Bimekizumab Demonstrated Sustained Efficacy and Safety Across the Full Spectrum of Axial Spondyloarthritis: 3-Year Results from Two Phase 3 Studies and Their Open-Label Extension

Xenofon Baraliakos,[1] Atul Deodhar,[2] Désirée van der Heijde,[3] Filip Van den Bosch,[4] Marina Magrey,[5] Walter P. Maksymowych,[6] Tetsuya Tomita,[7] Huji Xu,[8] Diana Voiniciuc,[9] Chetan Prajapati,[9] Myriam Manente,[10] Alexander Marten,[11] Lianne S. Gensler[12]

[1]Rheumazentrum Ruhrgebiet Herne, Ruhr-University Bochum, Bochum, Germany; [2]Oregon Health & Science University, Division of Arthritis and Rheumatic Diseases, Portland, USA; [3]Leiden University Medical Center, Department of Rheumatology, Leiden, Netherlands; [4]Ghent University and VIB Center for Inflammation Research, Department of Internal Medicine and Pediatrics, Ghent, Belgium; [5]Case Western Reserve University, University Hospitals, Cleveland, USA; [6]University of Alberta, Department of Medicine, Alberta, Canada; [7]Graduate School of Health Science, Morinomiya University of Medical Science, Osaka, Japan; [8]Shanghai Changzheng Hospital, Department of Rheumatology and Immunology, Affiliated to Second Military Medical University, Shanghai, People's Republic of China; [9]UCB, Slough, UK; [10]UCB, Brussels, Belgium; [11]UCB, Monheim am Rhein, Germany; [12]University of California, Department of Medicine, Division of Rheumatology, San Francisco, USA

POS0788

Objective

To assess the 3-year efficacy and safety of bimekizumab (BKZ) across the full disease spectrum of axial spondyloarthritis (axSpA).

Background

- BKZ is a monoclonal IgG1 antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A.
- BKZ has demonstrated consistent and sustained efficacy to 2 years in patients with non-radiographic (nr-) and radiographic (r-)axSpA in the parallel phase 3 studies BE MOBILE 1 and 2, respectively, and their combined open-label extension (OLE), and to 5 years in the phase 2b BE AGILE study in patients with r-axSpA.[1–3]
- Here, we report 3-year efficacy and safety data from the BE MOBILE 1 and 2 studies, and their ongoing combined OLE.

Methods

- Study designs for BE MOBILE 1 (nr-axSpA; NCT03928704) and BE MOBILE 2 (r-axSpA; NCT03928743) have been reported previously.[4] All patients received subcutaneous BKZ 160 mg every 4 weeks (Q4W) from Week 16; eligible patients could enter the OLE (BE MOVING; NCT04436640) at Week 52.
- Efficacy outcomes are reported up to 3 years for the randomised set (164 weeks [112-week OLE]; N=586).
  - Binary outcomes were assessed using modified non-responder imputation (mNRI) or non-responder imputation (NRI; patients not enrolled in the OLE were imputed as non-responders), continuous outcomes using multiple imputation (MI) and additional analyses using observed case (OC).
- MRI outcomes were assessed in the subset of patients in the MRI sub-studies. At baseline and Weeks 52, 104 and 164, MRI inflammation was evaluated using Spondyloarthritis Research Consortium of Canada (SPARCC) sacroiliac joint (SIJ) score (nr-axSpA only) and Berlin spine score (r-axSpA only) in a single reading campaign, with readers blinded to timepoint.
  - MRI remission was defined as achievement of SPARCC SIJ <2 or Berlin spine score ≤2 in patients with SPARCC SIJ ≥2 or Berlin spine score >2 at baseline, respectively.
- Pooled safety data are reported to 3 years for all patients who received ≥1 BKZ dose (N=574).

