Bimekizumab rates of oral candidiasis in patients with moderate to severe plaque psoriasis: Results from up to 4 years of five phase 3/3b studies

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Objective

To report long-term oral candidiasis rates in bimekizumab (BKZ)-treated patients with moderate to severe plaque psoriasis up to 4 years.

Synopsis

- Interleukin (IL)-17A/F pathways are involved in protection against fungal infections.[1]
- In patients with moderate to severe plaque psoriasis, the use of IL-17 inhibitors has been associated with increased risk of fungal infections, particularly Candida infections;[1] exploring recurrence rates and timing of infections may aid in understanding and improving patient outcomes.
- BKZ selectively inhibits both IL-17A and IL-17F;[2] it is important to understand how long-term BKZ treatment impacts oral candidiasis rates. Ensuring both dermatologists and patients are well informed can improve overall patient care and outcomes for oral candidiasis.[3] This could enable proactive monitoring and timely intervention.

Methods

- Final data were pooled from the 52-week BE VIVID, 56-week BE SURE and BE READY studies, their open-label extension (OLE), BE BRIGHT (4-year data) and BE RADIANT (3-year data; 48-week double-blinded period and 96-week OLE).[4–8]
  - Patients received BKZ 320 mg every 4 weeks (Q4W) to Week 16, then Q4W or every 8 weeks (Q8W) into the OLE (BKZ Total); all patients received BKZ Q8W from Week 64 (BE RADIANT)/OLE Week 48 (BE BRIGHT).[7,8]
  - Patients in BE VIVID, BE SURE, BE READY and BE RADIANT switched from ustekinumab (at Week 52), adalimumab (at Week 24), placebo (at Week 16) and secukinumab (at Week 48), respectively, to BKZ.
- Incidence rates per 100 patient-years (PY) of oral candidiasis treatment-emergent adverse events (TEAEs) are reported for all patients who received ≥1 BKZ dose (BKZ Total), as well as those who received BKZ Q4W/Q8W. Rates of recurrence of oral candidiasis (defined as ≥2 events) and the antifungal treatments used are also presented.
- The subgroup of patients who received BKZ Q4W to Week 16 then Q8W thereafter (BKZ Q4W/Q8W), the approved dosing regimen for most patients with psoriasis,[9] were also analyzed.

Results

- Up to 4 years (N=2,186), the incidence rate of Candida infections was 10.4/100 PY. Most cases were oral candidiasis (8.9/100 PY); 99.1% were mild/moderate, with no serious cases reported (**Table 1**).
- Out of 2,186 patients, eight discontinued treatment due to oral candidiasis. One of these was a severe case and six were recurrent cases. In the BKZ Q4W/Q8W subgroup, there were no discontinuations, with one severe case.
- Baseline characteristics were generally comparable between patients with no oral candidiasis and those with recurrent oral candidiasis (**Table 2**).
- Of patients who received BKZ, 78.8% had no oral candidiasis TEAEs up to 4 years. In patients with one or more oral candidiasis TEAE, most patients during the study period had one (10.3%) or two (5.4%) events; 2.1% had three, 1.7% had four and 1.8% had five or more (**Figure 1**).
- Among patients who had oral candidiasis TEAEs, 71.1% experienced their first occurrence within the first year of BKZ treatment, after which the cumulative rate of first occurrence increased at a slower rate (**Figure 2**).
- For all patients with oral candidiasis, most cases were treated with nystatin and/or fluconazole. The median duration of antifungal treatment was 13.0 (interquartile range: 19.0) days.
- Data were similar for the BKZ Q4W/Q8W subgroup of patients.

Conclusions

Up to 4 years, around 79% of bimekizumab-treated patients did not experience any oral candidiasis treatment-emergent adverse events. Among patients who did experience oral candidiasis, most had one or two events. Almost all (>99%) events were mild/moderate in severity, and very few led to study discontinuation.

Summary

Up to 4 years of bimekizumab treatment:

The incidence rate of oral candidiasis was **8.9/100 patient-years**, and **78.8%** of patients **did not have** oral candidiasis

Almost all (**99.1%**) oral candidiasis events were **mild/moderate**

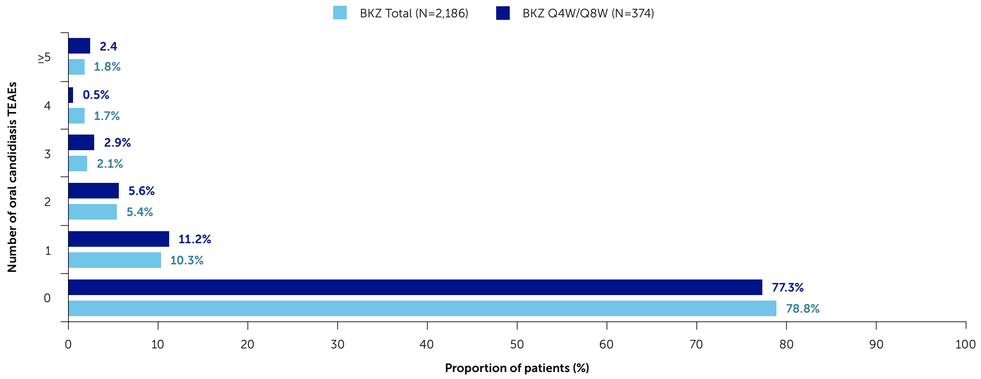
Most cases were treated with **nystatin** and/or **fluconazole**

