Bimekizumab efficacy through one year in patients with moderate to severe plaque psoriasis in subgroups defined by prior biologic treatment: Pooled results from four phase 3/3b trials

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Presented at the 42nd Annual Fall Clinical Dermatology Conference | Las Vegas, NV | October 20th–23rd, 2022

Synopsis

- Prior biologic treatment can impact responses to biologics in patients with moderate to severe plaque psoriasis.[1]

Objectives

To assess clinical and health-related quality of life (HRQoL) outcomes in bimekizumab (BKZ)-treated patients without prior biologic treatment (biologic-naïve) vs those with prior biologic treatment (biologic-experienced).

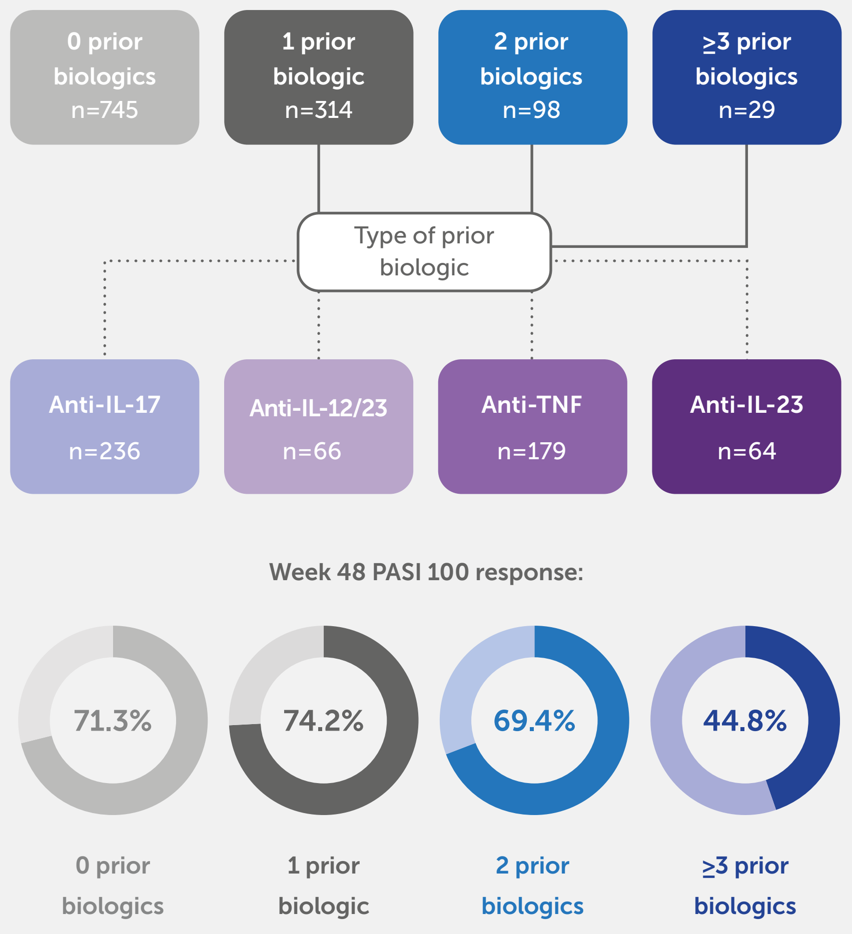
Methods

- Data were pooled from the BE SURE, BE VIVID, BE READY, and BE RADIANT phase 3/3b trials for patients with moderate to severe plaque psoriasis; full study designs have been published previously.[2–5]
- Patients included in these analyses were randomized at baseline to BKZ 320 mg every 4 weeks (Q4W), then received BKZ 320 mg Q4W or Q8W maintenance dosing from Week 16 for the remainder of the double-blinded trials. In this analysis, Q4W and Q8W treatment groups were combined (BKZ Total).
- Patients with previous primary failure (no response within 12 weeks) to either ≥1 anti-interleukin (IL)-17 or >1 other biologic treatment were excluded from all trials.
- We report ≥90% improvement from baseline in Psoriasis Area and Severity Index (PASI 90), complete skin clearance (PASI 100), and Dermatology Life Quality Index (DLQI) 0/1, indicating no effect of skin disease on a patient's life, through one year in patients who had received 0, 1, 2, or ≥3 prior biologics.
- We also report responses by type of prior biologic: anti-IL-17, anti-tumor necrosis factor (TNF), anti-IL-12/23, and anti-IL-23.
- Missing data were handled using non-responder imputation (NRI).