Results

Patients

- Of 586 randomised patients (nr-axSpA: 254; r-axSpA: 332), 494 (84.3%) entered the OLE at Week 52, with 425/494 (86.0%) completing Week 164 (nr-axSpA: 175; r-axSpA: 250) by September 2024. 10 patients were ongoing in the OLE at the time of the data-cut off.
- Of those who discontinued the main study or the OLE prior to Week 164 (127/586; 21.7%), most withdrew consent (57/127; 44.9%) or had an adverse event (40/127; 31.5%). 24/586 patients (4.1%) completed the main study but did not enter the OLE.

Efficacy

- Efficacy was sustained from 2 years to 3 years across nr-axSpA and r-axSpA populations (**Table 1**; **Figure 1–3**).[1]
- ASAS40 responses were maintained from Week 104 to Week 164 (**Figure 1**).
- At Week 164, ASDAS low disease activity (LDA; <2.1) was achieved by approximately 60% of patients with nr-axSpA and r-axSpA (**Figure 2**). ASDAS inactive disease (ID; <1.3) and ASAS partial remission were achieved by approximately a third of patients at Week 164 (**Table 1**; **Figure 2**).
- BKZ treatment led to sustained control of MRI inflammation from Week 104 to Week 164. At Week 164, 59.4% and 77.8% of patients achieved SPARCC SIJ and Berlin spine remission, respectively (**Figure 3**).

Safety

- Safety data to 3 years, including key safety topics of interest, are presented in **Table 2**.
- To Week 164, 90.4% (519/574) of patients with axSpA had ≥1 treatment-emergent adverse event (TEAE) on BKZ.
- Similar to Week 104, the most frequent TEAEs by preferred term (exposure-adjusted incidence rate per 100 patient-years [EAIR/100 PY]; MedDRA v19.0) to Week 164 were SARS-CoV-2 infection (COVID-19; 14.5), nasopharyngitis (9.9) and upper respiratory tract infection (5.8).
- No deaths or adjudicated major adverse cardiovascular events were reported.
- Of the 131 (22.8%; EAIR/100 PY: 9.4) patients who had fungal infections, 80 had *Candida* infections (13.9%; EAIR/100 PY: 5.3). Almost all *Candida* infections were mucocutaneous and mild/moderate, with one case each of severe oral and severe oesophageal infection; none were serious or systemic – 6 led to study discontinuation (oral [n=5] and oesophageal [n=1]).
- Hepatic events occurred in 74 patients (12.9%; EAIR/100 PY: 4.9); all were non-serious, and the majority were transient liver function test elevations or abnormalities – none led to permanent treatment discontinuation. There were no confirmed cases of Hy's law.
- No new safety signals were observed from Week 104 to Week 164; most EAIRs of TEAEs were similar between these timepoints.

Conclusions

Patients treated with bimekizumab demonstrated sustained clinical response and control of inflammation through 3 years across nr-axSpA and r-axSpA. No new safety signals were observed; bimekizumab was well tolerated with a favourable safety profile. These results support bimekizumab as a durable long-term treatment option across the full disease spectrum of axSpA.

Summary

Bimekizumab showed **sustained efficacy**, across the full disease spectrum of axSpA, **up to 3 years**. At Week 164:

~60% of patients achieved ASDAS <2.1

>59% and **>77%** of patients enrolled in the MRI sub-studies achieved SPARCC SIJ and Berlin spine remission, respectively[a]

No new safety signals were detected

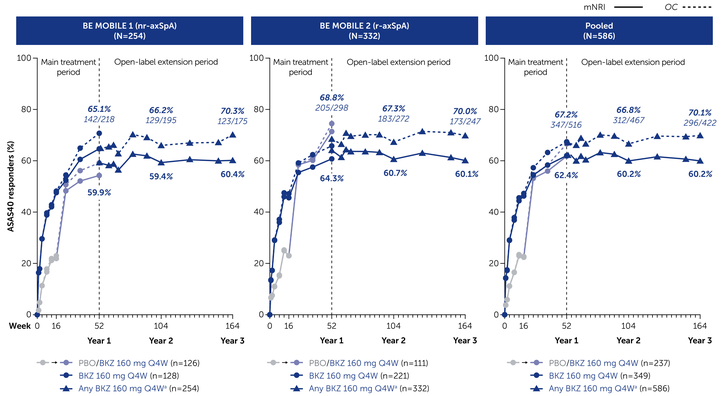
[a] Includes patients with recorded MRI inflammation data at baseline, Week 52, 104 and 164. MRI remission defined as MRI SIJ SPARCC <2 (nr-axSpA only) or Berlin MRI spine score ≤2 (r-axSpA only), in those with baseline MRI SIJ SPARCC score ≥2 or Berlin MRI spine score >2, respectively.

