Interim Results from an International Multicenter Observational Study of Real-World Bimekizumab Treatment of Psoriatic Arthritis

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Objective

To report interim data from the ongoing SPEAK observational study, describing the characteristics of patients with psoriatic arthritis (PsA) at bimekizumab (BKZ) treatment initiation, and health-related quality of life (HRQoL) outcomes to 24 weeks in a real-world setting.

Background

- PsA is a chronic inflammatory disease with a significant burden on patients' HRQoL.[1]
- BKZ, a monoclonal IgG1 antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A, has demonstrated sustained clinical efficacy to 3 years in clinical trials of patients with PsA.[2,3]
  - Improvements in HRQoL outcomes have been reported up to 3 years in patients with PsA treated with BKZ.[4]
- BKZ was approved for the treatment of PsA and axial spondyloarthritis (axSpA) in Europe in June 2023, and in the United States (US) in September 2024.[5,6] BKZ has also been approved in Europe and the US for the treatment of moderate to severe plaque psoriasis and hidradenitis suppurativa.[5,6]
- SPEAK is the first prospective, observational study in routine clinical practice evaluating HRQoL and clinical outcomes with BKZ treatment in patients with active PsA or axSpA in Europe.

Methods

- SPEAK is an ongoing 52-week, multi-country, observational study in Belgium, Czechia, France, Germany, Greece, Spain, and the United Kingdom (**Figure 1**).
  - Patient enrollment began in September 2023, 3 months after the approval of BKZ for the treatment of PsA and axSpA in Europe.[5]
- Adult patients with active PsA or axSpA newly initiating BKZ in routine clinical practice who consented to participate were included.
- The primary outcome of the SPEAK study for patients with PsA was change from baseline in PsA Impact of Disease 12-Item Questionnaire (PsAID-12) score to Week 52.
- This planned interim analysis, based on data to April 2, 2025 (~50% enrollment), reports the following outcomes for patients with PsA to 24 weeks:
  - PsAID-12 (disease impact on HRQoL): change from baseline in total score and individual domains
  - PGADA (disease activity): change from baseline
  - SF-36 PCS (physical functioning): change from baseline in norm-based T scores.
- Other exploratory clinical outcomes were assessed but were not available for this data cut.
- Baseline characteristics of patients with PsA prescribed BKZ are reported.
- Adverse events (AEs) are also reported to 24 weeks for patients with PsA.

Results

- By April 2025, baseline characteristics were available for 376 patients with PsA (**Table**).
  - Overall, 80 (21.3%) patients were biologic/targeted synthetic disease-modifying antirheumatic drug (b/tsDMARD)-naïve, 89 (23.7%) had 1 previous b/tsDMARD, 83 (22.1%) had 2 previous b/tsDMARDs, and 124 (33.0%) had ≥3 previous b/tsDMARDs.
  - Patients previously treated with ≥2 b/tsDMARDs had a greater disease duration prior to initiating BKZ treatment than patients previously treated with <2 b/tsDMARDs, and a greater proportion were female.
- Improvements in PsAID-12 total score (**Figure 2A**), PGADA score, and SF-36 PCS score (**Figure 3**) were observed to 24 weeks (baseline values in **Table**).
  - Improvements from baseline across all PsAID-12 single-item domain mean scores were observed to 24 weeks (**Figure 2B**).
- AEs were reported in 61.4% of patients with PsA; drug-related AEs were reported in 34.8% of patients.
  - 49 (13.0%) patients reported a serious AE
  - One (0.3%) patient reported uveitis; deemed not drug-related
  - 43 (11.4%) patients reported *Candida* infections: 29 (7.7%) patients reported oral candidiasis, deemed drug-related in 25 patients and led to BKZ discontinuation in 13 patients; two (0.5%) patients reported serious *Candida* infections
  - One (0.3%) patient reported a major adverse cardiovascular event (MACE; myocardial infarction); deemed not drug-related
  - There were no cases of inflammatory bowel disease (IBD) or suicidal ideation/behavior.

Conclusions

In this first interim report of patient-reported outcomes for patients with PsA treated with bimekizumab in routine clinical practice, patients reported improvements in HRQoL and disease activity as early as Week 2, which were sustained or further improved to Week 24. We also describe the characteristics of patients with PsA treated with bimekizumab in routine clinical practice. No new safety signals were identified.

