[12,13] April Armstrong[14]

[1]Department of Dermatology, Icahn School of Medicine at Mount Sinai, New York, NY, USA; [2]Dermatology Centre, Northern Care Alliance NHS Foundation Trust, Manchester, UK; [3]NIHR Manchester Biomedical Research Centre, Manchester University NHS Foundation Trust, Manchester Academic Health Science Centre, Manchester, UK; [4]The University of Melbourne, St. Vincent's Hospital Melbourne, Skin Health Institute, Carlton, Victoria, Australia; [5]Psoriasis Research and Treatment Center, Clinic of Dermatology, Venereology, and Allergology, Charité-Universitätsmedizin Berlin, corporate member of Freie Universität Berlin and Humboldt-Universität zu Berlin, Berlin, Germany; [6]Forefront Dermatology, Vienna, VA, USA; [7]Dr. Phillip Frost Department of Dermatology & Cutaneous Surgery, University of Miami Miller School of Medicine, Miami, FL, USA; [8]Department of Dermatology, George Washington University School of Medicine and Health Sciences, Washington, D.C., USA; [9]Division of Clinical Dermatology and Cutaneous Science, Department of Medicine, Dalhousie University, Halifax, NS, Canada; [10]UCB, Monheim am Rhein, Germany; [11]UCB, Smyrna, GA, USA; [12]Veramed, London, UK; [13]UCB, Slough, UK; [14]University of California Los Angeles (UCLA), Los Angeles, CA, USA.

Objective

To assess whether bimekizumab (BKZ) treated patients who achieve complete skin clearance (PASI 100; 100% improvement in Psoriasis Area and Severity Index) after 16 weeks of treatment maintain key efficacy thresholds at every visit, or the vast majority of visits, over 4 years.

Background

- Achieving and maintaining long-lasting skin clearance is key for patients living with psoriasis.[1,2] However, loss of disease control over time is often seen with biologics;[3] therefore, evaluating whether high efficacy levels are maintained at every visit, or the vast majority of visits, in the long-term is important.
- The National Psoriasis Foundation (NPF) has reported that the most preferred time for evaluating patient response after starting new therapies is 3 months. The NPF-defined target response at this time, and every 6 months following, is body surface area (BSA) ≤1%.[4]
- BKZ, a monoclonal IgG1 antibody which selectively inhibits interleukin (IL)-17F in addition to IL-17A,[5] is approved for the treatment of moderate to severe plaque psoriasis in the US.[6]

Methods

- Data were pooled from BE SURE, BE VIVID, and BE READY phase 3 trials, and their open-label extension (OLE) BE BRIGHT (**Figure 1**).[7–10]
- Included patients received BKZ 320 mg every 4 weeks (Q4W) to Week 16, then they received BKZ Q4W or every 8 weeks (Q8W) into the OLE; all received BKZ Q8W from Week 100/104 (OLE Week 48) or the next scheduled visit.
- Proportions of patients achieving PASI 100 at Week 16 who maintained BSA ≤1%, PASI 90/75 (≥90/75% improvement in PASI), and PASI ≤2 responses at every subsequent study visit from Week 16–Year 4 (Week 196/200; 29/30 further visits [study-dependent]) are reported.
- Proportions of patients who maintained their response at every visit except at most 1 and at most 2 are also reported.
- Data are reported for all patients who received continuous BKZ treatment from baseline and entered the OLE, 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).[6,11]
- Patients discontinuing treatment due to a lack of efficacy or treatment-related adverse events were considered non-responders at subsequent timepoints; last observation carried forward was used for other missing data (mNRI-LOCF).

Results

- Of 989 BKZ-randomized patients, 62.7% achieved PASI 100 at Week 16 (non-responder imputation).
- Overall, 503 BKZ-randomized patients who achieved PASI 100 at Week 16, received continuous BKZ and entered the OLE were included in these analyses (Q4W/Q8W: N=147).
- In patients who achieved clear skin at Week 16 (PASI 100), BSA ≤1%, PASI 90, PASI 75, and PASI ≤2 were maintained at every study visit from Week 16–Year 4 by 69.4%, 80.9%, 93.0%, and 81.3% of patients, respectively (mNRI-LOCF; **Figure 2**).
  - In the approved dose group (Q4W/Q8W), BSA ≤1%, PASI 90, PASI 75, and PASI ≤2 were maintained at every subsequent study visit through 4 years by 68.7%, 77.6%, 92.5%, and 78.2% of patients, respectively.
  - Baseline characteristics for Week 16 PASI 100 responders and those who maintained BSA ≤1% at every visit are presented in **Table 1**.
- Proportions of patients who maintained BSA ≤1%, PASI 90, PASI 75, and PASI ≤2 at every visit except at most 1 visit were 79.5%, 87.5%, 95.2%, and 87.9%, respectively, and at every visit except at most 2 visits were: 84.1%, 91.8%, 96.8%, and 91.7% (**Figure 2**).
  - Similar results were observed in the Q4W/Q8W group (**Figure 2**).

