Bimekizumab-Treated Patients with Axial Spondyloarthritis or Psoriatic Arthritis Report Low Long-Term Uveitis Rates: Updated 3-Year Results from Pooled Phase 2b and Phase 3 Studies

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Objective

To report updated long-term uveitis incidence in bimekizumab (BKZ)-treated patients with axial spondyloarthritis (axSpA) or psoriatic arthritis (PsA) in phase 2b/3 studies, with an additional year of treatment in the phase 3 studies since previously reported data.

Background

- Acute anterior uveitis is an extra-musculoskeletal manifestation that poses a significant burden on the quality of life of patients with spondyloarthritis (SpA).[1,2]
  - Incidence varies with SpA type and disease duration, with an estimated prevalence of 30–40% in patients with radiographic (r-)axSpA, 14.3% in patients with non-radiographic (nr-)axSpA and 5% in PsA.[3–5]
- Interleukin (IL)-17 is implicated in uveitis pathogenesis. Preliminary data have shown that IL-17F has a potential independent role in the pathogenesis of acute anterior uveitis; however, data demonstrating the efficacy of IL-17A inhibition for managing non-infectious uveitis are limited and conflicting.[6–10]
- BKZ is a monoclonal IgG1 antibody that selectively inhibits IL-17F in addition to IL-17A.[11]
- Published phase 3 data have shown lower uveitis exposure-adjusted incidence rates (EAIR) per 100 patient-years (PY) after 16 weeks in patients with nr- and r-axSpA treated with BKZ (1.8/100 PY) versus placebo (15.4/100 PY).[2]
- Phase 2b/3 data previously reported over a long-term exposure of approximately two years showed that uveitis rates remained low in BKZ-treated patients with axSpA (1.3/100 PY) and PsA (0.1/100 PY).[12]

Methods

- Safety data, including uveitis incidence, are reported for two pools, each comprising one phase 2b and two phase 3 studies and their open-label extensions, in patients with active axSpA (nr-axSpA and r-axSpA) or PsA (**Figure 1**).
- Uveitis events were identified using the preferred terms "autoimmune uveitis", "iridocyclitis", "iritis" and "uveitis", classified using the Medical Dictionary for Regulatory Activities (MedDRA) version (v)19.0; "acute anterior uveitis" was not a specific preferred term available in MedDRA v19.0.
- Uveitis incidence rates (EAIR/100 PY), uveitis recurrence rates (axSpA only) and number of uveitis events in each treatment year (axSpA phase 3 only) for patients who received ≥1 subcutaneous BKZ 160 mg dose every four weeks (Q4W) are reported (data cut-off in phase 3 studies, axSpA: September 2024; PsA: August 2024). Only TEAEs occurring during treatment with BKZ 160 mg Q4W were included.
- Recurrence of a uveitis event was defined based on which eye was affected and the time between events.
  - For the same eye, a uveitis event reoccurring after ≥90 days from the previous event was considered a recurrence.
  - An event was considered new if it occurred in the second eye, even if within 90 days of the previous event in the first eye.
  - If both eyes were affected at the same time, it was considered to be one event.

Results

Baseline characteristics

- The baseline characteristics of patients in the phase 2b/3 axSpA study pool (N=848) and PsA study pool (N=1,409) are shown in **Table 1**.
  - Of patients with axSpA and PsA, 130 (15.3%) and 21 (1.5%) had a history of uveitis, respectively.
  - Most patients with axSpA were HLA-B27 positive (717/848 [84.6%]).
- Compared with patients without uveitis, a higher percentage of patients who reported at least one uveitis event had r-axSpA, were HLA-B27 positive, were female and had a longer mean time since diagnosis (**Table 2**).