Table 1 Efficacy at 3 years (Week 164)

		BE MOBILE 1 (nr-axSpA) BKZ 160 mg Q4W[a] N=254	BE MOBILE 2 (r-axSpA) BKZ 160 mg Q4W[a] N=332
ASAS40	[NRI], n (%)	123 (48.4)	173 (52.1)
	[mNRI], %	60.4	60.1
	[OC], n/N (%)	123/175 (70.3)	173/247 (70.0)
ASAS partial remission	[NRI], n (%)	70 (27.6)	111 (33.4)
	[mNRI], %	32.4	36.5
ASDAS [MI]	Mean at baseline (SE)	3.7 (0.1)	3.7 (0.0)
	Mean CfB at Week 164 (SE)	−1.8 (0.1)	−1.8 (0.1)
ASDAS ID	[MI], %	28.6	31.0
BASDAI [MI]	Mean at baseline (SE)	6.8 (0.1)	6.5 (0.1)
	Mean CfB at Week 164 (SE)	−3.9 (0.2)	−3.9 (0.1)
Total resolution of enthesitis[b]	[NRI], n (%)	89 (47.8)[c]	112 (56.3)[d]
	[mNRI], %	53.0[c]	62.6[d]
MRI SPARCC SIJ[e] [OC]	Mean at baseline (SD)	9.5 (11.8)[f]	-
	Mean CfB at Week 164 (SD)	−7.5 (11.1)[f]	-
	Remission,[g] n (%)	19 (59.4)[h]	-
MRI Berlin spine[i] [OC]	Mean at baseline (SD)	-	3.7 (4.7)[j]
	Mean CfB at Week 164 (SD)	-	−2.8 (4.3)[j]
	Remission,[k] n (%)	-	28 (77.8)[l]

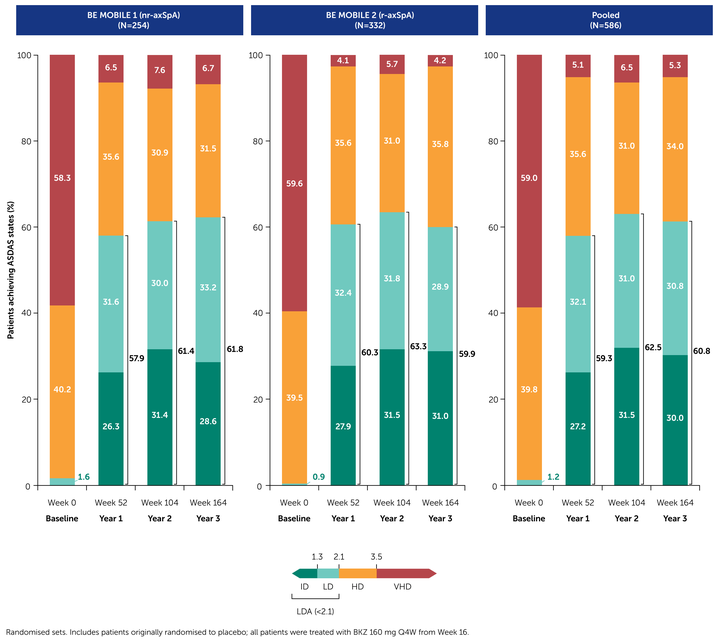
Randomised sets. mNRI considered all visits following discontinuation due to adverse events or lack of efficacy as non-response; all other missing data were imputed with MI and the response derived from the imputed values. **[a]** Includes patients originally randomised to placebo; all patients were treated with BKZ 160 mg Q4W from Week 16; **[b]** MASES>0 in patients with MASES >0 at baseline; **[c]** n=186; **[d]** n=199; **[e]** In patients enrolled in the MRI sub-study with MRI assessments at each of the 4 timepoints (Week 0, 52, 104 and 164; nr-axSpA only); **[f]** n=51; **[g]** Defined as SPARCC SIJ score <2, in patients with SPARCC SIJ score ≥2 at baseline and MRI assessments at the remaining 3 timepoints (Week 52, 104 and 164) in the MRI sub-study (nr-axSpA only); **[h]** n=32; **[i]** In patients enrolled in the MRI sub-study with MRI assessment at each of the 4 timepoints (Week 0, 52, 104 and 164; r-axSpA only); **[j]** n=74; **[k]** Defined as Berlin spine ≤2, in patients with Berlin spine score >2 at baseline and MRI assessments at the remaining 3 timepoints (Week 52, 104 and 164) in the MRI sub-study (r-axSpA only); **[l]** n=36.