These real-world findings complement data from the bimekizumab phase 3 trials, for both patient-reported outcomes and safety.[2–4]

Summary

The aim of this study was to evaluate patient-reported outcomes and HRQoL in patients initiating bimekizumab treatment in **real-world clinical practice.**

SPEAK is the **first observational study** to assess **bimekizumab in a real-world setting** in patients with **PsA**.

Interim data are reported to **24 weeks** for patient-reported outcomes.

Improvements in **HRQoL** outcomes and **disease activity** were observed to 24 weeks:

PsAID-12 Total	PGADA	SF-36 PCS
(mean CfB)	(mean CfB)	(mean CfB)
–1.9	**–17.5**	**+4.6**

No new safety signals were identified.

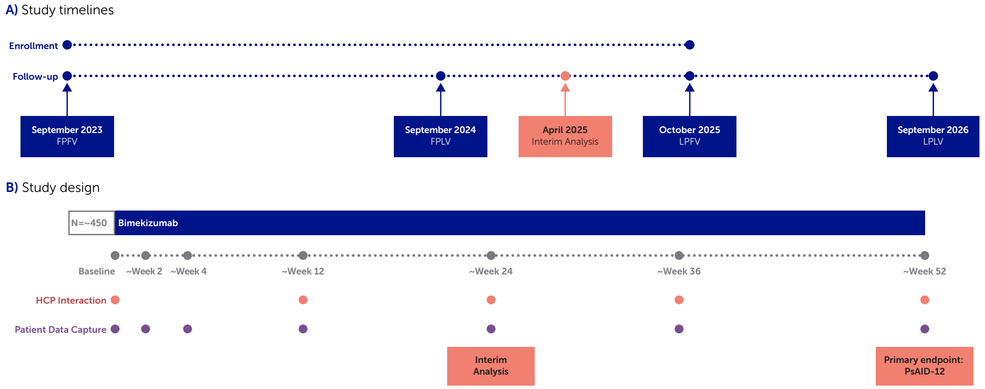
These interim results suggest **bimekizumab treatment** in the **real-world setting** led to **improvements in patient-reported outcomes**, with changes as early as two weeks after treatment initiation.

Table Baseline characteristics of patients with PsA in the SPEAK study

Characteristic, Mean (SD) unless otherwise stated	Previous b/tsDMARD exposure: b/tsDMARD-naïve n=80	1 b/tsDMARD n=89	≥2 b/tsDMARDs n=207	Total N=376
Age, years	51.6 (12.1)	50.8 (11.8)	53.2 (10.6)	52.3 (11.2)
Sex, male, n (%)	39 (48.8)	43 (48.3)	74 (35.7)	156 (41.5)
BMI, kg/m²	29.3 (6.5) [79]	30.9 (6.4) [88]	29.5 (6.2) [205]	29.8 (6.3) [372]
Time since diagnosis, years	4.7 (6.0)	7.2 (8.0)	11.6 (9.2) [206]	9.1 (8.8) [375]
History of IBD, n (%)	0 (0)	1 (1.1)	4 (1.9)	5 (1.3)
TJC	10.5 (8.3) [49]	10.2 (10.1) [64]	13.1 (12.3) [146]	11.9 (11.2) [259]
SJC	5.0 (4.9) [49]	6.7 (8.0) [64]	5.4 (6.6) [146]	5.7 (6.7) [259]
CRP, mg/L, median (min–max)	3.6 (0.0–46.0) [66]	3.3 (0.0–49.8) [67]	3.6 (0.0–112.0) [165]	3.6 (0.0–112.0) [298]
HAQ-DI	1.0 (0.6) [60]	1.2 (0.8) [74]	1.4 (0.7) [162]	1.3 (0.7) [296]
Pain VAS[a]	57.1 (20.6) [61]	55.4 (25.6) [74]	62.0 (22.0) [163]	59.4 (22.8) [298]
PsAID-12 total score	5.0 (1.9) [67]	5.3 (2.2) [77]	5.5 (2.1) [178]	5.4 (2.1) [322]
PGADA[b]	57.0 (19.3) [63]	57.6 (23.3) [74]	61.1 (21.3) [170]	59.4 (21.4) [307]
SF-36 PCS	37.7 (8.1) [61]	36.4 (9.4) [71]	34.3 (9.3) [157]	35.6 (9.2) [289]

