Long-term safety and tolerability of bimekizumab in patients with axial spondyloarthritis and psoriatic arthritis: Updated results from phase 2b/3 studies and their open-label extensions

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OBJECTIVES

- To present long-term safety data for bimekizumab (BKZ) in patients with active axial spondyloarthritis (axSpA) and active psoriatic arthritis (PsA), across phase 2b/3 trials and their open-label extensions (OLEs).
- To report the overall safety profile of BKZ in the subset of patients with PsA with pre-existing psoriasis (PSO) with a body surface area (BSA) ≥3%.

Summary

Bimekizumab demonstrated a consistent safety profile in patients with axSpA and PsA over extended periods of exposure

axSpA
N=848
2,513.8 PY

PsA
N=1,409
3,655.9 PY

Bimekizumab treatment led to:

↓ Low discontinuation rates

⊘ No systemic fungal infections

Background

- **BKZ** is a monoclonal IgG1 antibody that selectively inhibits interleukin **(IL)-17F in addition to IL-17A.**
- A previous analysis of pooled safety data from phase 2b/3 studies demonstrated that BKZ was generally well tolerated by patients with axSpA and PsA.[1]
- Separately for axSpA and PsA, we present **updated safety data** from phase 2b/3 studies, **including ongoing phase 3 OLEs.**

Methods

- Safety data are from two pools, each including three phase 2b/3 studies and their OLEs in axSpA and PsA, respectively (**Supplementary Figure;** QR code).[2–8]
- Exposure-adjusted incidence rates/100 patient-years (EAIR/100 PY) are reported for treatment-emergent adverse events (TEAEs; MedDRA v19.0) among patients who received ≥1 BKZ 160 mg dose, including in the subset of patients with PsA and PSO with a BSA ≥3%.

1. Mease PJ. et al. Arthritis Rheumatol 2023;75, Abstract 0511; **2.** Baraliakos X. et al. Arthritis Rheumatol 2022;74:1943–58 (NCT02963506, NCT03355573); **3.** Baraliakos X. et al. Ann Rheum Dis 2024;83:199–213 (NCT03928704, NCT03928743); **4.** Coates LC. et al. Arthritis Rheumatol 2022:74:1959–70 (NCT02969525, NCT03347110); **5.** Ritchlin CT. et al. Ann Rheum Dis 2023;82:1404–14 (NCT03895203); **6.** Coates LC. et al. RMD Open 2024;10:e003855 (NCT03896581); **7.** Baraliakos X. et al. Rheumatology 2025;keaf009 (NCT04436640); **8.** Mease PJ. et al. Rheumatol Ther 2024;11:1363–82 (NCT04009499). axSpA: axial spondyloarthritis; BKZ: bimekizumab; BSA: body surface area; EAIR: exposure-adjusted incidence rate; IL: interleukin; MedDRA: Medical Dictionary for Regulatory Activities; OLE: open label extension; PsA: psoriatic arthritis; PSO: psoriasis; PY: patient-years; TEAE: treatment-emergent adverse event.

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Link expiration: June 9, 2025

