Bimekizumab efficacy through Year 1 in patients with moderate to severe plaque psoriasis who had not achieved a PASI 90 response by Week 16: A pooled analysis from four phase 3/3b trials

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Synopsis

- A ≥90% reduction from baseline PASI (PASI 90) has been associated with improved quality of life.[1]
- High PASI 90 response rates, sustained through three years, have been observed in patients with moderate to severe plaque psoriasis treated with BKZ, a monoclonal IgG1 antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A.[2–7]

Objective

To evaluate Psoriasis Area and Severity Index (PASI) response, including patient-level PASI response, through Year 1 in patients who had not achieved a PASI 90 response at ≥1 visit up to and including Week 16, in four phase 3/3b trials of bimekizumab (BKZ) in moderate to severe plaque psoriasis.

Methods

- Data were pooled from the 52-week BE VIVID,[3] 56-week BE READY,[4] and 56-week BE SURE[5] double-blind phase 3 trials, and the 48-week double-blind period of the BE RADIANT phase 3b trial.[6]
- This analysis includes all patients randomized to receive BKZ 320 mg every 4 weeks (Q4W) from baseline to Week 16 (BKZ Total); at Week 16 patients either continued to receive BKZ 320 mg Q4W or switched to BKZ 320 mg Q8W until the end of the double-blind trial period.
- Analyses focus on patients who had not achieved PASI 90 at ≥1 visit up to and including Week 16 (PASI 90 non-responders by Week 16).
  - PASI response, including patient-level response, is reported through Year 1 (Week 52 for BE VIVID; Week 48 for other trials).
- Data are also reported through Year 1 for two additional subsets of PASI 90 non-responders by Week 16:
  - Patients randomized to BKZ 320 mg Q4W to Week 16, followed by BKZ 320 mg Q8W (BKZ Q4W/Q8W; a dosing regimen approved for the majority of patients).
  - Patients who completed the double-blind period of the phase 3/3b trials.
- Data are reported using non-responder imputation (NRI) and observed case (OC). Patients with missing data at a given week are considered non-responders in the NRI analysis.

Results

- Overall, 1,362 patients were randomized to receive BKZ Q4W at baseline (BKZ Total). Most patients treated with BKZ achieved PASI 90 at ≥1 visit by Week 16 (92.6%; 1,261/1,362) while only 7.1% (97/1,362) were PASI 90 non-responders by Week 16.
  - Baseline characteristics are presented in **Table 1**.
- PASI 90 non-responders by Week 16 (n=97) still achieved high PASI response during the double-blind trial.
  - At the Year 1 visit, 42.3% and 30.9% of PASI 90 non-responders by Week 16 achieved PASI 75 and PASI 90, respectively (NRI; **Figure 1**).
  - Up to and including the Week 16 visit, 72.2% of patients who had not achieved PASI 90 achieved PASI 75 at ≥1 visit; up to and including the Year 1 visit, 83.5% achieved PASI 75 at ≥1 visit (NRI).
  - Median (minimum, maximum) percentage change from baseline PASI increased from −77.31 (−89.7, 20.0) at Week 16 (n=78; OC) to −92.9 (−100.0, 90.7) at Year 1 (n=51; OC).
- Of the 97 PASI 90 non-responders by Week 16, 61.9% (n=60) completed their respective double-blind phase 3/3b trials.
  - Of these patients, 96.7% (58/60) and 55.0% (33/60) achieved PASI 75 and PASI 90, respectively, at ≥1 visit by Year 1 of the double-blind period (OC).
- The BKZ Q4W/Q8W subgroup (n=480/1,362) had 25 patients who were PASI 90 non-responders by Week 16.
  - Patient-level PASI response for patients treated with BKZ Q4W/Q8W is presented in **Figure 2** (OC); 96.0% (24/25) and 48.0% (12/25) of patients achieved PASI 75 and PASI 90, respectively, at ≥1 visit by Year 1 of the double-blind period (OC).
  - There were 15 patients who completed their respective double-blind phase 3/3b trials; of these, 100.0% (15/15) and 66.7% (10/15) achieved PASI 75 and PASI 90, respectively, at ≥1 visit by Year 1 of the double-blind period (OC).
- By Year 1, only 4.4% (60/1,362) of all patients treated with BKZ had not achieved PASI 90 at ≥1 visit.