Results

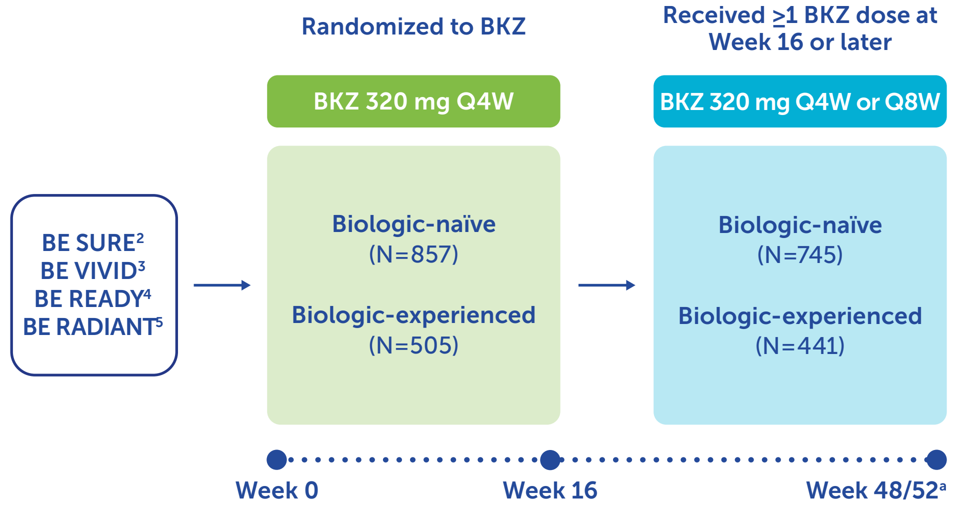
- 1,186 patients randomized to BKZ continued to the maintenance periods of the trials and received BKZ 320 mg Q4W or Q8W (BKZ Total); 745 were biologic-naïve, whilst 314, 98, and 29 had received 1, 2, or ≥3 prior biologics, respectively (Figure 1).
- Baseline characteristics were similar in biologic-naïve and biologic-experienced patients, with the exception of duration of psoriasis which was higher in biologic-experienced patients (Table 1).
- At Week 16 and Week 48, PASI 90 (Figure 2A), PASI 100 (Figure 3A), and DLQI 0/1 (Figure 4A) responses were consistently high in biologic-naïve patients, as well as in those who had received 1 or 2 prior biologics.
- Responses were numerically lower in the subgroup of patients who had received ≥3 prior biologics (Figure 2A–4A).
- In biologic-experienced patients, high levels of PASI 90, PASI 100, and DLQI 0/1 responses were observed across all subgroups by type of prior biologic (Figure 2B–4B).

Summary


Data were pooled from the BE SURE, BE VIVID, BE READY, and BE RADIANT phase 3/3b trials:
0 prior biologics n=745
1 prior biologic n=314
2 prior biologics n=98
≥3 prior biologics n=29
Type of prior biologic
Anti-IL-17 n=236
Anti-IL-12/23 n=66
Anti-TNF n=179
Anti-IL-23 n=64
Week 48 PASI 100 response:
71.3%
74.2%
69.4%
44.8%
0 prior biologics
1 prior biologic
2 prior biologics
≥3 prior biologics

High levels of skin clearance were observed with bimekizumab in patients who had recieved 0, 1, or 2 prior biologics, regardless of prior biologic used

