Maintenance of bimekizumab efficacy through 2 years in patients with moderate to severe plaque psoriasis: Pooled results from five phase 3/3b trials

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Objectives

To evaluate the long-term maintenance of Psoriasis Area and Severity Index (PASI) ≤2 and PASI=0 responses with bimekizumab (BKZ), using the largest available two-year data pool, in patients with moderate to severe plaque psoriasis.

Introduction

- Long-term treatment efficacy is an important consideration in chronic diseases such as psoriasis.
- BKZ has demonstrated high levels of skin clearance for the treatment of moderate to severe plaque psoriasis in phase 3/3b clinical trials.[1–4]

Methods

- Data were pooled from the BE SURE, BE VIVID and BE READY phase 3 trials, the BE BRIGHT open-label extension (OLE), and BE RADIANT (48-week double-blinded phase 3b trial and ongoing OLE).[1–5]
- Patients included in these analyses were randomized at baseline to BKZ 320 mg every four weeks (Q4W) to Week 16, followed by BKZ Q4W or every eight weeks (Q8W) maintenance dosing for the remainder of the double-blinded period of the trials (**Figure 1**).
- Upon OLE entry, patients received BKZ 320 mg Q4W or Q8W based on PASI (Psoriasis Area and Severity Index) response at the end of the feeder studies (**Figure 1**).
- We report the proportion of patients achieving PASI ≤2 and PASI=0 through two years of treatment (OLE Week 48) among BKZ-randomized Week 16 PASI ≤2 and PASI=0 responders, who remained on the same BKZ maintenance dose upon entering the relevant OLE (Q4W/Q8W/Q8W or Q4W/Q4W/Q4W).
- Missing data were imputed using non-responder imputation (NRI), modified NRI (mNRI), and observed case (OC).
  - For mNRI, patients who discontinued treatment due to lack of efficacy were considered non-responders; multiple imputation was used for all other missing data.

Results

- Baseline characteristics of Week 16 PASI ≤2 and PASI=0 responders who entered BE BRIGHT or the BE RADIANT OLE are reported in **Table 1**.
- At Week 16, 87.1% of the 1,362 patients randomized to BKZ 320 mg Q4W at baseline of the feeder studies achieved PASI ≤2 (NRI; **Figure 2A**) and 62.4% achieved PASI=0 (NRI; **Figure 2B**).
- Among Week 16 PASI ≤2 responders who entered the OLEs, 96.3% of the 349 patients on Q4W/Q8W/Q8W and 95.1% of the 449 patients on Q4W/Q4W/Q4W maintained PASI ≤2 through two years (OLE Week 48) (mNRI; **Figure 2A**).
- Of the Week 16 PASI=0 responders who entered the OLEs, 83.8% of the 267 patients on Q4W/Q8W/Q8W and 85.1% of the 316 patients on Q4W/Q4W/Q4W maintained PASI=0 through two years (OLE Week 48) (mNRI; **Figure 2B**).

Summary

The vast majority of BKZ-randomized patients with complete/near-complete skin clearance at Week 16 maintained their response through two years

Maintenance of **PASI ≤2** response in Week 16 responders after two years (OLE Week 48; mNRI)

Q4W/Q8W/Q8W (N=349): 96.3%

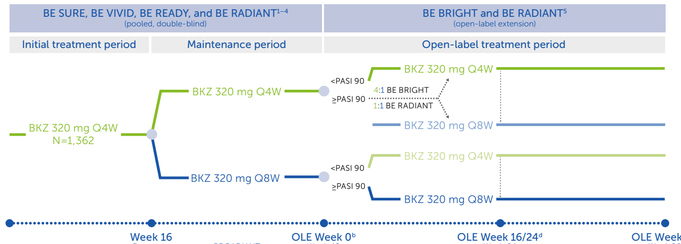
Q4W/Q4W/Q4W (N=449): 95.1%

Maintenance of **PASI=0** response in Week 16 responders after two years (OLE Week 48; mNRI)

