Achievement of Remission Defined by Absence of Objective Signs of Inflammation Versus ASDAS ID in Patients with Active Axial Spondyloarthritis Treated with Bimekizumab: 52-Week Results from Two Phase 3 Studies

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Objective

To compare achievement of remission defined using objective signs of inflammation (OSI) versus Axial Spondyloarthritis Disease Activity Score <1.3 (ASDAS Inactive Disease [ID]) across the full disease spectrum of patients with axial spondyloarthritis (axSpA) treated with bimekizumab (BKZ).

Background

- axSpA is a chronic inflammatory disease affecting the spine and sacroiliac joints (SIJ), encompassing both non-radiographic (nr-) and radiographic (r-)axSpA.
- BKZ, a monoclonal IgG1 antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A, has demonstrated sustained efficacy and safety to Week 52 in patients across the full disease spectrum of axSpA in the phase 3 studies BE MOBILE 1 (nr-axSpA) and BE MOBILE 2 (r-axSpA).[1]
- Achievement of remission is a crucial treatment goal and may guide clinical decisions.[2,3]

Methods

- BE MOBILE 1 (NCT03928704) and BE MOBILE 2 (NCT03928743) comprised a 16-week double-blind, placebo-controlled period followed by a 36-week maintenance period.
  - Patients were randomized 1:1 and 2:1 in BE MOBILE 1 and 2, respectively, to subcutaneous BKZ 160 mg every 4 weeks (Q4W) or placebo, with all patients receiving BKZ 160 mg from Week 16 onwards.
- Remission of OSI was defined as MRI remission of the SIJ and spine (MRI Spondyloarthritis Research Consortium of Canada [SPARCC] SIJ score <2 and Berlin MRI spine ≤2), C-reactive protein (CRP) ≤5 mg/L, and a swollen joint count (SJC) of 0.
- The proportion of patients from the BE MOBILE 1 and 2 MRI sub-studies achieving these criteria at Week 16 and Week 52 was compared with those achieving ASDAS ID, defined as ASDAS <1.3, in the same sub-population.
- No formal statistical analyses were conducted, and observed case (OC) data are reported.

Results

Baseline Characteristics

- Of 254 and 332 patients enrolled in the overall studies, 152 and 139 patients from the MRI sub-studies of BE MOBILE 1 and 2, respectively, were included in this analysis; baseline characteristics stratified by achievement of remission of OSI at Week 16 are presented in **Table 1**.

Achievement of Remission of OSI Compared with ASDAS ID

- Across the full disease spectrum of axSpA, at Week 16, a higher proportion of BKZ-randomized patients achieved remission of OSI compared with those achieving ASDAS ID (**Figures 1–2**).
- At Week 52, a higher proportion of BKZ-randomized patients achieved remission of OSI compared with those achieving ASDAS ID.
- Placebo-randomized patients, having switched to BKZ at Week 16, showed similar proportions achieving remission of OSI compared to those achieving ASDAS ID at Week 52 (**Figures 1–2**).
- Results were consistent between patients with nr-axSpA and r-axSpA.

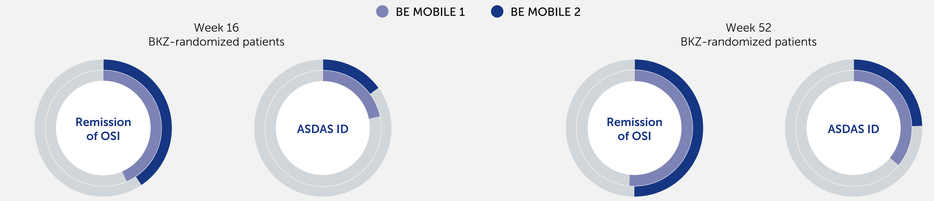
Conclusions

A higher proportion of patients receiving bimekizumab achieved remission based on OSI compared with ASDAS ID criteria across the full disease spectrum of axSpA. This highlights the potential limitations of using ASDAS ID alone to assess treatment efficacy. These findings underscore the need for further research to optimize endpoints in axSpA.