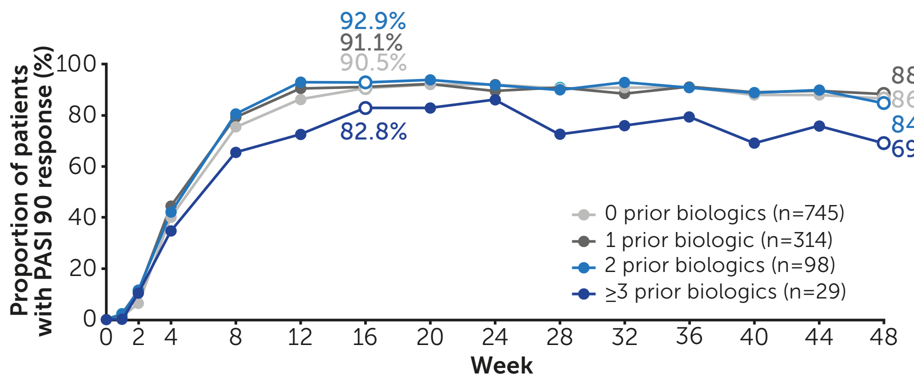
Figure 1 Study design: Included patients by number of prior biologics


Randomized to BKZ
Received ≥1 BKZ dose at Week 16 or later
BE SURE[2]
BE VIVID[3]
BE READY[4]
BE RADIANT[5]
BKZ 320 mg Q4W
BKZ 320 mg Q4W or Q8W
Biologic-naïve (N=857)
Biologic-experienced (N=505)
Biologic-naïve (N=745)
Biologic-experienced (N=441)
Week 0
Week 16
Week 48/52[a]

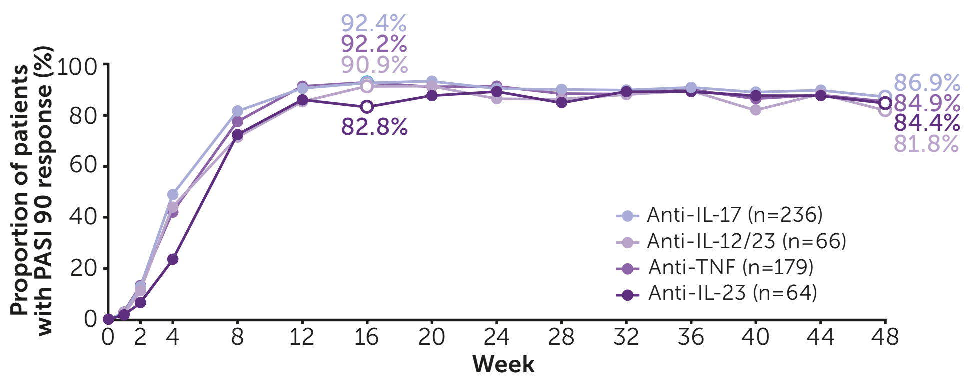
All studies included Q4W dosing from Week 0–16; BE SURE, BE READY, and BE RADIANT also included Q8W maintenance dosing to the end of the trial. Included patients received BKZ during the initial 16-week period, and during the maintenance period. [a]PASI outcomes are reported through Week 48 in all included trials; DLQI is reported to Week 48 in BE SURE, BE READY, and BE RADIANT, and Week 52 in BE VIVID, due to differences in scheduling of DLQI assessments.

Figure 2 PASI 90 response rates through Week 48 (NRI)

A) PASI 90 response by number of prior biologics



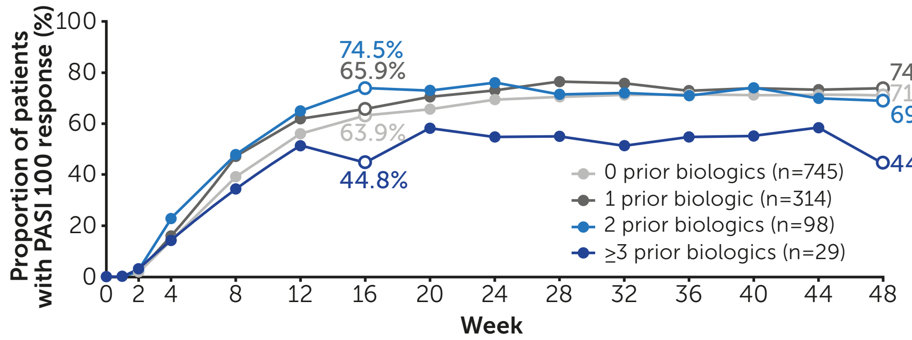
B) PASI 90 response by type of prior biologic