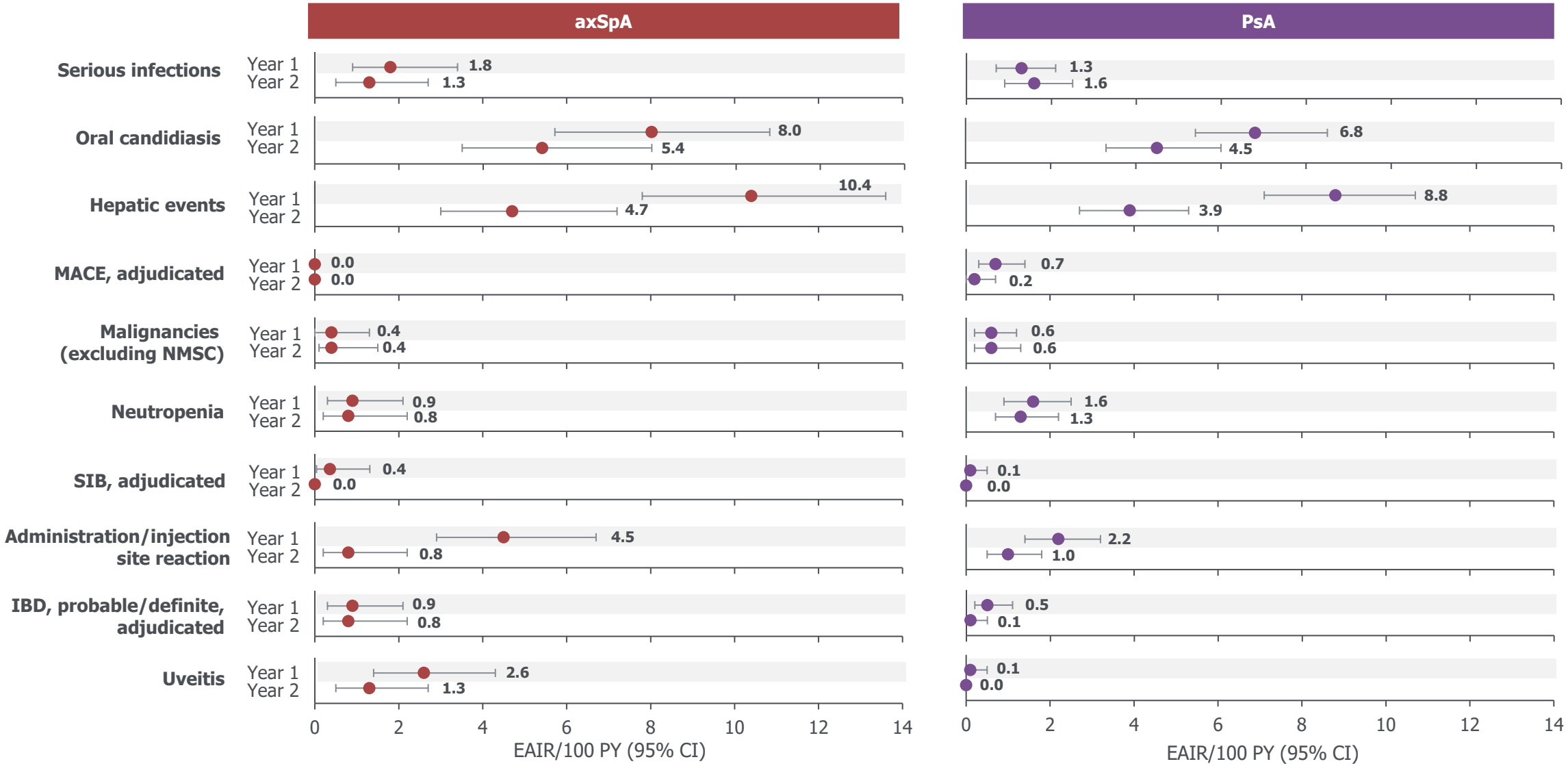
Summary of TEAEs Reported in Phase 2b/3 Studies up to the Phase 3 Data-Cut (July 2023)

n (%) [EAIR/100 PY]	axSpA BKZ 160 mg Q4W N=848 Exposure 2,513.8 PY	PsA BKZ 160 mg Q4W N=1,409 Exposure 3,655.9 PY
Overall		
Any TEAE	772 (91.0) [129.6]	1,239 (87.9) [126.9]
Severe TEAEs	78 (9.2) [3.2]	121 (8.6) [3.5]
Study discontinuations due to TEAEs	59 (7.0) [2.4]	104 (7.4) [2.9]
Drug-related TEAEs	410 (48.3) [25.2]	574 (40.7) [22.4]
Serious TEAEs	123 (14.5) [5.3]	197 (14.0) [5.8]
Deaths	3 (0.4) [0.1][a]	5 (0.4) [0.1][a]
Most common TEAEs[b]		
SARS-CoV-2 (COVID-19) infection[c]	224 (26.4) [9.9]	318 (22.6) [9.9]
Nasopharyngitis	182 (21.5) [8.4]	221 (15.7) [6.8]
Upper respiratory tract infection	114 (13.4) [5.0]	191 (13.6) [5.7]
Oral candidiasis	83 (9.8) [3.5]	132 (9.4) [3.8]
Headache	62 (7.3) [2.6]	87 (6.2) [2.5]
Diarrhea	55 (6.5) [2.3]	86 (6.1) [2.5]