Q4W/Q8W/Q8W (N=267): 83.8%

Q4W/Q4W/Q4W (N=316): 85.1%

Figure 1 Study design: Included patients



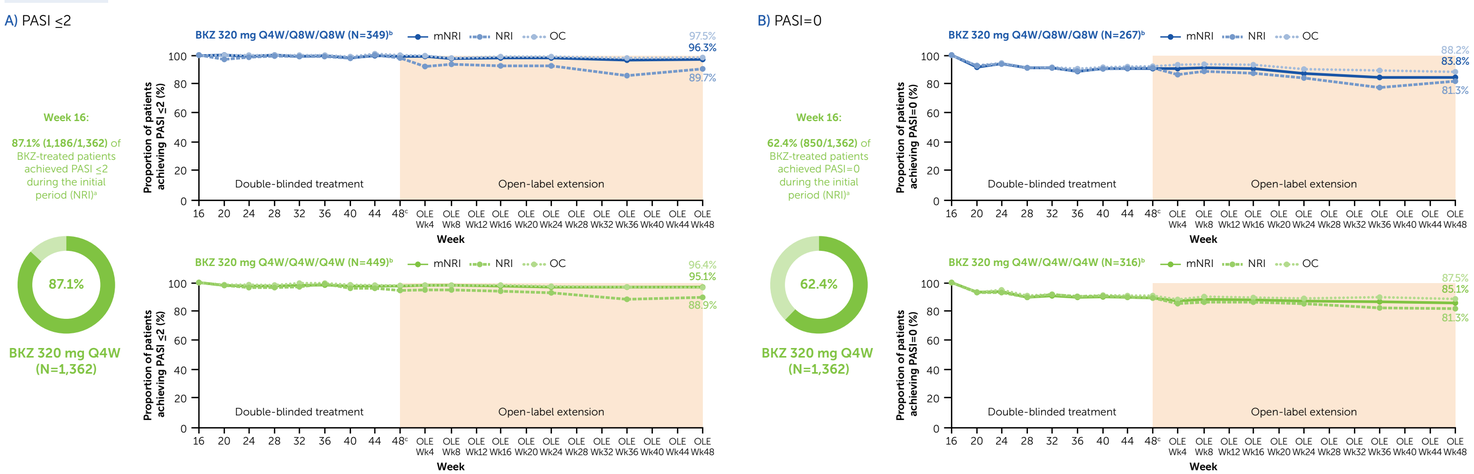
[a]Week numbers are based on feeder study baseline; [b]Patients who achieved ≥PASI 90 at Week 48 were randomized 4:1 in BE BRIGHT and 1:1 in BE RADIANT to receive BKZ 320 mg Q4W or BKZ 320 mg Q8W; [c]BE VIVID Week 52, and BE SURE and BE READY Weeks 52 and 56 were not included in the pooled analysis; [d]Dose switch: in BE BRIGHT, at OLE Week 24, patients who achieved ≥PASI 90 switched to Q8W dosing at the investigator's discretion; in BE RADIANT, at OLE Week 16 or the next scheduled visit, dose switches were added via a protocol amendment.

Table 1 Baseline characteristics: BKZ-randomized Week 16 responders

	PASI ≤2 responders (N=994)	PASI=0 responders (N=719)
Age (years), mean ± SD	45.0 ± 13.5	45.1 ± 13.3
Male, n (%)	689 (69.3)	497 (69.1)
Caucasian, n (%)	871 (87.6)	642 (89.3)
Weight (kg), mean ± SD	88.9 ± 20.7	87.9 ± 19.6
Duration of psoriasis (years), mean ± SD	18.2 ± 12.6	18.2 ± 12.6
PASI, mean ± SD	20.8 ± 7.5	20.8 ± 7.3
BSA (%), mean ± SD	26.3 ± 15.5	25.8 ± 15.0
IGA, n (%)		
3: moderate	661 (66.5)	476 (66.2)
4: severe	330 (33.2)	242 (33.7)
DLQI, mean ± SD	10.7 ± 6.4	10.9 ± 6.5
Any prior systemic therapy, n (%)	768 (77.3)	568 (79.0)
Prior biologic therapy, n (%)[a]	382 (38.4)	282 (39.2)

All BKZ-treated patients received BKZ 320 mg Q4W through Week 16. Data are reported for all patients with a response at Week 16 who enrolled in BE BRIGHT or the BE RADIANT OLE, regardless of dosing regimen. [a]Patients with multiple prior biologic use included in n (%).

Figure 2 Maintenance of PASI response through two years in BKZ-randomized Week 16 responders (pooled; mNRI, NRI, OC)



[a]Response at Week 16 in patients randomized to BKZ 320 mg Q4W at baseline (NRI); [b]Data reported for patients with a response at Week 16 who received continuous maintenance dosing regimens; [c]The BE SURE and BE READY feeder studies ran for 56 weeks, BE VIVID ran for 52 weeks, and BE RADIANT ran for 48 weeks; to pool data across all four studies, feeder study data from Weeks 52–56 were not included.

BKZ: bimekizumab; **BSA:** body surface area; **DLQI:** Dermatology Life Quality Index; **IGA:** Investigator's Global Assessment; **mNRI:** modified non responder imputation; **NRI:** non-responder imputation; **OC:** observed case; **OLE:** open-label extension; **PASI:** Psoriasis Area and Severity Index; **PASI 90:** ≥90% improvement from baseline in PASI; **Q4W:** every four weeks; **Q8W:** every eight weeks; **SD:** standard deviation; **Wk:** week.

