An Interim Analysis of Health-Related Quality of Life Outcomes from an International Multicentre Observational Study in Patients with Axial Spondyloarthritis Initiating Bimekizumab in Real-World Clinical Practice

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Objective

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

Background

- AxSpA 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 non-radiographic (nr-) and radiographic (r-)axSpA.[2,3]
  - Improvements in HRQoL outcomes have been reported to 3 years.[2,4]
- BKZ was approved for the treatment of axSpA and psoriatic arthritis (PsA) in Europe in June 2023 and in the United States (US) in September 2024. 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 axSpA or PsA 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 axSpA and PsA in Europe.[5]
- Adult patients with active axSpA or PsA who newly initiated BKZ in routine clinical practice who consented to participate were included.
- The primary outcome of the SPEAK study for patients with axSpA was change from baseline in Assessment of SpondyloArthritis international Society Health Index (ASAS HI) to Week 52.
- This planned interim analysis based on data to April 2, 2025 (~50% enrollment) reports the following outcomes for patients with axSpA up to 24 weeks as observed case:
  - ASAS HI (0–17): total score and individual items
  - Patient Global Assessment of Disease Activity (PGADA; 0–10 [rescaled to derive ASDAS])
  - 36-Item Short Form Survey Physical Component Summary (SF-36 PCS).
- Other exploratory clinical outcomes were assessed but not available for this data cut.
- Baseline characteristics of patients with axSpA prescribed BKZ are reported.
- Adverse events (AEs) are also reported to 24 weeks for patients with axSpA.

Results

- By April 2025, baseline characteristics were available for 197 patients with axSpA (nr-axSpA: 78; r-axSpA: 119; **Table**).
  - Overall, 38 patients (19.3%) were biologic/targeted synthetic disease-modifying antirheumatic drug (b/tsDMARD)-naïve, 56 (28.4%) had 1 previous b/tsDMARD, 42 (21.3%) had 2 previous b/tsDMARDs, and 61 (31.0%) had ≥3 previous b/tsDMARDs.
  - Patients previously treated with ≥2 b/tsDMARDs had a greater disease duration than patients previously treated with <2 b/tsDMARDs prior to initiating BKZ treatment.
- Improvements in ASAS HI were observed to 24 weeks, with a mean (SD) change from baseline (CfB) of −1.6 (3.0) at Week 24 (Figure 2A; baseline values in **Table**).
  - Improvements were observed across almost all ASAS HI individual items to Week 24 (**Figure 2B**).
- PGADA improved to Week 24 (mean [SD] CfB: −1.0 [2.5]) as did SF-36 PCS (mean [SD] CfB: +5.7 [7.3]; **Figure 3**).
- AEs were reported in 62.9% of patients with axSpA; drug-related AEs were reported in 33.0% of patients with axSpA.
  - Three cases of uveitis were reported by three patients (1.5%).
  - Of 197 patients, there were 16 cases of Candida infections in 15 patients (7.6%), including 12 cases of oral candidiasis, six of which led to BKZ discontinuation.
  - Eight patients (4.1%) reported serious infections, one of which was a serious Candida infection.
  - One patient (0.5%) reported a case of inflammatory bowel disease (IBD).
  - There were no cases of suicidal ideation or behavior.
  - One patient (0.3%) reported a major adverse cardiovascular event (MACE; myocardial infarction), deemed not drug related.

Conclusions

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

These real-world findings complement data from phase 3 trials, for patient-reported outcomes related to HRQoL and disease activity, as well as safety.[2]

Summary

The aim of this study was to evaluate patient-reported symptoms 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 **axSpA**.

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

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

ASAS HI (mean CfB)	PGADA[a] (mean CfB)	SF-36 PCS (mean CfB)
−1.6	−1.0	+5.7

No new safety signals were identified.

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

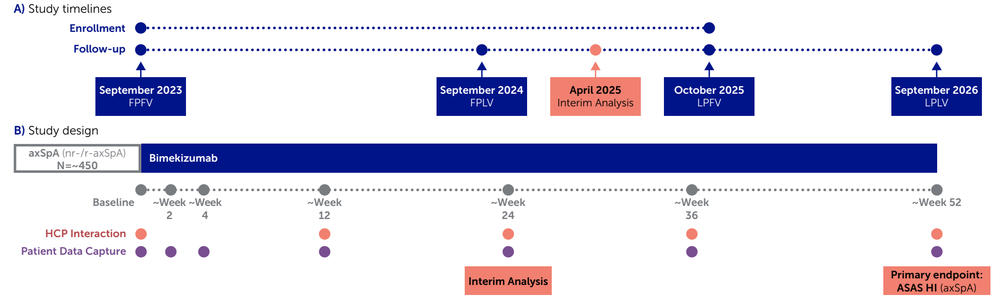
[a] The original PGADA 0–100-point visual analog scale (VAS) was rescaled to 0–10 and used to derive ASDAS.