Figure 1 Achievement of ASAS40 to 3 years (mNRI, OC)



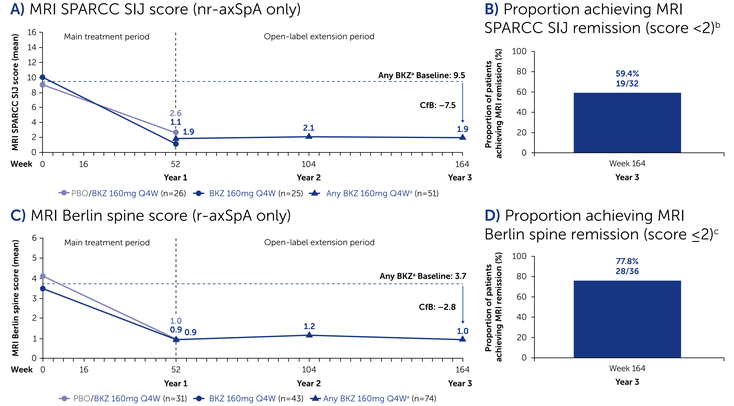
Randomised sets. mNRI considered all visits following discontinuation due to adverse events or lack of efficacy as non-response; all other missing data were imputed with MI and the response derived from the imputed values. Data labels at Week 52 are related to the Any BKZ group. **[a]** Includes patients originally randomised to placebo; all patients were treated with BKZ 160 mg Q4W from Week 16.

Figure 2 ASDAS states over time (MI)



Randomised sets. Includes patients originally randomised to placebo; all patients were treated with BKZ 160 mg Q4W from Week 16.

Figure 3 Absolute MRI inflammation scores and remission rates to 3 years (OC)



Only study participants enrolled in the respective MRI sub-study with recorded data at each of the timepoints shown are included in this analysis. MRI remission is defined as having a SPARCC <2 or Berlin MRI spine score ≤2. **[a]** Includes patients originally randomised to placebo; all patients were treated with BKZ 160 mg Q4W from Week 16; **[b]** SPARCC SIJ score <2, in patients with SPARCC SIJ score ≥2 at baseline and MRI assessments at the remaining 3 timepoints (Week 52, 104 and 164) in the MRI sub-study (nr-axSpA only); **[c]** Berlin spine ≤2, in patients with Berlin spine score >2 at baseline and MRI assessments at the remaining 3 timepoints (Week 52, 104 and 164) in the MRI sub-study (r-axSpA only).

Table 2 Safety overview to 3 years (Week 164)