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References: [1]Warren RB *et al.* N Engl J Med 2021;385:130–141. NCT03412747; [2]Reich K *et al.* Lancet 2021;397:487–498. NCT03370133; [3]Gordon KB *et al.* Lancet 2021;397:475–486. NCT03410992; [4]Reich K *et al.* N Engl J Med 2021;385:142–152. NCT03536884; [5]BE BRIGHT: NCT03598790. **Author Contributions:** Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: **DT, AA, ML, AB, CP, LP, MW, VV, CM, SW, DD, KBG**; Drafting of the publication, or revising it critically for important intellectual content: **DT, AA, ML, AB, CP, LP, MW, VV, CM, SW, DD, KBG**; Final approval of the publication: **DT, AA, ML, AB, CP, LP, MW, VV, CM, SW, DD, KBG**. **Author Disclosures: DT:** Honoraria for participation on advisory boards, as a speaker, and for consultancy from AbbVie, Almirall, Amgen, Biogen, Boehringer Ingelheim, BMS, Celltrion, Eli Lilly, Galapagos, Janssen, LEO Pharma, Novartis, Pfizer, Regeneron, Samsung, Sanofi Genzyme, and UCB Pharma; research grants received from LEO Pharma and Novartis. **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, EPI, Incyte, Janssen, LEO Pharma, Nimbus, Novartis, Ortho Dermatologics, Pfizer, Regeneron, Sun Pharma, Sanofi, and UCB Pharma. **ML:** Employee of Mount Sinai and receives research funds from AbbVie, Amgen, Arcutis, Avotres, Boehringer Ingelheim, Dermavant, Eli Lilly, Incyte, Janssen, Ortho Dermatologics, Regeneron, and UCB Pharma; consultant for Aditum Bio, Almirall, AltruBio, AnaptysBio, Arcutis, Aristea Therapeutics, Arrive Technologies, Avotres Therapeutics, BiomX, Boehringer Ingelheim, Bristol Myers Squibb, Cara Therapeutics, Castle Biosciences, Corrona, Dermavant Sciences, Dr. Reddy's Laboratories, Evelo Biosciences, Evommune, Facilitation of International Dermatology Education, Forte Biosciences, Foundation for Research and Education in Dermatology, Helsinn Therapeutics, Hexima, LEO Pharma, Meiji Seika Pharma, Mindera, Pfizer, Seanergy, and Verrica. **AB:** Has served as a speaker (received honoraria) for AbbVie, Arcutis, Bristol Myers Squibb, Eli Lilly, Pfizer, Regeneron, Sanofi, and UCB Pharma, served as a scientific adviser (received honoraria) for AbbVie, Abcentra, Affibody, Aligos, Almirall, Alumis, Amgen, Anaptysbio, Arcutis, Arena, Aslan, Athenex, Bluefin Biomedicine, Boehringer Ingelheim, Bristol Myers Squibb, Cara Therapeutics, Dermavant, EcoR1, Eli Lilly, Escient, Evelo, Evommune, Forte, Galderma, HighlightIl Pharma, Incyte, InnoventBio, Janssen, Landos, LEO Pharma, Merck, Novartis, Pfizer, Rapt, Regeneron, Sanofi Genzyme, Spherix Global Insights, Sun Pharma, TLL Pharmaceutical, TrialSpark, UCB Pharma, Vibliome, and Xencor, and has acted as a clinical study investigator (institution has received clinical study funds) for AbbVie, Acelyrin, Almirall, Amgen, Arcutis, Athenex, Boehringer Ingelheim, Bristol Myers Squibb, Concert, Dermavant, Eli Lilly , Evelo, Evommune, Galderma, Incyte, Janssen, Leo, Merck, Novartis, Pfizer, Regeneron, Sun Pharma, and UCB Pharma. **CP:** Consulting fees and/or grants from AbbVie, Almirall, Amgen, Boehringer Ingelheim, Celgene, GSK, Janssen Cilag, LEO Pharma, Eli Lilly, Novartis, Pierre Fabre, Pfizer, Sanofi Regeneron, and UCB Pharma. **LP:** Received consultancy/speaker's honoraria from and/or participated in trials sponsored by AbbVie, Almirall, Amgen, Baxalta, Biogen, Boehringer Ingelheim, Celgene, Eli Lilly, Gebro, Janssen, JS BIOCAD, LEO Pharma, Merck-Serono, MSD, Mylan, Novartis, Pfizer, Regeneron, Roche, Samsung-Bioepis, Sandoz, Sanofi Genzyme, and UCB Pharma. **MW, VV, CM, SW, DD:** Employees and shareholders of UCB Pharma. **KBG:** Has received consulting fees from AbbVie, Almirall, Amgen, Boehringer Ingelheim, BMS, Celgene, Dermira, Eli Lilly, Janssen, Novartis, Pfizer, Sun Pharma, and UCB Pharma; research support from AbbVie, BMS, Celgene, Eli Lilly, Janssen, Novartis, and UCB Pharma. **Acknowledgments:** This study was funded by UCB Pharma. We thank the patients and their caregivers in addition to the investigators and their teams who contributed to this study. The authors acknowledge Natalie Nunez Gomez, MD, UCB Pharma, Monheim, Germany, for critical review, Yasha Najafi, MSc, Costello Medical, London, UK, for medical writing and editorial assistance, and the Costello Medical design team, UK for graphic design assistance. All costs associated with development of this poster were funded by UCB Pharma.

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Conclusions

A high proportion of patients who achieved complete or near-complete skin clearance at Week 16 maintained their response through two years, regardless of BKZ maintenance dosing regimen (Q4W/Q8W/Q8W or Q4W/Q4W/Q4W).