

Bimekizumab Safety in Patients with Psoriasis Achieving Complete Skin Clearance: 4-year Analysis from 5 Phase 3/3b Trials

Diamant Thaçi,¹ Kenneth B. Gordon,² Richard G. Langley,³ Andrew Blauvelt,⁴ Mari Higashiyama,⁵ Denis Jullien,⁶ Katy White,⁷ Susanne Wiegatz,⁸ Delphine Deherder,⁹ Nancy Cross,¹⁰ Mark Lebwohl¹¹

¹Institute and Comprehensive Center for Inflammation Medicine, University of Lübeck, Lübeck, Germany; ²Department of Dermatology, Medical College of Wisconsin, Milwaukee, Wisconsin, USA; ³Division of Clinical Dermatology & Cutaneous Science, Department of Medicine, Dalhousie University, Halifax, Nova Scotia, Canada; ⁴Blauvelt Consulting LLC, Annapolis, Maryland, USA; ⁵Nippon Life Hospital, Department of Dermatology, Osaka, Japan; ⁶Department of Dermatology, Hôpital Edouard Herriot, Hospices Civils de Lyon, University of Lyon, Lyon, France; ⁷UCB, Slough, UK; ⁸UCB, Monheim am Rhein, Germany; ⁹UCB, Braine-l'Alleud, Belgium; ¹⁰UCB, Morrisville, North Carolina, USA; ¹¹Department of Dermatology, Icahn School of Medicine at Mount Sinai, New York, New York, USA.

Objective

To evaluate the safety of bimekizumab (BKZ) up to 4 years in patients with psoriasis achieving complete skin clearance at Week 16 (end of initial treatment periods) and Week 48 (last common timepoint in double-blinded periods) in phase 3/3b trials.

Synopsis

- BKZ is an IgG1 monoclonal antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A.¹
- BKZ has demonstrated a favorable safety profile and was well tolerated over 4 years in patients with moderate to severe plaque psoriasis.²
- In phase 3 trials, 59–68% of BKZ-treated patients achieved 100% improvement from baseline in Psoriasis Area and Severity Index (PASI 100; complete skin clearance) at Week 16,^{3–6} and 65–72% did so at Year 1 (Week 48/52/56).^{3,4,6}
- Here, we investigate whether patients achieving complete skin clearance at the end of the initial treatment and double-blinded periods experienced safety events in line with the overall BKZ-randomized population up to 4 years.

Methods

- Data were pooled from the BE SURE, BE VIVID, and BE READY phase 3 trials, their open-label extension (OLE) BE BRIGHT, and the BE RADIANT phase 3b trial (including its OLE).^{2–7}
- Included patients were randomized to BKZ 320 mg every 4 weeks (Q4W) and received BKZ Q4W or Q8W thereafter.
 - All patients received BKZ Q8W from Week 64 in BE RADIANT or Week 100/104 in BE BRIGHT, or the next scheduled clinic visit.
 - Patients who switched to placebo at Week 16 of BE READY were excluded.
- Treatment-emergent adverse events (TEAEs) are reported up to 4 years (Week 196/200) using exposure-adjusted incidence rates (EAIRs) per 100 patient-years (PY) in those:
 - Achieving PASI 100 at Week 16 (observed case [OC]);
 - Achieving PASI 100 at Week 48 (last common timepoint in double-blinded periods; OC);
 - Randomized to BKZ in phase 3/3b studies, regardless of PASI 100 response.