n (%) [EAIR/100 PY]	axSpA BKZ 160 mg Q4W N=848 Exposure 2,513.8 PY	PsA BKZ 160 mg Q4W N=1,409 Exposure 3,655.9 PY
Safety topics of interest		
Fungal infections	179 (21.1) [8.4]	253 (18.0) [7.9]
Candida infections	100 (11.8) [4.3]	161 (11.4) [4.7]
Fungal infections NEC	82 (9.7) [3.5]	111 (7.9) [3.2]
Tinea infections	20 (2.4) [0.8]	21 (1.5) [0.6]
Serious infections	34 (4.0) [1.4]	46 (3.3) [1.3]
Hepatic events[d]	119 (14.0) [5.3]	167 (11.9) [5.0]
Elevated liver enzymes[e]	91 (10.7) [3.9]	133 (9.4) [3.9]
>3x ULN ALT or AST[f]	48 (5.7) [2.0]	68 (4.8) [1.9]
>5x ULN ALT or AST[f]	21 (2.5) [0.8]	22 (1.6) [0.6]
MACE, adjudicated	4 (0.5) [0.2]	12 (0.9) [0.3]
Malignancies (Excluding NMSC)[g]	9 (1.1) [0.4]	19 (1.3) [0.5]
Neutropenia[h]	12 (1.4) [0.5]	42 (3.0) [1.2]
SIB, adjudicated[i]	3 (0.4) [0.1]	2 (0.1) [0.1]
Serious hypersensitivity reaction	0	0
Administration/injection site reaction	27 (3.2) [1.1]	33 (2.3) [0.9]
IBD, probable/definite, adjudicated	18 (2.1) [0.7][j]	8 (0.6) [0.2][k]
With prior history[l]	3 (20.0) [6.6]	1 (7.7) [2.9]
Without prior history[m]	15 (1.8) [0.6]	7 (0.5) [0.2]
Uveitis[n]	31 (3.7) [1.3]	3 (0.2) [0.1]
With prior history[o]	18 (13.8) [4.8]	1 (4.8) [2.4]
Without prior history[p]	13 (1.8) [0.6]	2 (0.1) [0.1]