Conclusions

High proportions of Week 16 PASI 100 responders maintained BSA ≤1% (NPF-defined target response),[4] PASI 90, PASI 75, and PASI ≤2 at every visit through 4 years. The vast majority maintained these responses at every visit except at most 2 visits through 4 years.

Summary

The vast majority of BKZ-treated patients with complete skin clearance at Week 16 (N=503) **maintained** their **BSA ≤1%**, **PASI 90**, **PASI 75**, and **PASI ≤2** responses at **every visit except at most 2 visits** from Week 16 **through 4 years**

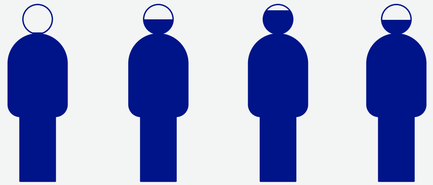
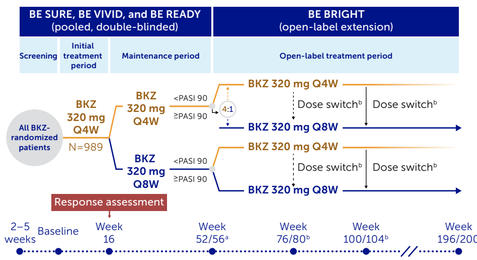
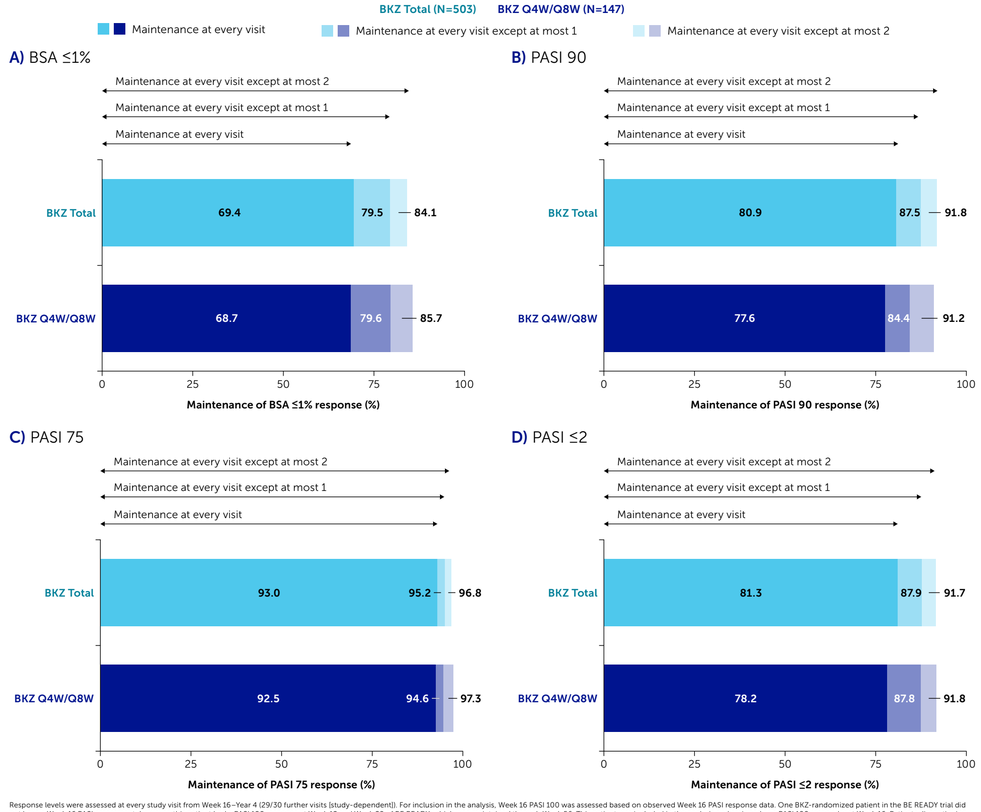


Figure 1 Study design



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 100 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 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 100 responders who maintained their response at every visit, and at every visit except at most 1, or except at most 2, through 4 years (mNRI-LOCF)



Response levels were assessed at every study visit from Week 16–Year 4 (29/30 further visits [study-dependent]). For inclusion in the analysis, Week 16 PASI 100 was assessed based on observed Week 16 PASI response data. One BKZ-randomized 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. Patients discontinuing treatment due to a lack of efficacy or treatment-related adverse events were considered non-responders at subsequent timepoints. LOCF was used to impute all other missing data.