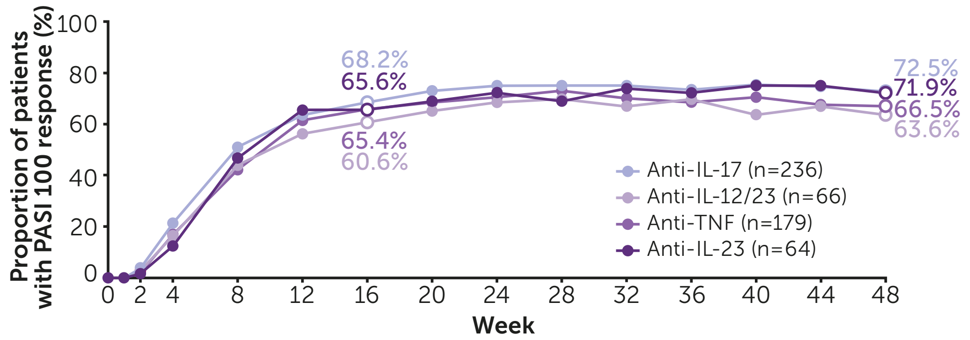
Week 48 was the last common timepoint across the included studies; BE SURE and BE READY ran for 56 weeks, BE VIVID ran for 52 weeks, and BE RADIANT ran for 48 weeks; to pool data across all four studies, data from Weeks 52–56 were not included.

Figure 3 PASI 100 response rates through Week 48 (NRI)

A) PASI 100 response by number of prior biologics



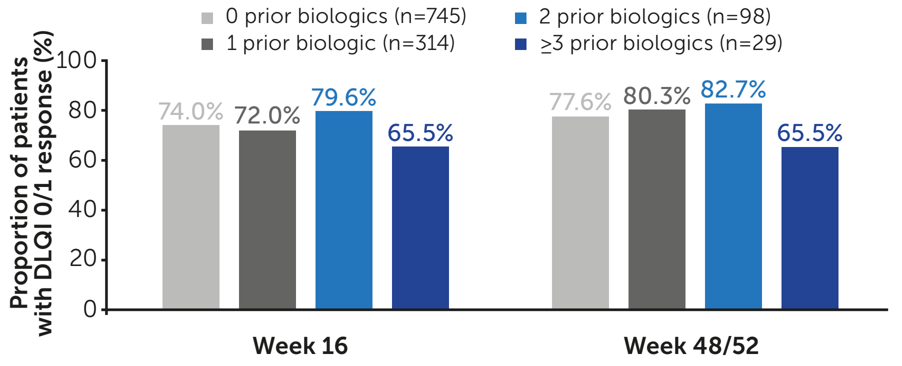
B) PASI 100 response by type of prior biologic