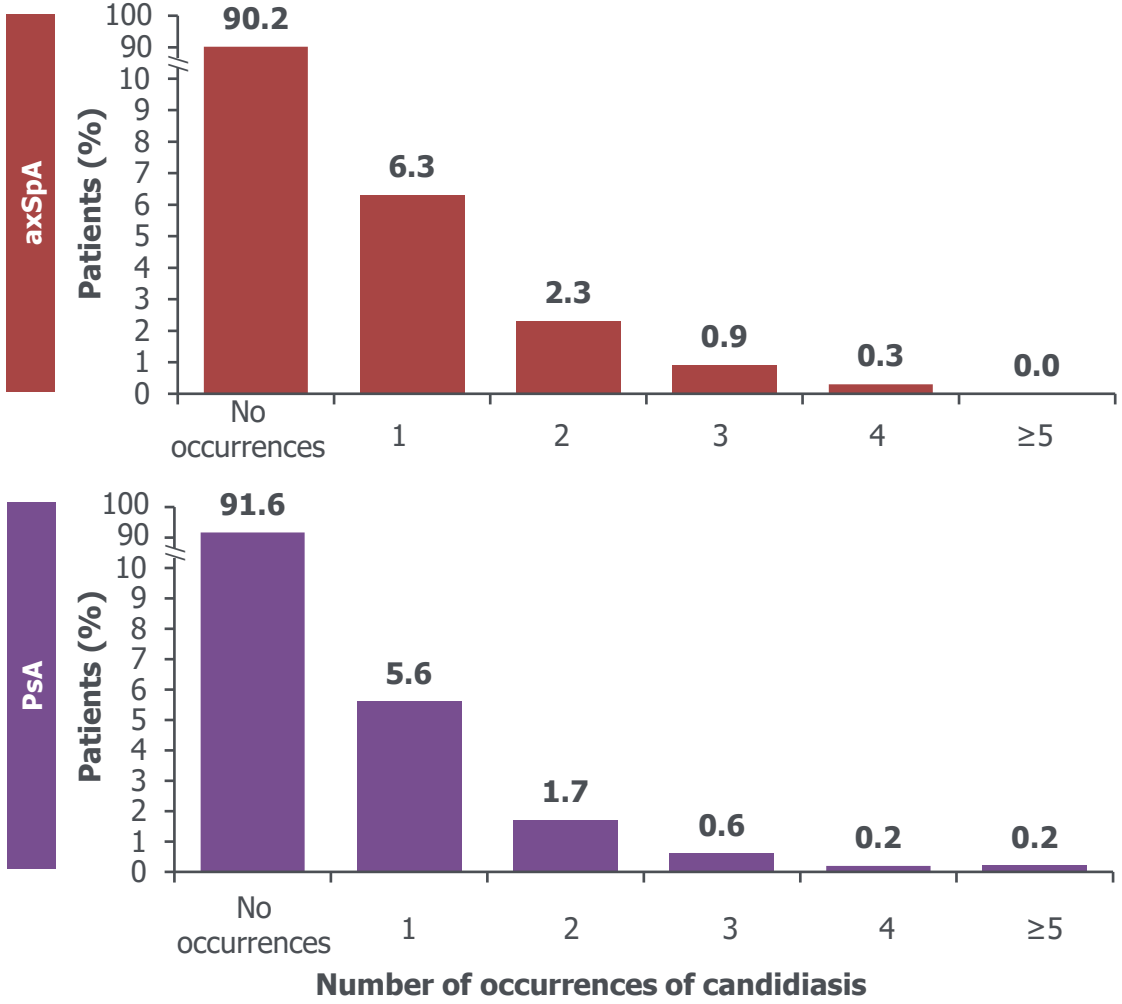
Data to the July 2023 data-cut shown, including all patients who received ≥1 dose of BKZ 160 mg Q4W in the phase 2b/3 studies. **[a]** By MedDRA v19.0 preferred term, axSpA: Cardiac arrest, Cardio-respiratory arrest, and Road traffic accident; PsA: Acute myocardial infarction, Cardiac arrest, Hepatobiliary neoplasm, Sudden death, and Traumatic shock (from a motorcycle accident). No deaths were considered drug-related by the investigator in any study; **[b]** TEAEs defined by MedDRA v19.0 preferred term (except SARS-CoV-2 infection), occurring in ≥6% of patients in both the axSpA and PsA patient pools; **[c]** Specific terms for SARS-CoV-2 (COVID-19) infections were not available in the MedDRA v19.0; confirmed or suspected cases were identified using the preferred terms "Corona virus infection" and "Coronavirus test positive; **[d]** Includes events described as drug-related hepatic disorders, excluding liver neoplasms; **[e]** Elevated liver enzymes include the following preferred terms reported as adverse events: increased/abnormal levels of ALT, AST, Blood bilirubin, Gamma-glutamyltransferase, Hepatic enzyme, Liver function test, Total bile acids, or Transaminases; **[f]** axSpA: n=847; PsA: n=1,407; **[g]** Includes all TEAEs identified using the SMQ="Malignant tumours (SMQ)"; **[h]** Neutropenia includes additional preferred terms identified based on UCB-defined search criteria; **[i]** All patients with adjudicated SIB had a history of psychiatric disorders or ongoing traumatic and stressful circumstances; **[j]** 9 (1.1%) patients with Crohn's disease, 6 (0.7%) Ulcerative colitis, 4 (0.5%) Unclassified; **[k]** 2 (0.1%) patients with Crohn's disease, 2 (0.1%) Ulcerative colitis, 4 (0.3%) Unclassified; **[l]** axSpA, n=15; PsA, n=13; **[m]** axSpA, n=833; PsA, n=1,396; **[n]** Includes the preferred terms Autoimmune uveitis, Uveitis, Iridocyclitis, and Iritis; **[o]** axSpA, n=130; PsA, n=21; **[p]** axSpA, n=718; PsA, n=1,388. ALT: alanine transaminase; AST: aspartate transaminase; axSpA: axial spondyloarthritis; BKZ: bimekizumab; EAIR: exposure-adjusted incidence rate; IBD: inflammatory bowel disease; MACE: major adverse cardiovascular event; MedDRA: medical dictionary for regulatory activities; NEC: not elsewhere classifiable; NMSC: non-melanoma skin cancer; OLE: open-label extension; PsA: psoriatic arthritis; PY: patient-years; Q4W: every four weeks; SIB: suicidal ideation or behaviour; SMQ: Standardised MedDRA Queries; TEAE: treatment-emergent adverse event; ULN: upper limit of normal.