Results

- Of those initially randomized to BKZ in phase 3/3b studies (N=1,255), 775 (61.8%) achieved PASI 100 at Week 16 and 849 (67.6%) achieved PASI 100 at Week 48.
- Up to 4 years, TEAE rates were 160.6/100 PY for Week 16 PASI 100 responders, 158.9/100 PY for Week 48 PASI 100 responders, and 181.4/100 PY for the overall BKZ-randomized population.
 - The rates of serious and severe TEAEs, discontinuations due to TEAEs, and TEAEs leading to death are shown in **Figure 1**.
- In line with the overall BKZ-randomized population, the three most common TEAEs up to 4 years were:
 - Nasopharyngitis (Week 16 responders: 12.1/100 PY; Week 48 responders: 12.8/100 PY; overall BKZ: 13.2/100 PY);
 - Oral candidiasis (Week 16 responders: 8.1/100 PY; Week 48 responders: 8.1/100 PY; overall BKZ: 8.5/100 PY);
 - Upper respiratory tract infection (Week 16 responders: 6.0/100 PY; Week 48 responders: 6.1/100 PY; overall BKZ: 6.5/100 PY).
- The vast majority of oral candidiasis events were mild or moderate, and rates were similar between groups (Week 16 responders: 98.4%; Week 48 responders: 98.8%; overall BKZ: 98.9%).
- Overall, oral candidiasis events led to discontinuation of four patients: one of these was a Week 16 PASI 100 responder and one was a Week 16 and Week 48 PASI 100 responder.
- Rates of other TEAEs of interest are shown in **Figure 2** and were generally similar between groups.

Conclusions

Bimekizumab was well tolerated through 4 years in patients who achieved complete skin clearance at Week 16 and Week 48; the safety profile in these PASI 100 responders was consistent with the overall BKZ-randomized population in moderate to severe plaque psoriasis.

Summary

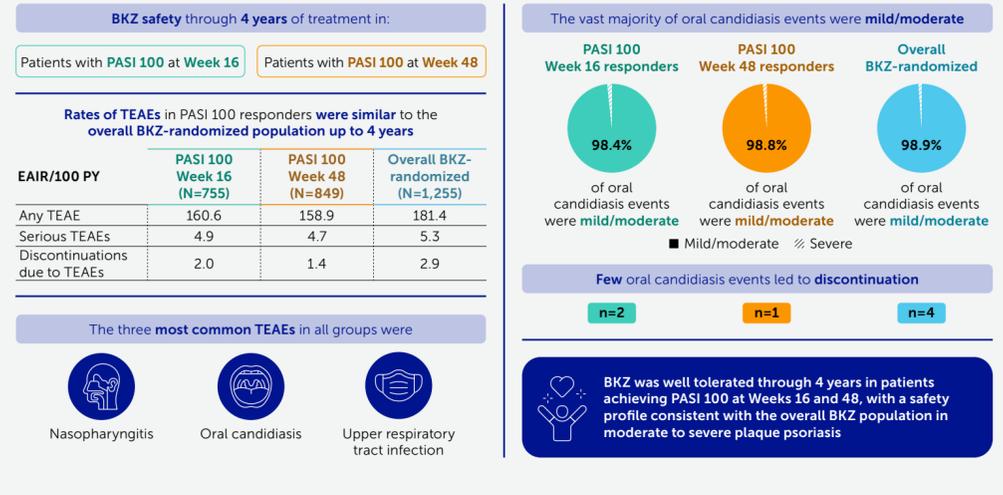
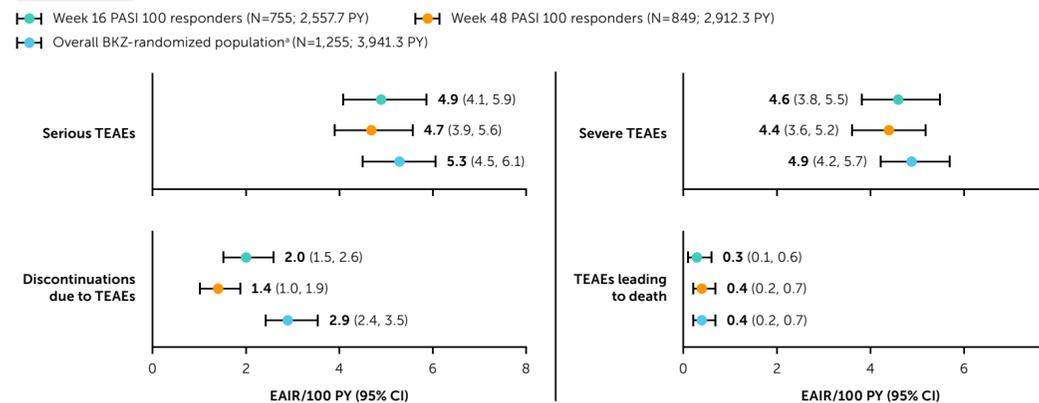