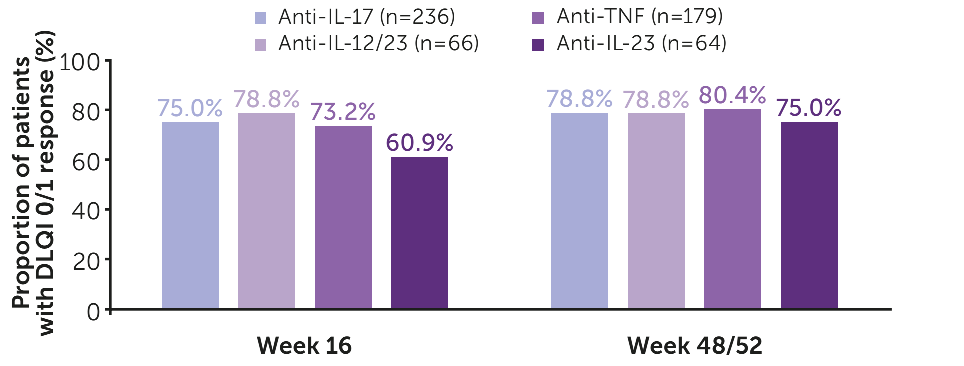
Week 48 was the last common timepoint across the included studies; BE SURE and BE READY ran for 56 weeks, BE VIVID ran for 52 weeks, and BE RADIANT ran for 48 weeks; to pool data across all four studies, data from Weeks 52–56 were not included.

Figure 4 DLQI 0/1 response rates at Week 16 and Week 48/52 (NRI)

A) DLQI 0/1 response by number of prior biologics



B) DLQI 0/1 response by type of prior biologic



Due to differences in scheduling of DLQI assessments in the trials, common visits at Week 16 (all trials), and Week 48 (BE SURE, BE READY, and BE RADIANT) and Week 52 (BE VIVID) are shown.

Table 1 Baseline characteristics

	Biologic-naïve (N=745)	Biologic-experienced (N=441)
Age (years), mean ± SD	43.7 ± 13.7	47.9 ± 13.6
Male, n (%)	514 (69.0)	312 (70.7)
Caucasian, n (%)	634 (85.1)	400 (90.7)
Weight (kg), mean ± SD	89.6 ± 22.0	89.2 ± 21.8
Duration of psoriasis (years), mean ± SD	15.7 ± 11.8	22.5 ± 12.8
PASI, mean ± SD	20.5 ± 7.5	21.4 ± 7.6
BSA (%), mean ± SD	25.8 ± 15.3	27.3 ± 16.3
IGA,[a] n (%)		
3: moderate	502 (67.4)	276 (62.6)
4: severe	241 (32.3)	164 (37.2)
DLQI, mean ± SD	10.1 ± 6.1	11.3 ± 6.9

Data are reported for those patients who had not previously received biologic treatment (biologic-naïve) and those who had previously received ≥1 biologic treatment (biologic-experienced) prior to enrolling in the trials. [a]n=2 biologic-naïve and n=1 biologic-experienced patients had baseline IGA of 2 (mild).

Conclusion

High levels of skin clearance and HRQoL benefit were observed with BKZ in biologic-naïve patients, and in those who had received 1 or 2 prior biologics.

Those who had received ≥3 prior biologics experienced lower responses, however, these data should be interpreted with caution due to the small number of patients in this subgroup.

In biologic-experienced patients, responses were generally consistent regardless of type of prior biologic used.

BKZ: bimekizumab; **BSA:** body surface area; **DLQI:** Dermatology Life Quality Index; **HRQoL:** health-related quality of life; **IGA:** Investigator's Global Assessment; **IL:** interleukin; **NRI:** non-responder imputation; **PASI 90/100:** ≥90%/100% improvement from baseline in the Psoriasis Area and Severity Index; **Q4W:** every 4 weeks; **Q8W:** every 8 weeks; **SD:** standard deviation; **TNF:** tumor necrosis factor.

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References: [1]Wade R et al. Systematic Reviews 2020; 9:132; [2]Warren RB et al. N Engl J Med 2021;385:130–141, NCT03412747; [3]Reich K et al. Lancet 2021;397:487–498, NCT03370133; [4]Gordon KB et al. Lancet 2021;397:475–486, NCT03410992; [5]Reich K et al. N Engl J Med 2021;385:142–152, NCT03536884.

