Bimekizumab safety in patients with psoriasis achieving complete skin clearance: 4-year analysis from 5 phase 3/3b trials

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Diamant Thaçi,[1] Kenneth B. Gordon,[2] Richard G. Langley,[3] Andrew Blauvelt,[4] Mari Higashiyama,[5] Denis Jullien,[6] Katy White,[7] Susanne Wiegratz,[8] Delphine Deherder,[9] Nancy Cross,[10] Mark Lebwohl[11]

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

Objective

To evaluate the safety of bimekizumab 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.

Introduction

- Bimekizumab (BKZ) is an IgG1 monoclonal antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A.[1]
- BKZ has demonstrated a favourable 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-randomised 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 randomised 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);
  - Randomised to BKZ in phase 3/3b studies, regardless of PASI 100 response.

Results

- Of those initially randomised 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-randomised 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-randomised 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-randomised population in moderate to severe plaque psoriasis.

Summary

BKZ safety through **4 years** of treatment in:

Patients with **PASI 100** at **Week 16** | Patients with **PASI 100** at **Week 48**

Rates of TEAEs in PASI 100 responders **were similar** to the **overall BKZ-randomised population up to 4 years**

EAIR/100 PY	PASI 100 Week 16 (N=755)	PASI 100 Week 48 (N=849)	Overall BKZ-randomised (N=1,255)
Any TEAE	160.6	158.9	181.4
Serious TEAEs	4.9	4.7	5.3
Discontinuations due to TEAEs	2.0	1.4	2.9

The three **most common TEAEs** in all groups were

- Nasopharyngitis
- Oral candidiasis
- Upper respiratory tract infection

The vast majority of oral candidiasis events were **mild/moderate**

PASI 100 Week 16 responders	PASI 100 Week 48 responders	Overall BKZ-randomised
98.4%	98.8%	98.9%
of oral candidiasis events were **mild/moderate**	of oral candidiasis events were **mild/moderate**	of oral candidiasis events were **mild/moderate**