Table Baseline characteristics of patients with axSpA in the SPEAK study

Characteristic Mean (SD) unless otherwise stated	Previous b/tsDMARD exposure: b/tsDMARD naive n=38	1 b/tsDMARD n=56	≥2 b/tsDMARDs n=103	Total N=197
Age, years	38.8 (10.7)	46.6 (13.0)	47.4 (12.4)	45.5 (12.7)
Sex, male, n (%)	20 (52.6)	27 (48.2)	45 (43.7)	92 (46.7)
BMI, kg/m²	28.6 (5.9)	28.8 (8.9) [54]	27.8 (6.0) [102]	28.2 (6.9) [194]
nr-axSpA, n (%)	18 (47.4)	23 (41.1)	37 (35.9)	78 (39.6)
r-axSpA, n (%)	20 (52.6)	33 (58.9)	66 (64.1)	119 (60.4)
Time since first symptoms, years	9.1 (7.5)	13.1 (10.6)	16.1 (11.9) [99]	13.9 (11.1) [193]
Time since diagnosis, years	3.7 (5.6)	7.6 (8.8)	11.0 (9.6) [101]	8.6 (9.1) [195]
History of uveitis, n (%)	3 (7.9)	12 (21.4)	16 (15.5)	31 (15.7)
History of IBD, n (%)	0 (0)	0 (0)	3 (2.9)	3 (1.5)
CRP, mg/L, median (min-max)	5.3 (0.3–62.0) [30]	4.0 (0.5–93.0) [40]	3.9 (0.0–90.0) [90]	4.0 (0.0–93.0) [160]
ASAS HI	7.7 (3.5)	8.8 (3.9) [46]	9.6 (3.7) [92]	9.0 (3.8) [176]
SF-36 PCS	37.5 (7.1) [37]	35.7 (6.6) [45]	33.7 (7.3) [84]	35.1 (7.2) [166]
PGADA	5.4 (1.8)	5.9 (2.0) [46]	6.3 (1.9) [92]	6.0 (1.9) [176]
ASDAS	3.2 (1.0) [29]	3.0 (0.9) [31]	3.2 (0.8) [79]	3.1 (0.9) [139]
BASDAI total score	5.5 (1.9) [37]	5.7 (1.7) [46]	6.0 (1.8) [92]	5.8 (1.8) [175]

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]. PGADA in this study was assessed using a 0–100 VAS. Data presented here are the rescaled score used to derive ASDAS and which ranges from 0 to 10.

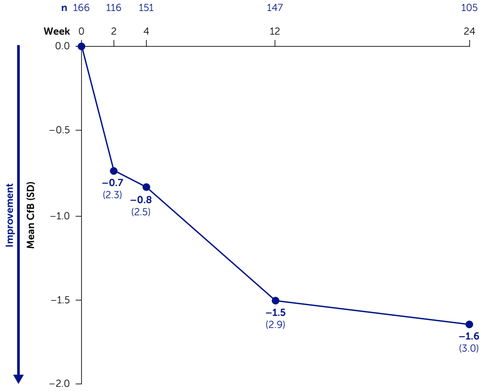
Figure 1 Study timelines and design



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

Figure 2 Improvements from baseline in (A) Assessment in SpondyloArthritis international Society Health Index (ASAS HI) total score and (B) across all ASAS HI individual items to Week 24 (OC)

A) ASAS HI total score



B) Proportion of patients responding 'I agree' to individual ASAS HI items to Week 24[a]