Patients with axSpA

- In patients with axSpA across the pooled phase 2b/3 data, BKZ 160 mg exposure was 2,748.9 PY.
  - Overall, uveitis occurred in 33/848 (3.9%) patients (EAIR [95% CI]: 1.2/100 PY [0.8, 1.7]; **Figure 2**).
  - In the additional year of treatment (Year 3, >104–156 weeks, from the phase 3 safety set only), only two further patients reported uveitis events, both of whom had a history of uveitis. The overall incidence rate observed at 3 years remained similar to the earlier data cut-off (July 2023; EAIR [95% CI]: 1.3/100 PY [0.9, 1.8]).[12]
  - Uveitis occurred in 20/130 (15.4%) patients (EAIR [95% CI]: 5.0/100 PY [3.0, 7.7]) with a history of uveitis and only 13/718 (1.8%) patients (EAIR [95% CI]: 0.6/100 PY [0.3, 1.0]) without (**Figure 2**).
  - Most patients (32/33) reported mild or moderate uveitis events. Two (0.2%) patients discontinued treatment due to uveitis; one patient had severe uveitis and a history of uveitis, and the other had no history of uveitis.
  - Among the patients who had a uveitis event, recurrence of uveitis occurred in 7/33 (21.2%) patients, comprising four patients with a history of uveitis at baseline and three patients without.
  - In the additional year of treatment (Year 3, >104–156 weeks, from the phase 3 safety set only), 8 uveitis events occurred; within each treatment year, there were more uveitis events in patients with a history of uveitis than those without (**Figure 3**).
  - Kaplan-Meier analyses showed no clear trend between the time of the first BKZ administration and the first incidence of uveitis in patients with axSpA (**Figure 4**).

Patients with PsA

- Incidence of uveitis in patients with PsA was low across the pooled phase 2b/3 data (BKZ 160 mg exposure: 4,264.7 PY).
  - Uveitis occurred in 4/1,409 (0.3%) patients overall (EAIR [95% CI]: 0.1/100 PY [0.0, 0.2]; **Figure 5**); wo of the four patients had a history of uveitis.
  - In the additional year of treatment, uveitis was reported in only one further patient with PsA, who had a history of uveitis. The overall incidence rate observed at 3 years remained similar to the earlier data cut-off (July 2023; EAIR [95% CI]: 0.1/100 PY [0.0, 0.2]).[12]
  - No uveitis events were severe or led to treatment discontinuation.

Conclusions

With one additional year of bimekizumab treatment over previously reported data, the incidence and overall risk of uveitis in patients with SpA receiving bimekizumab over a long-term period of three years remained low.

Summary

This analysis reported updated **long-term uveitis incidence** in patients with **axSpA** (2,748.9 PY exposure) and **PsA** (4,264.7 PY exposure) treated with **bimekizumab** across pooled phase 2b/3 studies, with an **additional year of treatment** in the phase 3 studies.

Overall, **uveitis incidence rates were low** in patients with **axSpA** and **PsA** treated with bimekizumab, and remained **similar to rates observed at the earlier data cut-off**:

axSpA 1.2/100 PY | **PsA 0.1/100 PY**

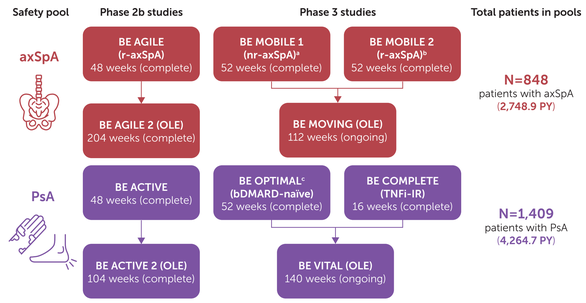
Only **three** further patients reported uveitis events with an **additional year of treatment**, all with a **history of uveitis** at baseline.

Uveitis events were **mild or moderate** in 32/33 (**axSpA**) and 4/4 (**PsA**) patients who reported uveitis.

No clear trend was observed between the **time of the first bimekizumab administration** and the **first incidence of uveitis** in patients with **axSpA** from Kaplan-Meier analyses.

The incidence of uveitis in patients receiving bimekizumab remained low with approximately 3 years of treatment. These data add to previous reports to suggest there is an **overall low risk of uveitis with long-term bimekizumab treatment** in patients with SpA.