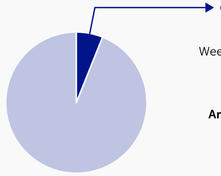
Conclusions

The majority of patients treated with BKZ, achieved PASI 90 at ≥1 visit by Week 16 in four phase 3/3b trials of BKZ in moderate to severe plaque psoriasis.

Among the limited number of patients who had not achieved PASI 90 at ≥1 visit by Week 16, the PASI 90 and PASI 75 response rates increased through Year 1.

Summary

We report **PASI responses** through Year 1 in patients who had not achieved a PASI 90 response by Week 16 of the phase 3/3b BKZ trials



Of the **7.1%** (97/1,362) of patients treated with BKZ who had not achieved PASI 90 at ≤1 visit by Week 16, **72%** achieved at least a PASI 75

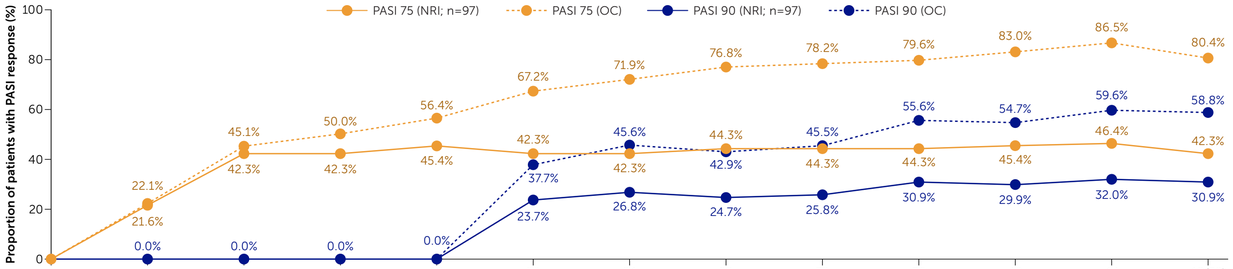
Among the PASI 90 non-responders by Week 16, 30.9% achieved PASI 90 at their Year 1 visit

Table 1 Baseline characteristics

	BKZ Total[a] N=1,362	PASI 90 responders by Week 16[b] n=1,261	PASI 90 non-responders by Week 16[c] n=97
Age (years), mean ± SD	45.1 ± 13.6	44.6 ± 13.6	51.6 ± 13.3
Male, n (%)	949 (69.7)	874 (69.3)	73 (75.3)
White, n (%)	1,188 (87.2)	1,110 (88.0)	74 (76.3)
Weight (kg), mean ± SD	89.7 ± 21.9	89.0 ± 21.1	99.5 ± 28.5
Duration of psoriasis (years), mean ± SD	18.2 ± 12.6	18.1 ± 12.5	20.1 ± 14.2
Any prior biologic therapy, n (%)	506 (37.2)	467 (37.0)	39 (40.2)
BSA (%), mean ± SD	26.0 ± 15.6	26.1 ± 15.6	24.9 ± 16.1
PASI, mean ± SD	20.7 ± 7.6	20.8 ± 7.6	19.7 ± 8.0

[a] Included all patients randomized to receive BKZ in the 52-week BE VIVID, 56-week BE READY, 56-week BE SURE double-blind phase 3 trials, and the 48-week double-blind period of the BE RADIANT phase 3b trial. The sum of responders (n=1,261) and non-responders (n=97) does not equal the overall population (N=1,362) because baseline PASI data were unavailable for four patients; [b] Included patients treated with BKZ, who achieved a PASI 90 response at ≥1 visit up to and including Week 16 (based on observed data); [c] Included patients who had not achieved a PASI 90 response at ≥1 visit up to and including Week 16 (based on observed data).