Figure 1 Summary of TEAEs up to 4 years

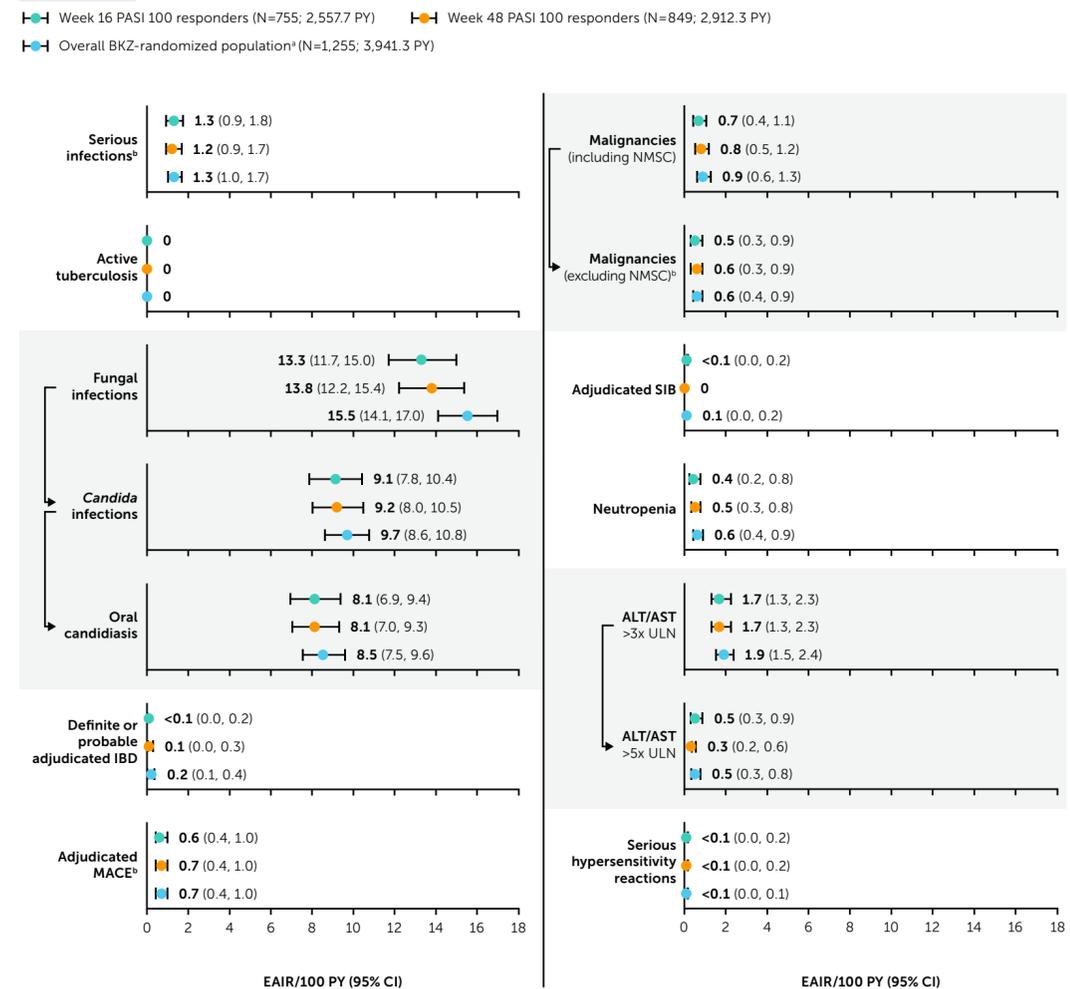


Patients who switched to placebo at Week 16 in BE READY were excluded. (a) All patients who were randomized to receive BKZ in the included phase 3/3b trials (excluding placebo switchers); discontinuations due to TEAEs may be subject to survivor bias due to the selection of responders.