8 out of 2,186 patients discontinued bimekizumab due to oral candidiasis

Table 1 Incidence of oral candidiasis TEAEs

Incidence rate per 100 PY, n (%)	BKZ Total (N=2,186)	BKZ Q4W/Q8W (N=374)
Any TEAE	8.9 464 (21.2)	8.3 85 (22.7)
Serious TEAEs	0	0
Discontinuation due to TEAEs	0.1 8 (0.4)	0
Severe TEAEs	0.1 9 (0.4)	0.1 1 (0.3)

Figure 1 Proportion of patients reporting oral candidiasis TEAEs up to 4 years[a]

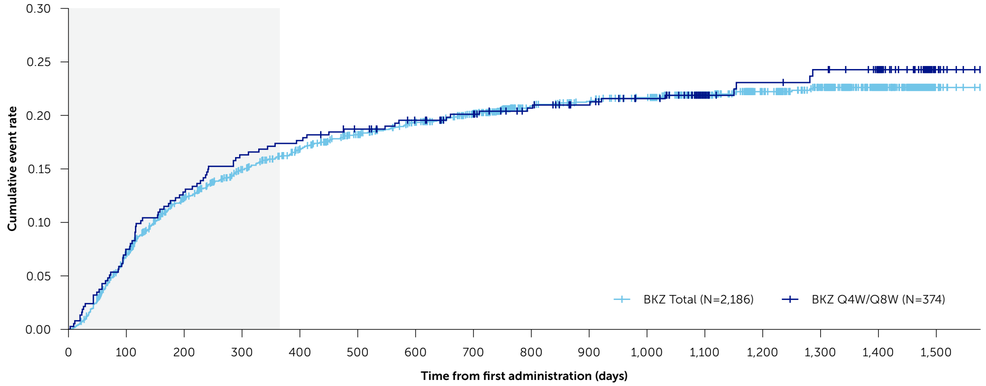


[a] Data were pooled over 4 years from BE BRIGHT (final data) and 3 years from BE RADIANT (final data).

Table 2 Baseline characteristics

	Patients with 0 oral candidiasis TEAEs throughout study		Patients with ≥2 oral candidiasis TEAEs throughout study	
	BKZ Total (N=1,722)	BKZ Q4W/Q8W (N=289)	BKZ Total (N=238)	BKZ Q4W/Q8W (N=43)
Age (years), mean (SD)	45.1 (13.7)	44.0 (14.0)	47.6 (13.6)	49.5 (14.5)
Sex, **male**, n (%)	1,200 (69.7)	206 (71.3)	172 (72.3)	30 (69.8)
Racial group, **White**, n (%)	1,443 (83.8)	270 (93.4)	210 (88.2)	42 (97.7)
Weight (kg), mean (SD)	90.0 (21.9)	89.6 (20.9)	85.4 (19.6)	86.0 (18.8)
BMI (kg/m²), mean (SD)	30.1 (6.8)	29.6 (6.4)	28.3 (5.8)	28.5 (5.1)
Duration of psoriasis (years), mean (SD)	17.6 (12.3)	18.3 (12.1)	18.7 (12.5)	19.9 (12.5)
Prior systemic therapy, n (%)	1,297 (75.3)	217 (75.1)	191 (80.3)	32 (74.4)
Prior biologic therapy, n (%)	640 (37.2)	102 (35.3)	89 (37.4)	12 (27.9)
Anti-TNF	268 (15.6)	41 (14.2)	39 (16.4)	2 (4.7)
Anti-IL-17	329 (19.1)	49 (17.0)	57 (23.9)	9 (20.9)

Figure 2 Time to first occurrence of oral candidiasis TEAEs up to 4 years[a,b]



BKZ: bimekizumab; **BMI:** body mass index; **IL:** interleukin; **OLE:** open-label extension; **PY:** patient-years; **Q4W:** every 4 weeks; **Q8W:** every 8 weeks; **SD:** standard deviation; **TEAE:** treatment-emergent adverse event; **TNF:** tumour necrosis factor.