Author contributions: Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: **ML**, **AA**, **JFM**, **ABG**, **LD**, **BG**, **SW**, **NC**, **BS**; Drafting of the publication, or revising it critically for important intellectual content: **ML**, **AA**, **JFM**, **ABG**, **LD**, **BG**, **SW**, **NC**, **BS**; Final approval of the publication: **ML**, **AA**, **JFM**, **ABG**, **LD**, **BG**, **SW**, **NC**, **BS**. **Disclosures: ML**: Employee of Mount Sinai and receives research funds from AbbVie, Amgen, Arcutis, Avotres, Boehringer Ingelheim, Dermavant, Eli Lilly, Incyte, Janssen Research & Development, LLC, Ortho Dermatologics, Regeneron, and UCB Pharma; consultant for Aditum Bio, Almirall, AltruBio Inc., AnaptysBio, Arcutis, Aristea Therapeutics, Arrive Technologies, Avotres Therapeutics, BiomX, Boehringer Ingelheim, Bristol Myers Squibb, Cara Therapeutics, Castle Biosciences, Corrona, Dermavant, Dr. Reddy's Laboratories, Evelo Biosciences, Evommune, Inc., Facilitatation of International Dermatology Education, Forte Biosciences, Foundation for Research and Education in Dermatology, Helsinn Therapeutics, Hexima Ltd., LEO Pharma, Meiji Seika Pharma, Mindera, Pfizer, Seanergy, and Verrica. **AA**: Research investigator and/or scientific advisor to AbbVie, Almirall, Arcutis, ASLAN, Boehringer Ingelheim, Bristol Myers Squibb, Dermavant, Dermira, Eli Lilly, EPI, Incyte, Janssen, LEO Pharma, Nimbus, Novartis, Ortho Dermatologics, Pfizer, Regeneron, Sun Pharma, Sanofi, and UCB Pharma. **JFM**: Consultant and/or investigator for AbbVie, Amgen, Biogen, Bristol Myers Squibb, Dermavant, Eli Lilly, Janssen, LEO Pharma, Pfizer, Novartis, Regeneron, Sanofi, Sun Pharma, and UCB Pharma. **ABG**: Honoraria as an advisory board member, non-promotional speaker, or consultant for Amgen, AnaptysBio, Avotres Therapeutics, Boehringer Ingelheim, Bristol Myers Squibb, Dermavant, Eli Lilly, Janssen, Novartis, Pfizer, Sanofi, Sun Pharma, UCB Pharma, and XBiotech (stock options for an RA project); research/educational grants from AnaptysBio, Bristol Myers Squibb, Janssen, Novartis, Ortho Dermatologics, Sun Pharma, and UCB Pharma; all funds go to the Icahn School of Medicine at Mount Sinai. **LD**, **BG**, **SW**, **NC**: Employees and shareholders of UCB Pharma. **BS**: Consultant (honoraria) for AbbVie, Almirall, Amgen, Arcutis, Arena, Aristea, Asana, Boehringer Ingelheim, Bristol Myers Squibb, Connect Biopharma, Dermavant, Eli Lilly, EPI Health, Evelo Biosciences, Immunic Therapeutics, Janssen, LEO Pharma, Maruho, Meiji Seika Pharma, Mindera Health, Novartis, Ono, Pfizer, Regeneron, Sanofi Genzyme, Sun Pharma, UCB Pharma, Union Therapeutics, Ventyxbio, and vTv Therapeutics; stock options for Connect Biopharma and Mindera Health; speaker for AbbVie, Eli Lilly, Janssen, Regeneron, and Sanofi Genzyme; Scientific Co-Director (consulting fee) for CorEvitas (formerly Corrona) Psoriasis Registry; investigator for AbbVie, Cara, CorEvitas Psoriasis Registry, Dermavant, Dermira, and Novartis; Editor-in-Chief (honorarium) for the Journal of Psoriasis and Psoriatic Arthritis.
Acknowledgements: These studies were funded by UCB Pharma. We thank the patients and their caregivers in addition to the investigators and their teams who contributed to these studies. The authors acknowledge Yasha Najafi, MSc, Costello Medical, London, UK, for medical writing and editorial assistance and the Design team, Costello Medical, UK for graphic design assistance. All costs associated with development of this poster were funded by UCB Pharma.

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