ALT: alanine aminotransferase; **AST:** aspartate aminotransferase; **BKZ:** bimekizumab; **CI:** confidence interval; **EAIR:** exposure-adjusted incidence rate; **IBD:** inflammatory bowel disease; **IL:** interleukin; **MACE:** major adverse cardiac event; **NMSC:** non-melanoma skin cancer; **OLE:** open-label extension; **PASI 100:** 100% improvement from baseline in Psoriasis Area and Severity Index; **PSOLAR:** Psoriasis Longitudinal Assessment and Registry; **PY:** patient-years; **Q4W:** every 4 weeks; **Q8W:** every 8 weeks; **SIB:** suicidal ideation and behavior; **TEAE:** treatment-emergent adverse event; **ULN:** upper limit of normal.

References: ¹Adams R et al. Front Immunol 2020;11:1894. ²Blauvelt A et al. J Am Acad Dermatol 2025;93:644–53 (NCT03598790). ³Warren RB et al. N Engl J Med 2021;385:130–41 (NCT03412747). ⁴Reich K et al. Lancet 2021;397:487–98 (NCT03370133). ⁵Gordon KB et al. Lancet 2021;397:475–86 (NCT03410992). ⁶Reich K, N Engl J Med 2021;385:142–52 (NCT03536884). ⁷Warren RB et al. Br J Dermatol 2025;193:44–55. ⁸Papp KA et al. J Drugs Dermatol 2015;14:706–14. ⁹Papp KA et al. J Drugs Dermatol 2020;19:571–2. **Author Contributions:** Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: **DT, KBG, RGL, AB, MH, DJ, KW, SW, DD, NC, ML.** Drafting of the publication, or reviewing it critically for important intellectual content: **DT, KBG, RGL, AB, MH, DJ, KW, SW, DD, NC, ML.** Final approval of the publication: **DT, KBG, RGL, AB, MH, DJ, KW, SW, DD, NC, ML.** **Author Disclosures:** DT: Investigator and/or consultant/advisor for AbbVie, Almirall, Amgen, Boehringer Ingelheim, Bristol Myers Squibb, Celtrion, Eli Lilly, Galderma, Johnson & Johnson, Kyowa Kirin, LEO Pharma, L'Oréal, New Bridge, Novartis, Pfizer, Regeneron, Sanofi, Takeda, Target-RWE, UCB, and Vichy; received consulting fees from AbbVie, Almirall, Amgen, Boehringer Ingelheim, Bristol Myers Squibb, Celtrion, Dermira, Eli Lilly, Janssen, Novartis, Pfizer, Sun Pharma, and UCB; research support from AbbVie, Bristol Myers Squibb, Celtrion, Eli Lilly, Janssen, Novartis, and UCB. **RGL:** Principal investigator for AbbVie, Amgen, Boehringer Ingelheim, Celtrion, Eli Lilly, LEO Pharma, Merck, Novartis, Pfizer, and UCB; served on scientific advisory boards for AbbVie, Amgen, Boehringer Ingelheim, Celtrion, Eli Lilly, LEO Pharma, Merck, Novartis, Pfizer, and UCB; provided lectures for AbbVie, Amgen, Celtrion, Eli Lilly, LEO Pharma, Merck, Novartis, and Pfizer. **AB:** Served as a speaker (received honoraria) for Almirall, Eli Lilly and Company, Sanofi, and UCB; served as a scientific adviser (received honoraria) for AbbVie, Almirall, Amgen, AnaptysBio, Apogee, Arcutis, Astra, Boehringer Ingelheim, Bristol Myers Squibb, Celtrion, Corvus, Dermavant, Eli Lilly, Galderma, GlaxoSmithKline, Immunovant, Incyte, IQVIA, Janssen, LEO Pharma, Lipidio, Merck, Novartis, Oruka, Paragon, Pfizer, Rani Therapeutics, Regeneron, Sanofi, Spherix Global Insights, Sun Pharma, Syncona, Takeda, UCB, Union, and Zal