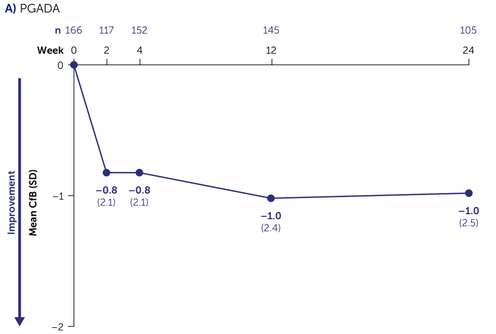
	Baseline (n=166)	Week 2 (n=116)	Week 4 (n=151)	Week 12 (n=147)	Week 24 (n=105)
Item 1: Pain sometimes disrupts my normal activities	91.0	81.9	83.4	74.8	80.0
Item 2: I find it hard to stand for long	89.2	86.2	78.1	81.6	73.3
Item 5: I am often exhausted	85.5	85.3	82.8	76.2	79.0
Item 3: I have problems running	85.5	79.3	80.1	73.5	70.5
Item 16: I sleep badly at night	85.5	73.3	70.2	66.7	70.5
Item 6: I am less motivated to do anything that requires physical effort	68.1	61.2	64.9	52.4	53.3
Item 13: I often get frustrated	63.9	56.9	59.6	57.1	57.1
Item 11: I find it hard to concentrate	59.0	56.9	55.0	46.9	51.4
Item 12: I am restricted in traveling because of my mobility	51.2	52.6	49.0	47.6	40.0
Item 15: I have experienced financial changes because of my rheumatic disease	38.0	37.9	39.7	42.9	42.9
Item 7: I have lost interest in sex	34.3	31.0	28.5	25.9	30.5
Item 9: I am finding it hard to make contact with people	28.3	26.7	27.2	20.4	22.9
Item 17: I cannot overcome my difficulties	27.7	25.0	30.5	25.9	29.5
Item 14: I find it difficult to wash my hair	25.3	19.8	17.9	17.0	14.3
Item 8: I have difficulty operating the pedals in my car	24.1	19.0	16.6	17.0	12.4
Item 4: I have problems using toilet facilities	22.3	14.7	17.9	14.3	10.5
Item 10: I am not able to walk outdoors on flat ground	15.7	9.5	11.9	10.9	8.6

>90–≤100%
>80–≤90%
>70–≤80%
>60–≤70%
>50–≤60%
>40–≤50%
>30–≤40%
>20–≤30%
>10–≤20%
>0–≤10%

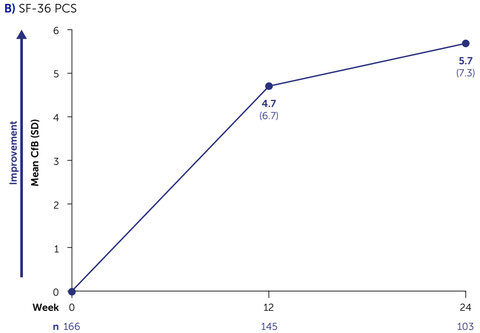
Full analysis set. **[a]** Items are ordered by decreasing percentage of patients reporting 'I agree' at baseline. Patients with missing data at each timepoint were not included in the analysis. Dates are approximate depending on how close to baseline the first dose was received.

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)

A) PGADA



B) SF-36 PCS



Full analysis set. Values were rounded to 1 decimal place. The SF-36 PCS is a norm-based T-score with mean (SD) of 50 (10) in the US general population,[7] where higher scores reflect better HRQoL. PGADA in this study was assessed using a 0–100 VAS (higher scores indicate higher disease activity); data presented here are the rescaled scores used to derive ASDAS and which range from 0 to 10. Dates are approximate depending on how close to baseline the first dose was received.

AE: adverse event; **ASAS:** Assessment in SpondyloArthritis international Society; **ASDAS:** Axial Spondyloarthritis Disease Activity Score; **axSpA:** axial spondyloarthritis; **BASDAI:** Bath Ankylosing Spondylitis Disease Activity Index; **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; **HCP:** healthcare professional; **HI:** health index; **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; **nr-axSpA:** non-radiographic axial spondyloarthritis; **OC:** observed case; **PCS:** Physical Component Summary; **PGADA:** Patient Global Assessment of Disease Activity; **PsA:** psoriatic arthritis; **r-axSpA:** radiographic axial spondyloarthritis; **SD:** standard deviation; **SF-36:** 36-Item Short-Form Health Survey; **tsDMARD:** targeted synthetic disease-modifying anti rheumatic drug; **US:** United States; **VAS:** visual analog scale.

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Author Contributions: Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: **XB**, **UK**, **KdV**, **AR-W**, **JRG**, **JAW**, **DP**, **DN**, **MO**, **FC**, **M-AB**, **HB**, **RB**, **PO**, **CdlL**, **WT**; Drafting of the publication, or reviewing it critically for important intellectual content: **XB**, **UK**, **KdV**, **AR-W**, **JRG**, **JAW**, **DP**, **DN**, **MO**, **FC**, **M-AB**, **HB**, **RB**, **PO**, **CdlL**, **WT**; Final approval of the publication: **XB**, **UK**, **KdV**, **AR-W**, **JRG**, **JAW**, **DP**, **DN**, **MO**, **FC**, **M-AB**, **HB**, **RB**, **PO**, **CdlL**, **WT**. **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; 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; consulting 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, 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. **FC**, **M-AB**, **MO**, **HB**, **RB**: Employees and stockholders of UCB. **PO:** Employee of UCB. **CdlL:** Consultant to 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 Celia Menckeberg, PhD, UCB, Breda, The Netherlands, for publication coordination, Georgina Gregory, PhD, Costello Medical, Manchester, 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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