Table 1 Baseline characteristics for Week 16 PASI 100 responders and those who maintained BSA ≤1% at every visit

	BKZ Total Week 16 PASI 100 responders (N=503)	BKZ Q4W/Q8W Week 16 PASI 100 responders (N=147)	BKZ Total Continuous BSA ≤1% responders at every visit (N=349)	BKZ Q4W/Q8W Continuous BSA ≤1% responders at every visit (N=101)
Age (years), mean (SD)	44.8 (13.2)	44.4 (13.5)	44.2 (12.9)	44.0 (13.7)
Sex, **male**, n (%)	352 (70.0)	102 (69.4)	249 (71.3)	69 (68.3)
Racial group, **white**, n (%)	441 (87.7)	139 (94.6)	310 (88.8)	95 (94.1)
Weight (kg), mean (SD)	87.8 (19.3)	87.4 (18.9)	87.7 (18.8)	85.4 (18.2)
Duration of psoriasis (years)				
Mean (SD)	18.0 (12.3)	19.6 (12.4)	17.1 (11.6)	19.5 (11.8)
Q1	8.4	9.5	7.7	9.5
Median	15.6	18.4	14.6	18.4
Q3	25.4	27.4	24.5	25.7
≤2 years, n (%)	23 (4.6)	5 (3.4)	14 (4.0)	2 (2.0)
PASI, mean (SD)	21.3 (7.2)	20.7 (7.0)	21.0 (7.0)	20.8 (7.0)
BSA (%), mean (SD)	26.7 (14.9)	24.3 (11.9)	26.3 (14.6)	24.0 (11.8)
IGA, n (%)				
3: moderate	331 (65.8)[a]	102 (69.4)	239 (68.5)	72 (71.3)
4: severe	171 (34.0)	45 (30.6)	110 (31.5)	29 (28.7)
DLQI, mean (SD)	10.9 (6.4)	11.0 (6.2)	10.5 (6.3)	10.8 (6.2)
Any prior systemic therapy, n (%)	415 (82.5)	122 (83.0)	288 (82.5)	83 (82.2)
Any prior biologic therapy, n (%)	210 (41.7)	58 (39.5)	142 (40.7)	39 (38.6)
Anti-TNF	74 (14.7)	16 (10.9)	47 (13.5)	8 (7.9)
Anti-IL-17	126 (25.0)	34 (23.1)	88 (25.2)	23 (22.8)
Anti-IL-23	29 (5.8)	13 (8.8)	21 (6.0)	10 (9.9)
Anti-IL-12/23	28 (5.6)	10 (6.8)	19 (5.4)	8 (7.9)

Only patients who entered the OLE were included in these analyses. **[a]** 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; **NPF:** National Psoriasis Foundation; **OLE:** open-label extension; **PASI:** Psoriasis Area and Severity Index; **PASI 75/90/100:** ≥75%/≥90%/100% improvement from baseline in PASI; **SD:** standard deviation; **Q1:** first quartile; **Q3:** third quartile; **Q4W:** every 4 weeks; **Q8W:** every 8 weeks; **TNF:** tumor necrosis factor.