Safety Topics of Interest by Year of BKZ Treatment in the Phase 3 Studies



Data from the July 2023 data-cut shown, including all at-risk patients who received ≥1 dose of BKZ 160 mg Q4W in Weeks 0–52 (axSpA, N=574; PsA, N=1,211) or Weeks >52–104 (axSpA, N=518; PsA, N=1,110) of the phase 3 studies. Patients were considered at-risk for up to 140 days after the last dose of BKZ. axSpA: axial spondyloarthritis; BKZ: bimekizumab; CI: confidence interval; EAIR: exposure-adjusted incidence rate; IBD: inflammatory bowel disease; MACE: major adverse cardiovascular event; NMSC: non-melanoma skin cancer; PsA: psoriatic arthritis; PY: patient-years; Q4W: every 4 weeks; SIB: suicidal ideation or behaviour.

Low Recurrence of Oral Candidiasis in Individual Patients with axSpA and PsA During the First 2 Years of Treatment with BKZ in the Phase 3 Studies[a]



Summary of TEAEs in Patients with PsA and PSO with Baseline BSA ≥3% in Phase 2b/3 Studies[b]

n (%) [EAIR/100 PY]	PsA (with PSO and baseline BSA ≥3%) BKZ 160 mg Q4W n=803; exposure 2,102 PY
Overall	
Any TEAE	675 (84.1) [105.8]
Severe TEAEs	65 (8.1) [3.2]
Study discontinuations due to TEAEs	50 (6.2) [2.4]
Drug-related TEAEs	292 (36.4) [18.9]
Serious TEAEs	91 (11.3) [4.6]
Deaths	3 (0.4) [0.1]
Safety topics of interest	
Serious infections	22 (2.7) [1.1]

Results Summary

- The majority of fungal infections were **candidiasis;** mostly **mild/moderate,** mucocutaneous; none were systemic. Most patients with oral candidiasis had 1 event, and few cases led to permanent treatment discontinuation (axSpA: 0.2/100 PY; PsA: 0.4/100 PY).
- **No cases** of **active tuberculosis** or **completed suicide** were reported in any study.
- In the phase 3 studies, EAIRs of safety topics of interest generally **remained stable or decreased** in the second year of BKZ treatment.
- In PsA patients with pre-existing psoriasis (BSA ≥3%), EAIR/100 PY were **consistent** with overall PsA analyses across phase 2b/3 studies.

[a] Data from the July 2023 data-cut shown, including all patients who received ≥1 dose of BKZ 160 mg Q4W in the phase 3 studies (axSpA, N=574; PsA, N=1,211). Data labels indicate percentage of patients reporting the respective number of occurrences of oral candidiasis TEAEs (preferred term according to MedDRA v19.0) with relative day of onset during Weeks 0–104 of treatment with BKZ; **[b]** Data to the July 2023 data-cut shown, including all patients who received ≥1 dose of BKZ 160 mg Q4W in the phase 2b/3 studies. axSpA: axial spondyloarthritis; BKZ: bimekizumab; BSA: body surface area; EAIR: exposure-adjusted incidence rate; PsA: psoriatic arthritis; PSO: psoriasis; PY: patient-years; Q4W: every four weeks; TEAE: treatment-emergent adverse event.

CONCLUSIONS

With an additional year of exposure, the long-term safety profile of bimekizumab in patients with axSpA and PsA remained consistent with prior analyses;[1] no new safety signals or concerns were raised.

The incidence rate of oral candidiasis decreased over time and few cases led to treatment discontinuation.

These observations support the favorable benefit-risk profile of bimekizumab for the long-term treatment of axSpA and PsA, including in patients with pre-existing PSO.

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1. Mease PJ. et al. Arthritis Rheumatol 2023;75, Abstract 0511. axSpA: axial spondyloarthritis; PsA: psoriatic arthritis; PSO: psoriasis.