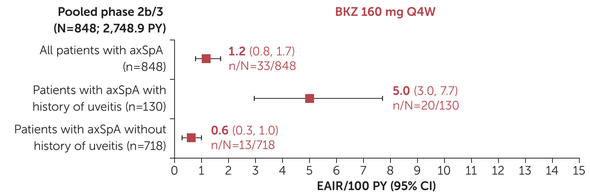
Figure 1 Two safety pools (axSpA, PsA) of patients treated with BKZ 160 mg Q4W across six phase 2b/3 studies and their open-label extensions



Data from September 2024 (axSpA) and August 2024 (PsA) data-cuts shown; including all patients who received ≥1 dose of bimekizumab 160 mg Q4W in the phase 2b/3 studies. Duration of overall treatment period shown; bimekizumab treatment duration by data-cut varied between patients, depending on study duration and initial randomisation in the feeder studies. **[a]** Patients with nr-axSpA met Assessment of SpondyloArthritis international Society (ASAS) classification criteria. Patients with radiographic sacroiliitis were excluded; **[b]** Patients with r-axSpA met modified New York criteria and fulfilled ASAS classification criteria; **[c]** BE OPTIMAL also included an adalimumab treatment arm. Data from patients treated with adalimumab were not included in the PsA safety pool prior to switching to bimekizumab but were included following the switch.

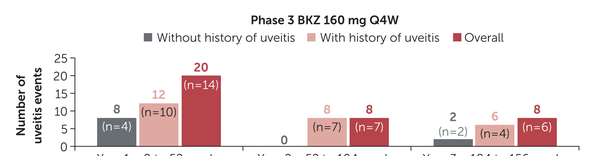
BE AGILE: NCT02963506; BE AGILE 2: NCT03355573; BE MOBILE 1: NCT03928704; BE MOBILE 2: NCT03928743; BE MOVING: NCT04436640; BE ACTIVE: NCT02969525; BE ACTIVE 2: NCT03347110; BE OPTIMAL: NCT03895203; BE COMPLETE: NCT03896581; BE VITAL: NCT04009499.

Figure 2 Incidence of uveitis in patients with axSpA, stratified by history of uveitis



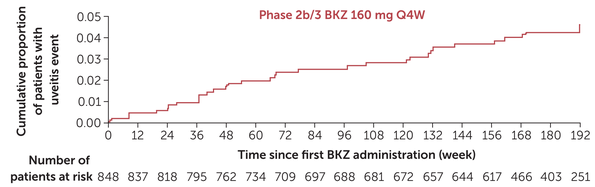
Pooled axSpA safety set.

Figure 3 Uveitis events by treatment year in BKZ-treated patients with axSpA, stratified by history of uveitis



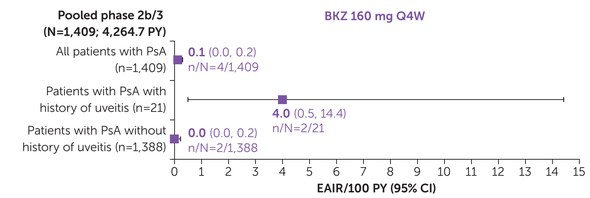
Phase 3 pooled axSpA safety set. Treatment periods after 52 weeks represent the open-label extension period. N numbers shown within the bars indicate the number of patients, stratified by uveitis history, experiencing uveitis events during each treatment period. Patients could have had more than one uveitis event within each treatment period.

Figure 4 Kaplan-Meier estimates for time to first uveitis event in patients with axSpA



Pooled axSpA safety set. Time to first occurrence of uveitis (weeks) was calculated as (date of first onset of uveitis – date of first BKZ 160 mg administration + 1)/7.

Figure 5 Incidence of uveitis in patients with PsA, stratified by history of uveitis



Pooled PsA safety set.

Table 1 Baseline demographics and characteristics in the pooled axSpA and PsA phase 2b/3 trials