References: [1]Tada Y et al. J Dermatol 2021;48:1665–74; [2]Rasmussen MK et al. Acta Derm Venereol 2019;99:158–63; [3]Elberdín L. Dermatol Ther (Heidelb) 2022;12:761–70; [4]Armstrong AW et al. J Am Acad Dermatol 2017;76:290–8; [5]Adams R et al. Front Immunol 2020;11:1894; [6]Bimzelx® US Prescribing Information. 2023. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/761151s000lbl.pdf [Accessed November 2024]; [7]Reich K et al. Lancet 2021;397:487–98 (NCT03370133); [8]Warren RB et al. N Engl J Med 2021;385:130–41 (NCT03412747); [9]Gordon KB et al. Lancet 2021;397:475–86 (NCT03598790); [10]Strober B et al. Br J Dermatol 2023;188:749–59 (NCT03598790); [11]Bimzelx® Summary of Product Characteristics. 2024. Available at: https://www.ema.europa.eu/en/medicines/human/EPAR/bimzelx [Accessed November 2024]. **Author Contributions:** Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: **ML**, **RBW**, **PF**, **GK**, **NTI**, **RGL**, **BS**, **BH**, **HH**, **RW**, **AA**. Drafting of the publication, or reviewing it critically for important intellectual content: **ML**, **RBW**, **PF**, **GK**, **NTI**, **RGL**, **BS**, **BH**, **HH**, **RW**, **AA**. Final approval of the publication: **ML**, **RBW**, **PF**, **GK**, **NTI**, **RGL**, **BS**, **BH**, **HH**, **RW**, **AA**. **Author Disclosures: ML:** Employee of Mount Sinai and receives research funds from Abbvie, Amgen, Arcutis, Avotres, Boehringer Ingelheim, Cara Therapeutics, Dermavant Sciences, Eli Lilly and Company, Incyte, Inozyme, Johnson & Johnson, Ortho Dermatologics, Pfizer, Sanofi-Regeneron, and UCB; consultant for Almirall, AltruBio, AnaptysBio, Apogee, Arcutis, AstraZeneca, Atomwise, Avotres, Bristol Myers Squibb, Castle Biosciences, Cellfrion, CorEvitas, Dermavant Sciences, 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. **RBW:** Consulting fees from AbbVie, Almirall, Amgen, Arena, Astellas, Avillion, Biogen, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, DICE Therapeutics, Eli Lilly and Company, GSK, Johnson & Johnson, LEO Pharma, Meiji Pharma, Novartis, Pfizer, RAPT Therapeutics, Sanofi, Sun Pharma, UCB, and Union; research grants to his institution from AbbVie, Almirall, Amgen, Celgene, Eli Lilly and Company, Johnson & Johnson, LEO Pharma, Novartis, Pfizer, and UCB; honoraria from AbbVie, Almirall, Bristol Myers Squibb, Eli Lilly and Company, Galderma, Johnson & Johnson, and Novartis. **PF:** Grant support from AbbVie, Alumis, Amgen, Bristol Myers Squibb, Celgene, Eli Lilly and Company, Johnson & Johnson, LEO Pharma, Merck, Novartis, Pfizer, Sanofi, and Sun Pharma; served as an investigator for AbbVie, Akaal, Amgen, Arcutis, Argenx, Aslan, AstraZeneca, Avalo, Boehringer Ingelheim, Botanix, Bristol Myers Squibb, Celgene, Celtaxsys, Claruvis, CSL, Cutanea, Dermira, Eli Lilly and Company, Evelo, Galderma, Genentech, Geneseq, GenesisCare, GSK, Hexima, Incyte, Johnson & Johnson, Kymab, LEO Pharma, MedImmune, Merck, Novartis, Pfizer, Regeneron, Reistone, Roche, Sanofi, Sun Pharma, Takeda, Teva, UCB, Valeant, and Zai Lab; served on advisory boards for AbbVie, Amgen, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Eli Lilly and Company, Galderma, GSK, Johnson & Johnson, LEO Pharma, Mayne Pharma, Merck, Novartis, Pfizer, Sanofi, Sun Pharma, UCB, and Valeant; served as a consultant for Apogee, Aslan, Bristol Myers Squibb, Eli Lilly and Company, Galderma, GenesisCare, Johnson & Johnson, LEO Pharma, Mayne Pharma, MedImmune, Novartis, Oruka, Pfizer, Roche, UCB, and Wintermute; received travel grants from AbbVie, Eli Lilly and Company, Galderma, Johnson & Johnson, LEO Pharma, Merck, Novartis, Pfizer, Roche, Sun Pharma, and Sanofi; served as a speaker for or received honoraria from AbbVie, Almirall, Amgen, Bristol Myers Squibb, Celgene, Eli Lilly and Company, Galderma, GSK, Johnson & Johnson, LEO Pharma, Merck, Novartis, Pfizer, Roche, Sanofi, Sun Pharma, UCB, and Valeant. **GK:** Received travel grants or honoraria, has been a consultant member of advisory boards and speaker bureaus or has served as an investigator for AbbVie, Actelion, Almirall, Amgen, Basilea, Biogen, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Eli Lilly and Company, Hexal-Sandoz, Johnson & Johnson, LEO Pharma, MSD, Novartis, Pfizer, Sanofi, Takeda, and UCB. **NTI:** Received funding as a speaker, consultant, advisor or investigator for AbbVie, Almirall, Bristol Myers Squibb, Castle Biosciences, Dermavant Sciences, DermTech, Galderma, Incyte, Journey, LEO Pharma, Eli Lilly and Company, National Eczema Association, Ortho Dermatologics, Pfizer, RBC Consultants, Regeneron, Sanofi, Sun Pharma, Topix, UCB, and Verrica. **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. **BS**, **BH**, **HH:** Employees and shareholders 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:** 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.

To receive a copy of this poster, scan the QR code.

Link expiration: July 13, 2025