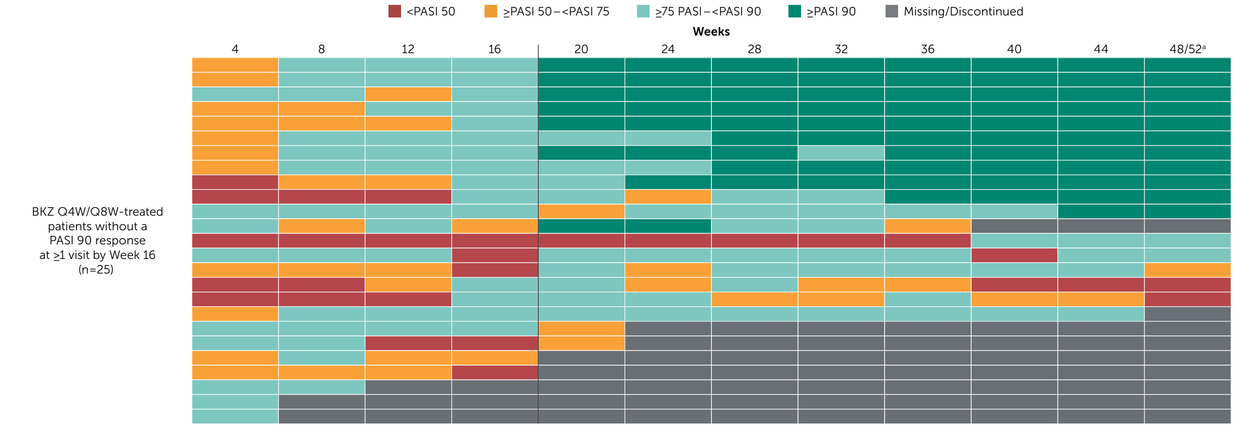
Figure 1 PASI 75 and PASI 90 response rates at each visit among PASI 90 non-responders by Week 16 in BKZ Total[a] (NRI, OC)



	4	8	12	16	20	24	28	32	36	40	44	48/52[b]
PASI 75 (OC) n/Nsub[c]	21/95	41/91	41/82	44/78	41/61	41/57	43/56	43/55	43/54	44/53	45/52	41/51
PASI 90 (OC) n/Nsub[c]	0/95	0/91	0/82	0/78	23/61	26/57	24/56	25/55	30/54	29/53	31/52	30/51

[a] Included patients treated with BKZ, who had not achieved a PASI 90 response at ≥1 visit up to and including Week 16 (based on observed data); [b] This analysis considered Week 48 as the Year 1 timepoint for the BE SURE, BE READY, and BE RADIANT trials, and Week 52 as the Year 1 timepoint for the BE VIVID trial; [c] Nsub represents the number of patients with a non-missing measurement.

Figure 2 Patient-level PASI response by visit among PASI 90 non-responders by Week 16 treated with BKZ Q4W/Q8W (OC)



[a] This analysis considered Week 48 as the Year 1 timepoint for the BE SURE, BE READY, and BE RADIANT trials, and Week 52 as the Year 1 timepoint for the BE VIVID trial; therefore, the final visits of the double-blind period of BE READY and BE SURE are not included here.

BKZ: bimekizumab; **BSA:** body surface area; **IgG1:** immunoglobulin G1; **IL:** interleukin; **NRI:** non-responder imputation; **OC:** observed case; **PASI:** Psoriasis Area and Severity Index; **PASI 50/75/90:** ≥50%/≥75%/≥90% improvement from baseline PASI; **Q4W:** every 4 weeks; **Q8W:** every 8 weeks, **SD:** standard deviation.

