

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 Armstrong¹⁴

Synopsis

- 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) $\leq 1\%$.
- Bimekizumab (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

Objective

To assess whether 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.

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 $\leq 1\%$, PASI 90/75 ($\geq 90/75\%$ 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 $\leq 1\%$, 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 $\leq 1\%$, 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 $\leq 1\%$ at every visit are presented in Table 1.
- Proportions of patients who maintained BSA $\leq 1\%$, 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 $\leq 1\%$ (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 $\leq 1\%$, PASI 90, PASI 75, and PASI ≤ 2 responses at every visit except at most 2 visits from Week 16 through 4 years

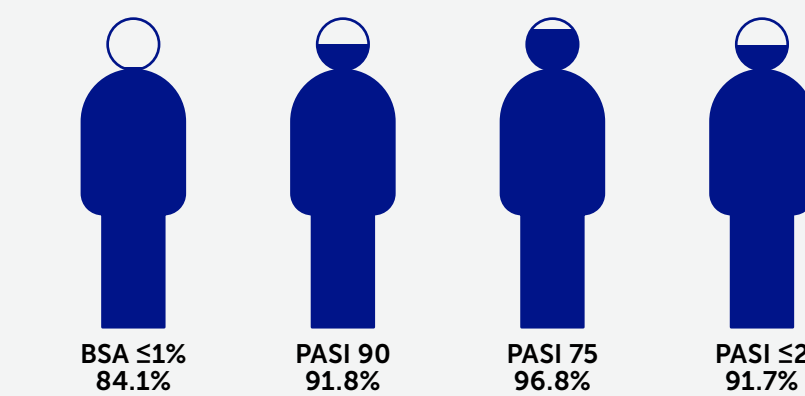


Table 1 Baseline characteristics for Week 16 PASI 100 responders and those who maintained BSA $\leq 1\%$ at every visit

	BKZ Total Week 16 PASI 100 responders (N=503)	BKZ Q4W/Q8W Week 16 PASI 100 responders (N=147)	BKZ Total Continuous BSA $\leq 1\%$ responders at every visit (N=349)	BKZ Q4W/Q8W Continuous BSA $\leq 1\%$ 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. ^aOne additional patient had an IGA of 2 (mid) 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: $\geq 75\%/90\%/100\%$ 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.

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

References: Tada Y et al. J Dermatol 2021;48:1665-74; Rasmussen MK et al. Acta Derm Venereol 2019;99:158-63; Elberdin L. Dermatol Ther (Heidelb) 2022;12:761-70; Armstrong AW et al. J Am Acad Dermatol 2017;76:290-8; Adams R et al. Front Immunol 2020;11:1894; "Bimzelx" US Prescribing Information, 2023. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/761151s000lbl.pdf [Accessed November 2024]; Reich K et al. Lancet 2021;397:487-98 (NCT03370133); Warren RB et al. N Engl J Med 2021;385:130-41 (NCT03412747); Gordon KB et al. Lancet 2021;397:475-86 (NCT03410992); Strober B et al. Br J Dermatol 2023;188:749-59 (NCT03598790); "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. 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Figure 1 Study design