	axSpA	PsA
	BKZ 160 mg Q4W (N=848)	BKZ 160 mg Q4W (N=1,409)
Age, years, mean (SD)	40.3 (11.9)	49.3 (12.4)
Male, n (%)	606 (71.5)	672 (47.7)
r-axSpA, n (%)	604 (71.2)	N/A
BMI, kg/m^2, mean (SD)	27.0 (5.5)	29.4 (6.3)
HLA-B27 positive, n (%)	717 (84.6)[a]	203 (18.3)[b]
Geographic regions, n (%)		
Asia	88 (10.4)	99 (7.0)
Eastern Europe	543 (64.0)	908 (64.4)
North America	37 (4.4)	238 (16.9)
Western Europe	180 (21.2)	164 (11.6)
Time since first symptoms, years, mean (SD)	12.4 (9.9)	Not reported
Time since first diagnosis, years, mean (SD)	6.1 (7.8)	7.0 (8.0)[c]
History of uveitis, n (%)	130 (15.3)	21 (1.5)
History of enthesitis, n (%)	168 (19.8)[d]	457 (32.4)
Prior TNFi exposure, n (%)	108 (12.7)	425 (30.2)
Baseline concomitant medications, n (%)		
csDMARDs	198 (23.3)	909 (64.5)
NSAIDs	689 (81.3)	834 (59.2)
Corticosteroids	70 (8.3)	219 (15.5)
CRP, mg/L, geometric mean (geometric CV, %)	7.1 (238.1)	4.2 (254.1)
CRP >/≥5 mg/L, n (%)[e]	545 (64.3)	645 (45.8)

Pooled axSpA and PsA safety sets. **[a]** Six patients had missing HLA-B27 status; **[b]** N=1,111 (excludes the phase 2b studies); 36 patients had missing HLA-B27 status; **[c]** N=1,396; **[d]** Type of enthesitis was only collected in Phase 3 studies, therefore only heel/calcaneal enthesitis (n/N=124/574) and non-heel/noncalcaneal enthesitis (n/N=57/574) data from the Phase 3 studies are presented in this table; **[e]** CRP >5 mg/L reported for patients with axSpA and ≥5 mg/L reported for patients with PsA.

Table 2 Baseline demographics and characteristics split by patients with and without a uveitis event in the pooled axSpA phase 2b/3 trials

	axSpA	
	Patients with a uveitis event (n=33)	Patients without a uveitis event (n=815)
Age, years, mean (SD)	39.2 (11.8)	40.3 (11.9)
Male, n (%)	21 (63.6)	585 (71.8)
r-axSpA, n (%)	26 (78.8)	578 (70.9)
BMI, kg/m^2, mean (SD)	27.2 (5.5)	27.0 (5.5)
HLA-B27 positive, n (%)	31 (93.9)	686 (84.2)
Geographic region, n (%)		
Asia	4 (12.1)	84 (10.3)
Eastern Europe	24 (72.7)	519 (63.7)
North America	2 (6.1)	35 (4.3)
Western Europe	3 (9.1)	177 (21.7)
Time since first symptoms, years, mean (SD)	14.5 (10.4)	12.3 (9.9)
Time since first diagnosis, years, mean (SD)	7.0 (9.0)	6.0 (7.7)
History of uveitis, n (%)	20 (60.6)	110 (13.5)
Prior TNFi exposure, n (%)	5 (15.2)	103 (12.6)
Baseline concomitant medications, n (%)		
csDMARDs	7 (21.2)	191 (23.4)
NSAIDs	29 (87.9)	660 (81.0)
Corticosteroids	4 (12.1)	66 (8.1)
CRP, mg/L, geometric mean (geometric CV, %)	9.4 (196.0)	7.1 (239.8)[a]
CRP >5 mg/L, n (%)	23 (69.7)	522 (64.0)
ASDAS, mean (SD)	3.9 (0.8)	3.8 (0.8)

Pooled axSpA safety set. **[a]** n=814.

ASAS: Assessment of SpondyloArthritis international Society; **ASDAS:** Ankylosing Spondylitis Disease Activity Score; **axSpA:** axial spondyloarthritis; **bDMARD:** biologic disease-modifying antirheumatic drug; **BKZ:** bimekizumab; **BMI:** body mass index; **CI:** confidence interval; **CRP:** C-reactive protein; **csDMARD:** conventional synthetic disease-modifying antirheumatic drug; **CV:** coefficient of variation; **EAIR:** exposure-adjusted incidence rate; **HLA-B27:** human leukocyte antigen B27; **IL:** interleukin; **MedDRA:** Medical Dictionary for Regulatory Activities; **N/A:** not applicable; **nr-axSpA:** non-radiographic axial spondyloarthritis; **NSAID:** non-steroidal anti-inflammatory drug; **OLE:** open-label extension; **PsA:** psoriatic arthritis; **PY:** patient-years; **Q4W:** every 4 weeks; **r-axSpA:** radiographic axial spondyloarthritis; **SD:** standard deviation; **SpA:** spondyloarthritis; **TEAE:** treatment-emergent adverse event; **TNFi:** tumour necrosis factor inhibitor; **TNFi-IR:** prior inadequate response or intolerance to tumour necrosis factor inhibitors; **ULN:** upper limit of normal.