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References: [1]Rasmussen MK et al. Acta Derm Venereol 2019;99(2):158–63; [2]Papp KA et al. J Am Acad Dermatol 2018;79(2):277–86; [3]Reich K et al. Lancet 2021;397(10273):487–98, NCT03370133; [4]Gordon KB et al. Lancet 2021;397(10273):475–86, NCT03410992; [5]Warren RB et al. N Engl J Med 2021;385(2):130–41, NCT03412747; [6]Reich K et al. N Engl J Med 2021;385(2):142–52, NCT03536884; [7]Strober B et al. Br J Dermatol 2023;188(6):749–59, NCT03598790. **Author Contributions:** Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: **GH**, **ABG**, **AA**, **BS**, **JS**, **HH**, **LD**, **ML**; drafting of the publication, or reviewing it critically for important intellectual content: **GH**, **ABG**, **AA**, **BS**, **JS**, **HH**, **LD**, **ML**; final approval of the publication: **GH**, **ABG**, **AA**, **BS**, **JS**, **HH**, **LD**, **ML**. **Author Disclosures: GH:** Investigator, consultant, advisor, or speaker for AbbVie; Amgen, Athenex, Boehringer Ingelheim, Bond Avillion, Bristol Myers Squibb, Castle Biosciences, Celgene, Dermavant, Dermtech, Eli Lilly and Company, Incyte, Janssen, LEO Pharma, MC2, Ortho Dermatologics, Pfizer, Regeneron, Sanofi, Sun Pharma, and UCB Pharma; **ABG:** Received research/educational grants from AnaptysBio, Bristol Myers Squibb, Highlights Therapeutics, MoonLake Immunotherapeutics, Novartis, and UCB Pharma (all paid to Mount Sinai School of Medicine); received honoraria as an advisory board member and consultant for Amgen, AnaptysBio, Avotres, Boehringer Ingelheim, Bristol Myers Squibb, DICE Therapeutics, Eli Lilly and Company, Highlights Therapeutics, Janssen, Novartis, Sanofi, UCB Pharma, and Xbiotech. **AA:** Research investigator and/or scientific advisor to AbbVie, Almirall, Arcutis, ASLAN, Boehringer Ingelheim, Bristol Myers Squibb, Dermavant, Dermira, Eli Lilly and Company, EPI, Incyte, Janssen, LEO Pharma, Nimbus, Novartis, Ortho Dermatologics, Pfizer, Regeneron, Sun Pharma, Sanofi, and UCB Pharma. **BS:** Consultant (honoraria) for AbbVie, Acelyrin, Alamar, Almirall, Alumis, Amgen, Arcutis, Arena, Aristea, Asana, Boehringer Ingelheim, Bristol Myers Squibb, Capital One, Celltrion, CorEvitas, Dermavant, Eli Lilly and Company, Imagenebio, Janssen, Kangpu Pharmaceuticals, LEO Pharma, Maruho, Meiji Seika Pharma, Monte Carlo, Novartis, Pfizer, Protagonist, Rapt, Regeneron, Sanofi, SG Cowen, Sun Pharma, Takeda, UCB Pharma, Union Therapeutics, Ventyxbio, and vTv Therapeutics; stock options from Connect Biopharma, Mindera Health; speaker for AbbVie, Arcutis, Dermavant, Eli Lilly and Company, Incyte, Janssen, Regeneron, and Sanofi; Scientific Co-Director (consulting fee) for CorEvitas Psoriasis Registry; investigator for CorEvitas Psoriasis Registry; Editor-in-Chief (honorarium) for Journal of Psoriasis and Psoriatic Arthritis. **JS:** Honoraria and/or consulting fees from Amgen, Celgene, Dermavant, National Psoriasis Foundation, Ortho Dermatologics, and Regeneron; grants and consulting fees from AbbVie, Actelion, Boehringer Ingelheim, Dermira, Eli Lilly and Company, Janssen, LEO Pharma, Novartis, and UCB Pharma; research grants from Cassiopeia, Galderma, and Pfizer. **HH**, **LD:** Employees and shareholders of UCB Pharma. **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, Novartis, Ortho Dermatologics, Regeneron, and UCB Pharma; consultant for Almirall, AltruBio, Inc., AnaptysBio, Arcutis, Arena Pharmaceuticals, Aristea Therapeutics, AstraZeneca, Avotres, BioMX, 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, Hexima Ltd., Incyte, LEO Pharma, Meiji Seika Pharma, Mindera, National Society of Cutaneous Medicine, New York College of Podiatric Medicine, Pfizer, Seanergy, Strata, Sun Pharma, Trevi, Verrica, and Vial. **Acknowledgements:** This study was funded by UCB Pharma. We would like to thank the patients and their caregivers in addition to the investigators and their teams who contributed to this study. The authors acknowledge Nnenna Ene, BA, Costello Medical, Boston, MA, for medical writing support, and the Costello Medical Creative team for design support. All costs associated with development of this poster were funded by UCB Pharma.

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