n (%) [EAIR/100 PY]	BKZ 160 mg Q4W[a] (N=574; 1,664.7 PY)
Any TEAE	519 (90.4) [139.0]
Serious TEAEs	76 (13.2) [4.9]
Study discontinuation due to TEAEs	36 (6.3) [2.2]
Drug-related TEAEs[b]	290 (50.5) [28.7]
Severe TEAEs	47 (8.2) [3.0]
Death	0
Most frequent TEAEs[c]	
SARS-CoV-2 (COVID-19) infection[d]	195 (34.0) [14.5]
Nasopharyngitis	139 (24.2) [9.9]
Upper respiratory tract infection	88 (15.3) [5.8]
Safety topics of interest	
Serious infections	20 (3.5) [1.2]
Opportunistic infections	14 (2.4) [0.9]
Active tuberculosis	0
Fungal infections	131 (22.8) [9.4]
Candida infections	80 (13.9) [5.3]
Oral candidiasis	66 (11.5) [4.3]
Fungal infections NEC	52 (9.1) [3.3]
Tinea infections	21 (3.7) [1.3]
Neutropenia[e]	10 (1.7) [0.6]
Serious hypersensitivity reactions	0
Administration/injection site reactions[f]	26 (4.5) [1.6]
Adjudicated suicidal ideation and behavior	2 (0.3) [0.1]
Adjudicated MACE	0
Elevated liver enzymes[g]	55 (9.6) [3.6]
>3X ULN ALT or AST	31 (5.4) [1.9]
Malignancies, excluding non melanoma skin cancer	8 (1.4) [0.5]
Adjudicated IBD (definite or probable)	9 (1.6) [0.5]
With prior history[h]	1 (12.5) [4.5]
Without prior history	8 (1.4) [0.5]
Uveitis[i]	25 (4.4) [1.5]
With prior history	18 (18.9) [7.0]
Without prior history	7 (1.5) [0.5]

Safety set. Includes all data available up to the last Week 164 visit at the time of the data cut (September 2024). MedDRA (v19.0). **[a]** Includes patients originally randomised to placebo; all patients were treated with BKZ 160 mg Q4W from Week 16; **[b]** Per study investigator assessment; **[c]** Reported by preferred term in order of decreasing frequency; **[d]** 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"; **[e]** Includes the preferred term neutropenia; **[f]** Includes the high-level terms "administration site reactions NEC" and "injection site reactions"; **[g]** Elevated liver enzymes included 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; **[h]** 8/574 (1.4%) patients had a medical history of IBD at baseline; **[i]** Includes the preferred terms autoimmune uveitis, uveitis, iridocyclitis and iritis; **[j]** 95/574 (16.6%) patients had a medical history of uveitis at baseline.

ALT: alanine aminotransferase; **ASAS:** Assessment of SpondyloArthritis international Society; **ASAS40:** ASAS 40% response; **ASDAS:** Axial Spondyloarthritis Disease Activity Score; **AST:** aspartate aminotransferase; **axSpA:** axial spondyloarthritis; **BASDAI:** Bath Ankylosing Spondylitis Disease Activity Index; **BKZ:** bimekizumab; **CfB:** change from baseline; **EAIR:** exposure-adjusted incidence rate; **HD:** high disease; **IBD:** inflammatory bowel disease; **ID:** inactive disease; **LD:** low disease; **LDA:** low disease activity; **MACE:** major adverse cardiovascular event; **MASES:** Maastricht Ankylosing Spondylitis Enthesitis Score; **MI:** multiple imputation; **mNRI:** modified non-responder imputation; **MRI:** magnetic resonance imaging; **NEC:** not elsewhere classified; **nr-axSpA:** non-radiographic axSpA; **NRI:** non-responder imputation; **OC:** observed case; **PBO:** placebo; **PY:** patient-years; **Q4W:** every 4 weeks; **r-axSpA:** radiographic axSpA; **SD:** standard deviation; **SE:** standard error; **SIJ:** sacroiliac joint; **SPARCC:** Spondyloarthritis Research Consortium of Canada; **TEAE:** treatment-emergent adverse event; **ULN:** upper limit of normal; **VHD:** very high disease.

References: [1]Baraliakos X. Rheumatology (Oxford) 2025;keaf009; [2]Deodhar A. RMD Open 2025;11:e005081; [3]Baraliakos X. Ann Rheum Dis 2024;83:199–213; [4]van der Heijde D. Ann Rheum Dis 2023;82:515–26.