References: [1]Armstrong AW et al. Dermatol Ther (Heidelb) 2022;12:787–800; [2]Adams R et al. Front Immunol 2020;11:1894; [3]Armstrong AW et al. Am J Clin Dermatol 2016;17:329–36; [4]Reich K et al. Lancet 2021;397:487–98 (NCT03370133); [5]Warren RB et al. N Engl J Med 2021;385:130–41 (NCT03412747); [6]Gordon KB et al. Lancet 2021;397:475–86 (NCT03410992); [7]Strober B et al. Br J Dermatol 2023;188:749–59 (NCT03598790); [8]Warren RB et al. Br J Dermatol 2025:00:1–12 (NCT03536884); [9]European Medicines Agency. Bimekizumab Summary of Product Characteristics. 2025. Available at: https://www.ema.europa.eu/en/documents/product-information/bimzelx-epar-product-information_en.pdf [Accessed June 2025]. **Author Contributions:** Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: **RBW**, **DT**, **AA**, **MG**, **KBG**, **BS**, **DD**, **SK**, **ML**; Drafting of the publication, or reviewing it critically for important intellectual content: **RBW**, **DT**, **AA**, **MG**, **KBG**, **BS**, **DD**, **SK**, **ML**; Final approval of the publication: **RBW**, **DT**, **AA**, **MG**, **KBG**, **BS**, **DD**, **SK**, **ML**. **Author Disclosures: RBW:** Consulting fees from AbbVie, Almirall, Amgen, Arena, Astellas, Avillion, Biogen, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, DICE Therapeutics, Eli Lilly and Company, GSK, Janssen, LEO Pharma, Meiji Pharma, Novartis, Pfizer, RAPT Therapeutics, Sanofi, Sun Pharma, UCB and Union; research grants to his institution from AbbVie, Almirall, Amgen, Celgene, Eli Lilly and Company, Janssen, LEO Pharma, Novartis, Pfizer and UCB; honoraria from AbbVie, Almirall, Bristol Myers Squibb, Eli Lilly and Company, Galderma, Janssen and Novartis. **DT:** Investigator and/or consultant/advisor for AbbVie, Almirall, Amgen, Bristol Myers Squibb, Boehringer Ingelheim, Celltrion, Eli Lilly, Galderma, Incyte, Johnson and Johnson, Kyowa Kirin, LEO Pharma, L'Oreal, New Bridge, Novartis, Pfizer, Regeneron, Samsung, Sanofi, Stada, Takeda, Target-RWE, UCB, and Vichy; received grants from AbbVie, LEO Pharma, and Novartis. **AA:** Has served as a research investigator and/or scientific advisor to AbbVie, Almirall, Arcutis, ASLAN Pharmaceuticals, Boehringer Ingelheim, Bristol Myers Squibb, Dermavant, Dermira, Eli Lilly and Company, EPI, Incyte, Janssen, LEO Pharma, Nimbus, Novartis, Ortho Dermatologics, Pfizer, Regeneron, Sanofi, Sun Pharma and UCB. **MG:** Investigator, speaker, consultant or advisory board member for AbbVie, Acelyrin, Akros, Amgen, AnaptysBio, Arcutis, Aristea, ASLAN Pharmaceuticals, Bausch Health, Boehringer Ingelheim, Bristol Myers Squibb, Dermavant, Dermira, Eli Lilly and Company, Galderma, GSK, Incyte, JAMP Pharma, Janssen, Kyowa Kirin, L'Oréal, MedImmune, Meiji Pharma, MoonLake Immunotherapeutics, Nektar Therapeutics, Nimbus, Novartis, Pfizer, Regeneron, Reistone, Sanofi, Sun Pharma, Takeda, Tarsus, UCB, Union, Ventyx and Vyne. **KBG:** Has received consulting fees from AbbVie, Almirall, Amgen, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Dermira, Eli Lilly and Company, Janssen, Novartis, Pfizer, Sun Pharma and UCB; research support from AbbVie, Bristol Myers Squibb, Celgene, Eli Lilly and Company, Janssen, Novartis and UCB. **BS, DD:** Employees and shareholders of UCB. **SK:** Consultant for Aclipse Therapeutics, Aliada Therapeutics, Allay Therapeutics, Autobahn Therapeutics, Biolacuna, Cognition Therapeutics, Colorado Prevention Center, Karuna Therapeutics, Kisbee Therapeutics, LB Pharmaceuticals, Nesos, Novartis, Onward Medical, PharPoint Research, Summit Analytical, Therini Bio, Tonix Pharmaceuticals, Tornado Therapeutics, UCB, Whitsell Innovations, Worldwide Clinical Trials, and Zosano Pharma. **ML:** Employee of Mount Sinai and receives research funds from AbbVie, Amgen, Arcutis, Avotres, Boehringer Ingelheim, Cara Therapeutics, Dermavant Sciences, Eli Lilly and Company, Incyte, Inozyme, Janssen Research & Development, LLC, Ortho Dermatologics, Pfizer, Sanofi-Regeneron and UCB; consultant for Almirall, AltruBio Inc., AnaptysBio, Apogee, Arcutis Inc., AstraZeneca, Atomwise, Avotres, Brickell Biotech, Boehringer Ingelheim, Bristol Myers Squibb, Castle Biosciences, Celltrion, CorEvitas, Dermavant Sciences, EPI, Evommune Inc., 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:** This study was funded by UCB. 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