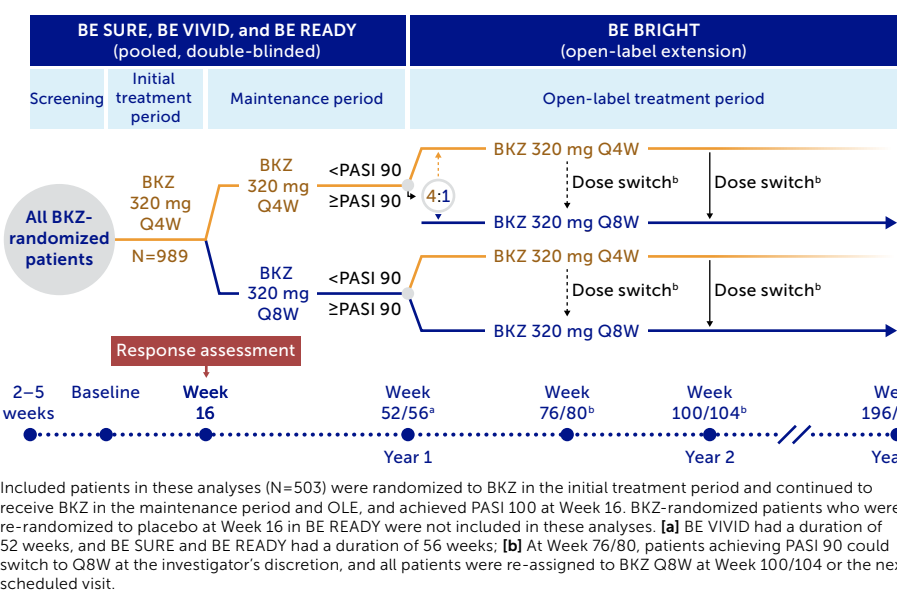
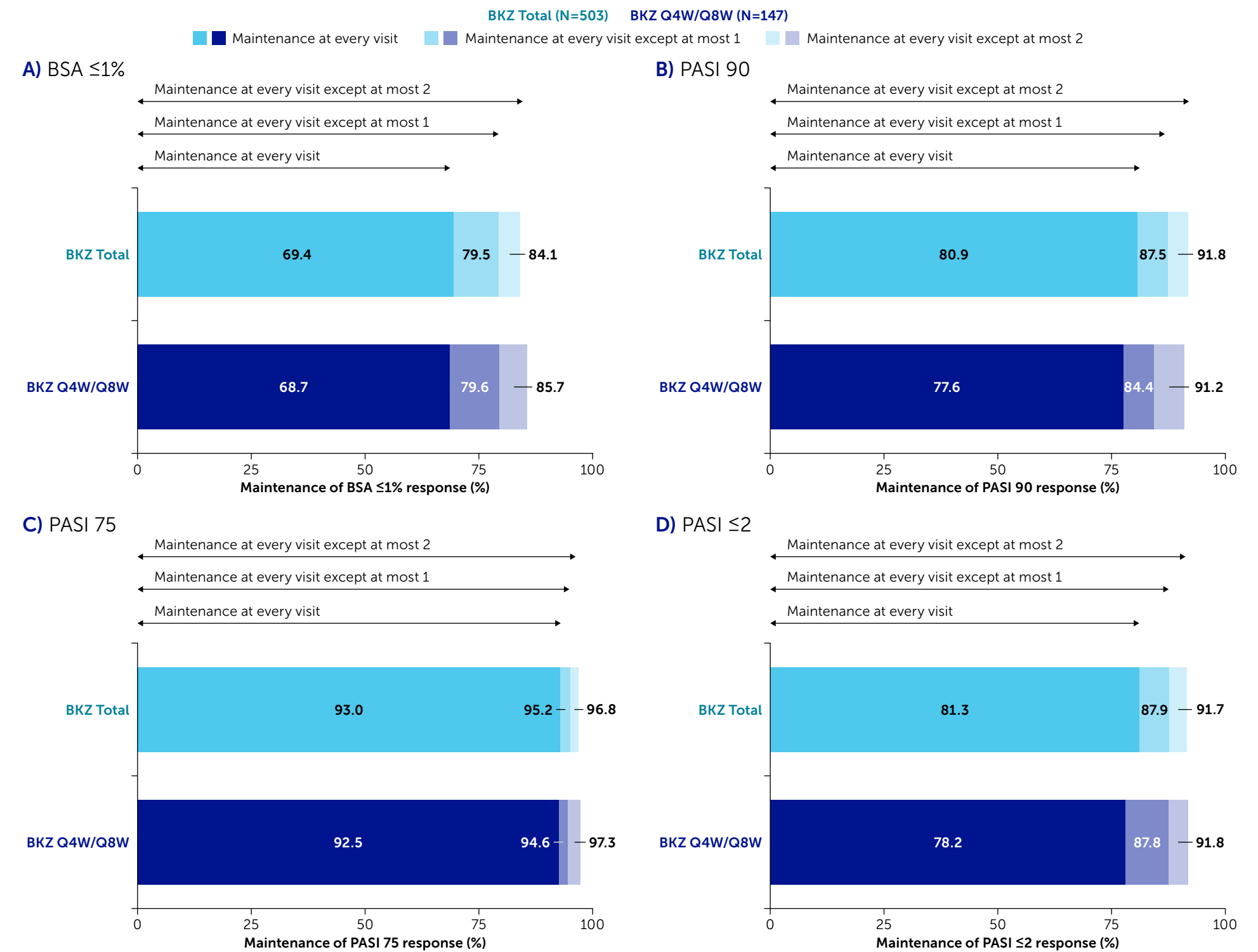


Figure 2

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.



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