Author Contributions: Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: **XB**, **AD**, **DvdH**, **FVdB**, **MMag**, **WPM**, **TT**, **HX**, **DV**, **CP**, **MMan**, **AM**, **LSG**. Drafting of the publication, or reviewing it critically for important intellectual content: **XB**, **AD**, **DvdH**, **FVdB**, **MMag**, **WPM**, **TT**, **HX**, **DV**, **CP**, **MMan**, **AM**, **LSG**. Final approval of the publication: **XB**, **AD**, **DvdH**, **FVdB**, **MMag**, **WPM**, **TT**, **HX**, **DV**, **CP**, **MMan**, **AM**, **LSG**. **Author Disclosures: XB:** Speakers bureau for AbbVie, Advanz, Alexion, Alphasigma, Amgen, BMS, Cesas, Celltrion, Clarivate, Galapagos, JbJ, Lilly, MoonLake, Novartis, Peervoice, Pfizer, Roche, Sandoz, Springer, Stada, Takeda, UCB and Zuellig; consultant for AbbVie, Advanz, Alexion, Alphasigma, Amgen, BMS, Cesas, Celltrion, Clarivate, Galapagos, JbJ, Lilly, MoonLake, Novartis, Peervoice, Pfizer, Roche, Sandoz, Springer, Stada, Takeda, UCB and Zuellig; grant/research support from AbbVie, Celltrion, Janssen, MoonLake and Novartis. **AD:** Speaker for Eli Lilly, JbJ, Novartis, Pfizer and UCB; consultant for BMS, Eli Lilly, JbJ, MoonLake, Novartis, Pfizer and UCB; grant/research support from BMS, Eli Lilly, JbJ, Novartis, Pfizer and UCB. **DvdH:** Consultant for AbbVie, Alfasigma, ArgenX, BMS, Eli Lilly, GreyWolf Therapeutics, Janssen, Novartis, Pfizer, Takeda and UCB; associate editor Annals Rheumatic Diseases, editorial board member Journal of Rheumatology and RMD Open, Advisor Assessment Axial Spondyloarthritis international Society and director of Imaging Rheumatology BV. **FVdB:** Consultancy fees from AbbVie, Alfasigma, Amgen, Eli Lilly, GreyWolf Therapeutics, Janssen, Novartis, Pfizer and UCB; speakers bureau fees from AbbVie, Amgen, Janssen, Merck, Novartis, Pfizer and UCB. **MMag:** Consultancy fees from AbbVie, BMS, Eli Lilly, Novartis, Pfizer and UCB; research grants from AbbVie, BMS and UCB. **WPM:** Honoraria/consulting fees from AbbVie, BMS, Boehringer-Ingelheim, Celgene, Eli Lilly, Galapagos, Janssen, Novartis, Pfizer and UCB; research grants from AbbVie, BMS, Eli Lilly, Galapagos, Pfizer and UCB; educational grants from AbbVie, Novartis and Pfizer; Chief Medical Officer for CARE ARTHRITIS. **TT:** Consultancy fees from AbbVie, Eli Lilly, Gilead, Novartis, Pfizer; speaker fees from AbbVie, Astellas, Bristol-Myers Squibb, Eisai, Eli Lilly, Janssen, Kyowa Kirin, Mitsubishi-Tanabe, Novartis and Pfizer. **HX:** Speaker for AbbVie, Janssen, Novartis, Pfizer and UCB; consultant for AbbVie, Beigene, BioMap, IASO, Pfizer and UCB; clinical investigator for Peking-Tsinghua Center for Life Sciences. **DV:** Former contractor for UCB and former employee of Veramed. **CP:** Contractor for UCB and employee of Veramed. **MMan:** Employee and shareholder of UCB. **AM:** Employee of UCB. **LSG:** Grants from UCB paid to institution; consulting fees from Acelyrin, Eli Lilly, Janssen, Novartis, Pfizer and UCB. **Acknowledgements:** We would like to thank the patients and their caregivers in addition to all the investigators and their teams who contributed to this study. The authors acknowledge Celia Menckeberg, PhD, UCB, for publication coordination, Syaujina Fakhira, MSc, Costello Medical, Cambridge, 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.

To receive a copy of this poster, scan the QR code.
Link expiration:
12 September 2025