References: [1]Robinson PC. Arthritis Rheumatol 2015;67:140–51; [2]Brown MA. Ann Rheum Dis 2024;83:1722–30; [3]Taurog JD. N Engl J Med 2016;374:2563–74; [4]Lopez-Medina C. RMD Open 2019;5:e001108; [5]De Vicente Delmas A. RMD Open 2023;9:e002781; [6]Huang JCC. Ocul Immunol Inflamm 2021;29:558–65; [7]Hysa E. Eur J Clin Invest 2021;51:e13572; [8]Dick AD. Opthalmology 2013;120:777–87; [9]Kwon OC. Rheumatology (Oxford) 2025;64:588–96; [10]Letko E. Opthalmology 2015;122:939–48; [11]Bimzelx® EU SmPC. Available at: https://www.ema.europa.eu/en/documents/product-information/bimzelx-epar-product-information_en.pdf (Accessed May 2026); [12]van der Horst-Bruinsma IE. Arthritis Rheumatol 2024;76(suppl 9). Abstract 2351. **Author Contributions:** Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: **MR**, **IEvdHB**, **FAvG**, **NH**, **LSG**, **MM**, **CP**, **KW**, **AD**, **MAB**. Drafting of the publication, or reviewing it critically for important intellectual content: **MR**, **IEvdHB**, **FAvG**, **NH**, **LSG**, **MM**, **CP**, **KW**, **AD**, **MAB**. Final approval of the publication: **MR**, **IEvdHB**, **FAvG**, **NH**, **LSG**, **MM**, **CP**, **KW**, **AD**, **MAB**. **Author Disclosures: MR:** Speakers bureau from AbbVie, Boehringer Ingelheim, Eli Lilly, Janssen, Novartis, Pfizer and UCB; consultant of AbbVie, Eli Lilly, Janssen, Novartis and UCB. **IEvdHB:** Consultant for AbbVie, Eli Lilly, MSD, Novartis and UCB; unrestricted grants received for investigator-initiated studies from AbbVie, MSD, Pfizer and UCB; fees received for lectures from AbbVie, BMS, MSD and Pfizer. **FAvG:** Grants from Jacobus Stichting, Novartis, Stichting ASAS, Stichting Vrienden van Sole Mio and UCB; fees from Novartis; personal fees from AbbVie, BMS, Eli Lilly and MSD. **NH:** Consultant for AbbVie, Eli Lilly, Novartis and UCB. **LSG:** Grants from UCB paid to institution; consultant for Acelyrin, Eli Lilly, Janssen, Novartis, Pfizer and UCB. **MM**, **KW:** Employees and shareholders of UCB. **CP:** Contractor for UCB and employee of Veramed. **AD:** Speaker for Eli Lilly, J&J, Novartis, Pfizer and UCB; consultant for BMS, Eli Lilly, J&J, MoonLake, Novartis, Pfizer and UCB; grant/research support from BMS, Eli Lilly, J&J, Novartis, Pfizer and UCB. **MAB:** Grant/research support from UCB; consultant for Altis Medicines, Clementia, Grey Wolf Therapeutics, Incyte, Ipsen, Regeneron and Xinthera. **Acknowledgements:** We would like to thank the patients and their caregivers in addition to all the investigators and their teams who contributed to these studies. The authors also thank Celia Menckeberg, PhD, of UCB, for editorial review during poster development and publication coordination, Zamir Salman, MSc, of Costello Medical, London, UK, for medical writing and editorial assistance, and the Costello Medical Creative team for design support. Funded by UCB. All costs associated with development of this presentation were funded by UCB.

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