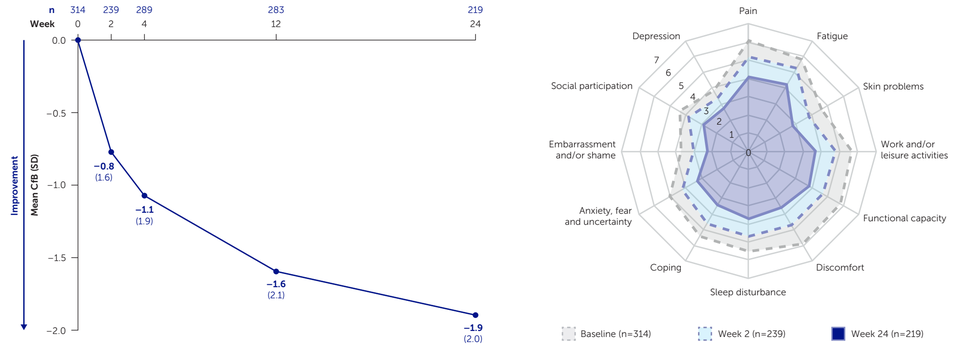
Safety analysis set (includes all patients enrolled into the study). Where the number of patients with available data for a specific baseline characteristic differed from the overall population size, the number of patients with available data has been given in square brackets [n]. **[a]** Pain was assessed using the Patient's Assessment of Arthritis Pain VAS which ranges from 0 to 100, 0 representing 'no pain' and 100 'most severe pain'; **[b]** PGADA in this study uses a 0–100 VAS.

Figure 1 Study timelines and design



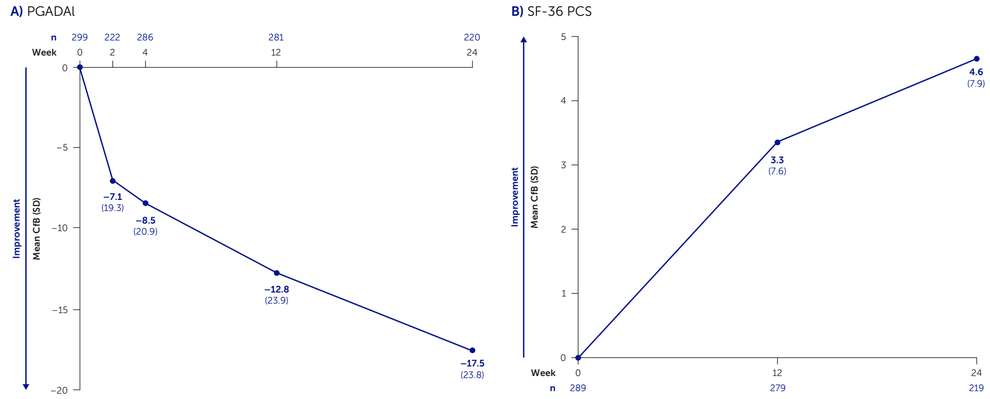
Dates are approximate depending on how close to baseline the first dose was received.

Figure 2 Improvements from baseline in (A) PsA Impact of Disease 12-item (PsAID-12) questionnaire total score and (B) across all PsAID-12 single-item domain mean scores to Week 24 (OC)



Full analysis set. PsAID-12 scores range from 0–10 (higher scores indicate worse status).

Figure 3 Change from baseline in (A) Patient Global Assessment of Disease Activity (PGADA) and (B) SF-36 Physical Component Summary (PCS) scores to Week 24 (OC)



Full analysis set. PGADA scores range from 0–100 (higher scores indicate higher disease activity); the SF-36 PCS is a norm-based T-score with a mean (SD) of 50 (10) in the general US population where higher scores reflects better HRQoL.[7]

AE: adverse event; **axSpA:** axial spondyloarthritis; **bDMARD:** biologic disease-modifying antirheumatic drug; **BKZ:** bimekizumab; **BMI:** body mass index; **CfB:** change from baseline; **CRP:** C-reactive protein; **FPFV:** first patient first visit; **FPLV:** first patient last visit; **HAQ-DI:** Health Assessment Questionnaire-Disability Index; **HCP:** healthcare professional; **HRQoL:** health-related quality of life; **IBD:** inflammatory bowel disease; **IL:** interleukin; **LPFV:** last patient first visit; **LPLV:** last patient last visit; **MACE:** major adverse cardiovascular event; **OC:** observed case; **PGADA:** Patient Global Assessment of Disease Activity; **PsA:** psoriatic arthritis; **PsAID-12:** 12-item PsA Impact of Disease; **SD:** standard deviation; **SF-36 PCS:** 36-item Short Form Health Survey Physical Component Summary; **SJC:** swollen joint count; **TJC:** tender joint count; **tsDMARD:** targeted synthetic disease-modifying antirheumatic drug; **US:** United States; **VAS:** visual analog scale.