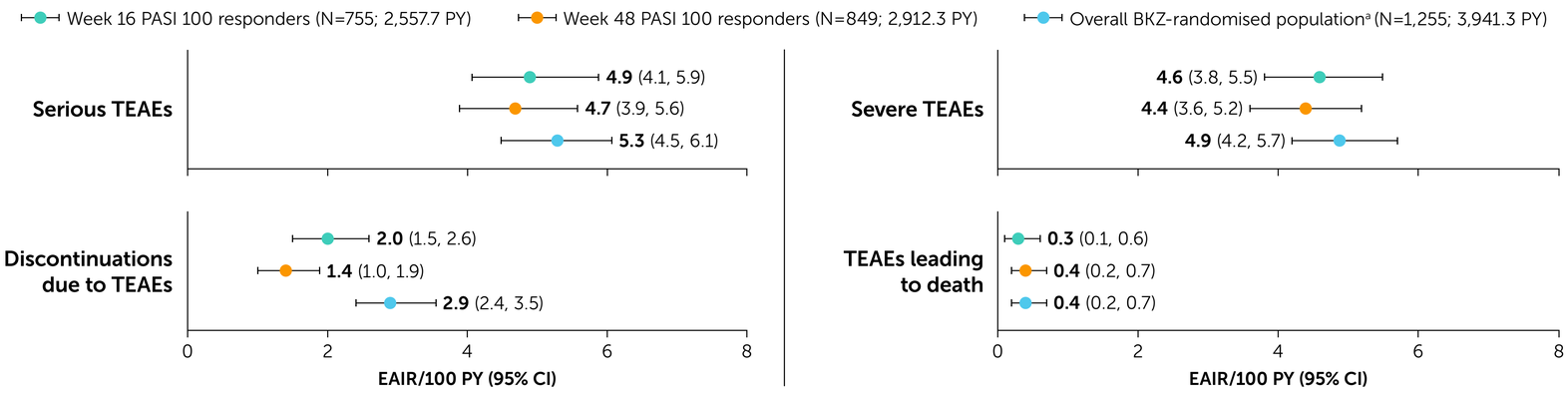
■ Mild/moderate ▨ Severe

Few oral candidiasis events led to **discontinuation**

n=2 | n=1 | n=4

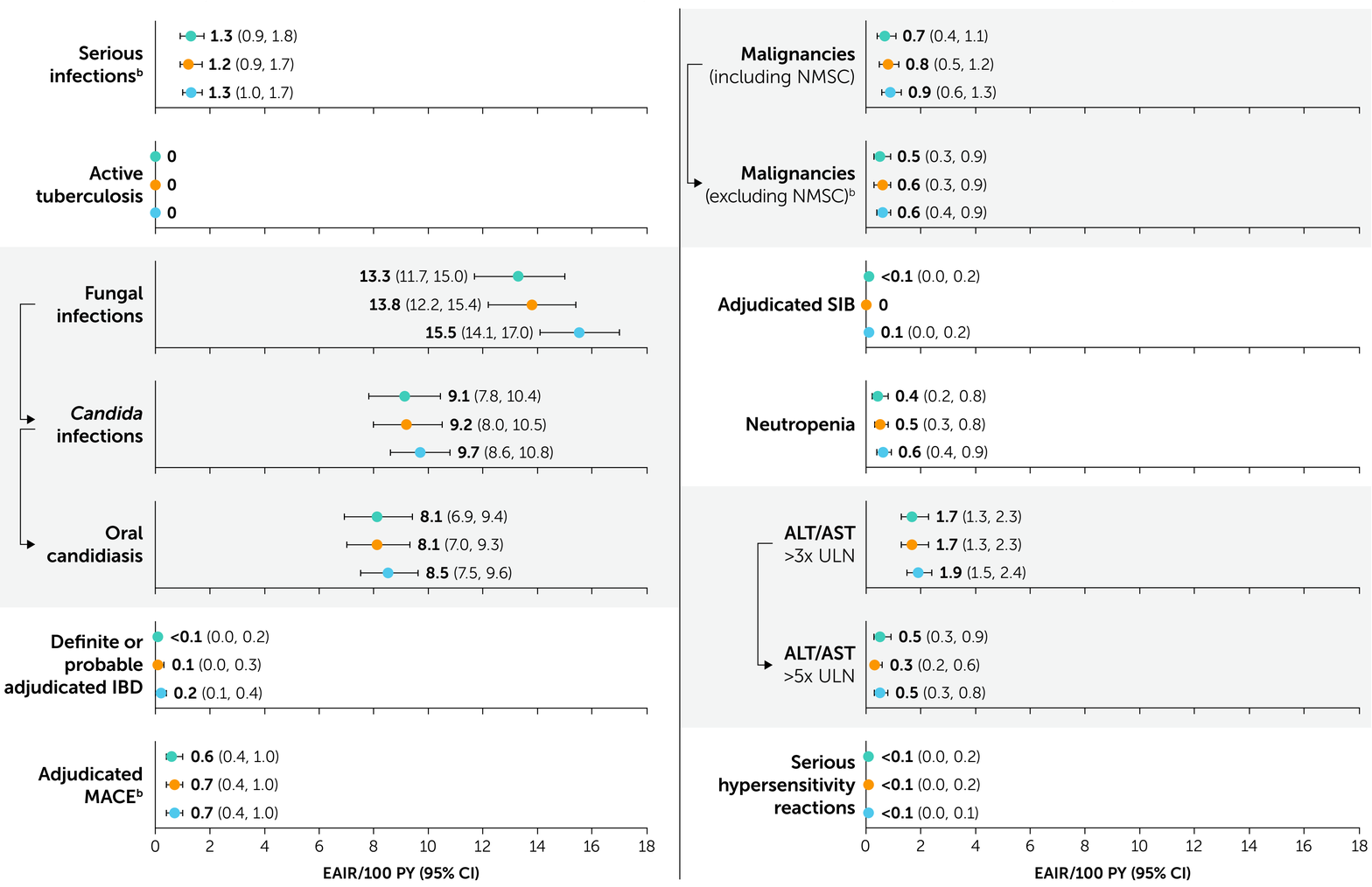
BKZ was well tolerated through 4 years in patients achieving PASI 100 at Weeks 16 and 48, with a safety profile consistent with the overall BKZ population in moderate to severe plaque psoriasis

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 randomised 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.

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 randomised 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.[8,9]

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 behaviour; **TEAE:** treatment-emergent adverse event; **ULN:** upper limit of normal.

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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, Celltrion, Eli Lilly, Galderma, Johnson & Johnson, Kyowa Kirin, LEO Pharma, L'Oréal, New Bridge, Novartis, Pfizer, Regeneron, Samsung, Sanofi, Takeda, Target-RWE, UCB, and Vichy; received grants from AbbVie, LEO Pharma, and Novartis. **KBG:** Received consulting fees from AbbVie, Almirall, Amgen, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Dermira, Eli Lilly, Janssen, Novartis, Pfizer, Sun Pharma, and UCB; research support from AbbVie, Bristol Myers Squibb, Celgene, Eli Lilly, Janssen, Novartis, and UCB. **RGL:** Principal investigator for AbbVie, Amgen, Boehringer Ingelheim, Celgene, Eli Lilly, LEO Pharma, Merck, Novartis, Pfizer, and UCB; served on scientific advisory boards for AbbVie, Amgen, Boehringer Ingelheim, Celgene, Eli Lilly, LEO Pharma, Merck, Novartis, Pfizer, and UCB; provided lectures for AbbVie, Amgen, Celgene, Eli Lilly, LEO Pharma, Merck, Novartis, and Pfizer. **AB:** Served as a speaker (received honoraria) for Almirall, Eli Lilly and Company, Sanofi, and UCB; has served as a scientific adviser (received honoraria) for AbbVie, Almirall, Alumis, Amgen, AnaptysBio, Apogee, Arcutis, Boehringer Ingelheim, Bristol Myers Squibb, Celltrion, 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 Zai Lab; has acted as a clinical study investigator (institution has received clinical study funds) for AbbVie, Acelyrin, Almirall, Alumis, Amgen, Arcutis, Boehringer Ingelheim, Bristol Myers Squibb, Dermavant, Eli Lilly, Galderma, Incyte, Janssen, LEO Pharma, Merck, Novartis, Pfizer, Regeneron, Sanofi, Sun Pharma, Takeda, and UCB; owns stock in Lipidio and Oruka. **MH:** Principal investigator for Alumis, 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, Celgene, 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, Celgene, Eli Lilly, Janssen-Cilag, LEO Pharma, MEDAC, Novartis, and Pfizer; travel/accommodation expenses covered or reimbursed by AbbVie, Amgen, Biogen, Celgene, 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, Clexio, Cara Therapeutics, Dermavant, Eli Lilly, Incyte, Inozyme, Johnson & Johnson, Ortho Dermatologics, Pfizer, Sanofi-Regeneron, and UCB; consultant for Almirall, Aikium, AltruBio, Amgen, AnaptysBio, Apogee, Arcutis, AstraZeneca, Atomwise, Avotres Therapeutics, Brickell Biotech, Boehringer Ingelheim, 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, Incyte, LEO Pharma, Meiji Seika Pharma, Mindera, Pfizer, Sanofi-Regeneron, Seanergy, Strata, Takeda, Trevi, and Verrica. **Acknowledgements:** These studies were funded by UCB. 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