Lab; acted as a clinical study investigator (institution has received clinical study funds) for AbbVie, Acelyrin, Almirall, Amgen, Arcutis, Boehringer Ingelheim, Bristol Myers Squibb, Dermavant, Eli Lilly, Galderma, Johnson & Johnson, LEO Pharma, Merck, Novartis, Pfizer, Regeneron, Sanofi, Sun Pharma, Takeda, and UCB; owns stock in Lipidio and Oruka. **MH:** Principal investigator for Amgen, Bristol Myers Squibb, Janssen, Takeda, and UCB; acted as a clinical study investigator (institution has received clinical study funds) for AbbVie and Bristol Myers Squibb. **DJ:** Served as a board member and/or consultant for AbbVie, Almirall, Amgen, Biogen, Boehringer Ingelheim, Bristol Myers Squibb, Celtrion, Eli Lilly, Fresenius Kabi, Janssen-Cilag, LEO Pharma, MEDAC, MSD, Novartis, Pfizer, Sanofi, and UCB; received payment for development of educational presentations including service on speakers' bureaus from AbbVie, Celtrion, Eli Lilly, Janssen-Cilag, LEO Pharma, MEDAC, Novartis, and Pfizer; travel/accommodation expenses covered or reimbursed by AbbVie, Amgen, Biogen, Celtrion, Eli Lilly and Company, Fresenius Kabi, Janssen-Cilag, LEO Pharma, MEDAC, MSD, Novartis, Pfizer, Sanofi, and UCB. **KW, SW, DD, NC:** Employees and shareholders of UCB. **ML:** Employee of Mount Sinai and receives research funds from AbbVie, Amgen, Arcutis, Avotres, Boehringer Ingelheim, Cara Therapeutics, Clevio, Dermavant, Eli Lilly, Incyte, Inozyme, Johnson & Johnson, Pfizer, Sanofi-Regeneron, and UCB; consultant for Almirall, Alkerm, AltruBio, Amgen, Apogee, Arcutis, AstraZeneca, Atornwise, Avotres Therapeutics, Boehringer Ingelheim, Bristol Myers Squibb, Castle Biosciences, Celtrion, CorEViTas, Dermavant Sciences, Dermisquared, Evimmune Inc., Facilitation of International Dermatology Education, Forté Biosciences, Galderma, Genentech, Incyte, LEO Pharma, Mayne Pharmaceuticals, Meiji Seika Pharma, Mindera, Mirium Pharmaceuticals, Oruka, Pfizer, Sanofi-Regeneron, Revolo, Seanergy, Strata, Sun Pharma, Takeda, Trevi, and Verrica. **Acknowledgements:** These studies were funded by UCB. We thank the patients and their caregivers in addition to the investigators and their teams who contributed to these studies. The authors acknowledge Inés Dueñas Pousa, PhD, UCB, Madrid, Spain for publication coordination, Meg Smith, PhD, Costello Medical, Manchester, UK for medical writing and editorial assistance and the Costello Medical Creative team for design support. All costs associated with development of this poster were funded by UCB.

Figure 2 TEAEs of interest up to 4 years



Patients who switched to placebo at Week 16 in BE READY were excluded. (a) All patients who were randomized to receive BKZ in the included phase 3/3b trials (excluding placebo switchers); (b) Ranges of EAIRs reported with other biologics in the PSOLAR registry were: serious infections: 0.93–2.91/100 PY; adjudicated MACE: 0.51–0.64/100 PY; malignancies (excluding NMSC): 0.48–0.84/100 PY.¹³



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