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Author Disclosures: XB: Speakers bureau for AbbVie, Advanz, Alexion, Alphasigma, Amgen, BMS, Celltrion, Cesas, Clarivate, Galapagos, Johnson & Johnson, Eli Lilly, MoonLake, Novartis, Peervoice, Pfizer, Roche, Sandoz, Springer, Stada, Takeda, UCB, and Zuellig; paid instructor for AbbVie, Advanz, Alexion, Alphasigma, Amgen, BMS, Celltrion, Cesas, Clarivate, Galapagos, Johnson & Johnson, Eli Lilly, MoonLake, Novartis, Peervoice, Pfizer, Roche, Sandoz, Springer, Stada, Takeda, UCB, and Zuellig; consultant for AbbVie, Advanz, Alexion, Alphasigma, Amgen, BMS, Celltrion, Cesas, Clarivate, Galapagos, Johnson & Johnson, Eli Lilly, MoonLake, Novartis, Peervoice, Pfizer, Roche, Sandoz, Springer, Stada, Takeda, UCB, and Zuellig; grant/research support from AbbVie, Celltrion, Janssen, MoonLake, and Novartis. **UK:** Grant and research support and consultancy fees from AbbVie, Amgen, Biocad, Biogen, BMS, Chugai, Eli Lilly, Fresenius, GBA, Gilead, Grünenthal, GSK, Hexal, Janssen, MSD, Novartis, onkowissen.de, Pfizer, Roche, UCB, and Viatris. **KdV:** Speakers bureau for AbbVie, Alphasigma, Amgen, BMS, Galapagos, Johnson & Johnson, Eli Lilly, Novartis, and UCB; consultant for AbbVie, Alphasigma, Amgen, BMS, Galapagos, Johnson & Johnson, Eli Lilly, MoonLake, Novartis, Roche, Sandoz. **AR-W:** Speaker fees from AbbVie, Amgen, Biocon, Biogen, BMS, Chugai, Fresenius-Kabi, Johnson & Johnson, Eli Lilly, Nordic-Pharma, Novartis, Pfizer, UCB, and Viatris; consultant for AbbVie, Celltrion, Johnson & Johnson, Eli Lilly, Nordic Pharma, Novartis, Pfizer, Sandoz, and UCB. **JRG:** Speaker for AbbVie, Eli Lilly, Johnson & Johnson, Novartis, and UCB; consultant for AbbVie, Johnson & Johnson, Novartis, and UCB; grant/research support from Novartis, Johnson & Johnson, and Pfizer. **JAW:** Consultant for/grant support from AbbVie, Amgen, Eli Lilly, Janssen, Merck, Novartis, Pfizer, Spyre, and UCB. **DP:** Speaker for AbbVie, BMS, Eli Lilly, MSD, Novartis, Pfizer, and UCB; consultant for AbbVie, Biocad, Eli Lilly, Gilead, GSK, MSD, MoonLake, Novartis, Pfizer, Samsung Bioepis, and UCB; grant/research support from AbbVie, Eli Lilly, MSD, Novartis, and Pfizer. **DN:** Research support from AbbVie, BMS, Eli Lilly, Gilead, Incannex, Janssen, Novartis, Pfizer, Servatus, Sun Pharma, and UCB; advisory board or speaker fees from AbbVie, AstraZeneca, Janssen, Novartis, Pfizer, Sandoz, and UCB. **MO, FC, M-AB, HB, JL, RB:** Employees and shareholders of UCB. **PO:** Employee of UCB. **WT:** Research grants, consulting fees, speaking fees and/or honoraria from AbbVie, Amgen, BMS, Celgene, Eli Lilly, GSK, Janssen, MSD, Novartis, Ono Pharma, Pfizer, Takeda, and UCB. **Presenter Disclosures: RP:** Employee of UCB. **Acknowledgments:** We would like to thank the patients in addition to all the investigators and their teams who contributed to this study. The authors acknowledge Heather Edens, PhD, UCB, and Lyes Derouiche, PhD, UCB, for publication coordination, Orla Woodward, PhD, Costello Medical, London, UK for medical writing and editorial assistance, and the Costello Medical Creative team for design support. This study was funded by UCB. All costs associated with development of this poster were funded by UCB.

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Link expiration: August 15, 2026