Summary

In this analysis, remission of OSI in axSpA is defined as achievement of **all three** of the following:
remission of MRI inflammation in the SIJ (SPARCC SIJ <2) and spine (Berlin spine ≤2),
normalization of CRP (CRP <=5 mg/L), and resolution of joint swelling (SJC=0)

Across the full spectrum of axSpA, treatment with **bimekizumab resulted in a higher proportion of patients achieving remission of OSI** compared with an established measure of remission, ASDAS ID

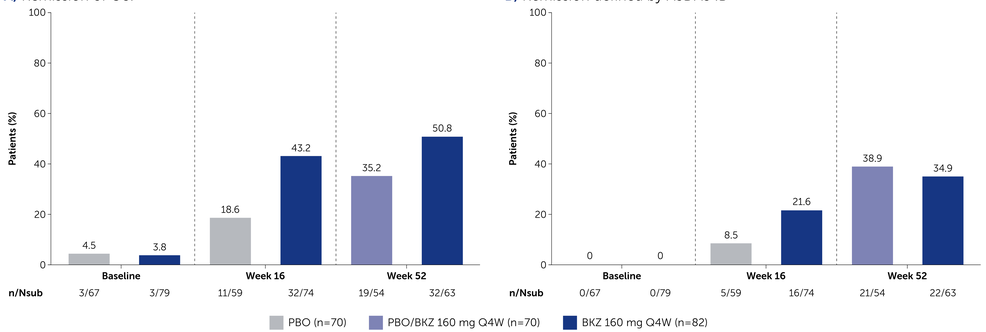


These findings **highlight the potential limitations of using ASDAS ID alone** to assess treatment efficacy and underscore the need for **further research to optimize endpoints in axSpA**

Table 1 Baseline characteristics of patients enrolled in the MRI sub-studies of BE MOBILE 1 and 2, stratified by the achievement of remission of OSI at Week 16

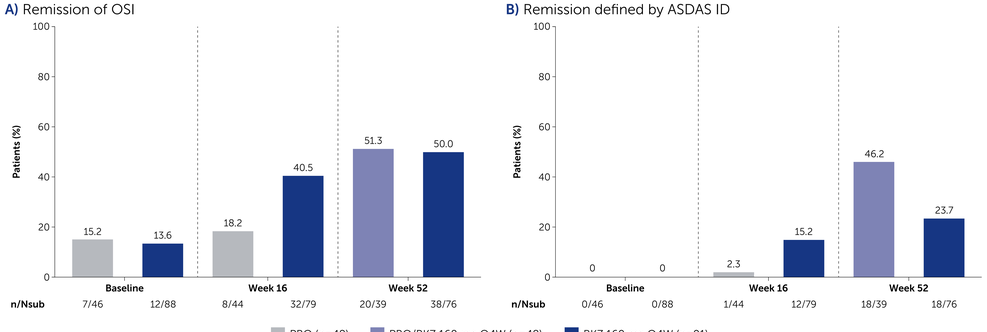
	Patients achieving remission of OSI at Week 16				Patients not achieving remission of OSI at Week 16			
	nr-axSpA		r-axSpA		nr-axSpA		r-axSpA	
	PBO n=11	BKZ 160 mg Q4W n=32	PBO n=8	BKZ 160 mg Q4W n=32	PBO n=48	BKZ 160 mg Q4W n=42	PBO n=36	BKZ 160 mg Q4W n=47
Age, years, mean (SD)	37.5 (12.0)	36.7 (10.7)	42.4 (11.4)	41.5 (12.5)	40.0 (12.1)	40.2 (12.6)	37.9 (13.3)	40.5 (12.5)
Male, n (%)	5 (45.5)	21 (65.6)	5 (62.5)	26 (81.3)	21 (43.8)	24 (57.1)	24 (66.7)	32 (68.1)
Time since first axSpA symptoms, years, mean (SD)	8.2 (7.2)	8.9 (8.4)	15.1 (8.7)	14.8 (11.0)	8.8 (9.3)	9.0 (7.9)	12.2 (9.5)	13.6 (12.0)
HLA-B27 positive, n (%)	10 (90.9)	27 (84.4)	6 (75.0)	29 (90.6)	33 (68.8)	31 (73.8)	30 (83.3)	41 (87.2)
MRI SPARCC SIJ Mean (SD) ≥2, n (%)	4.3 (4.7) 6 (54.5)	6.7 (9.0) 18 (56.3)	0.3 (0.5) 0	3.1 (4.8) 12 (37.5)	12.3 (14.3) 34 (70.8)	8.9 (10.8) 27 (64.3)	4.9 (6.6) 20 (55.6)	8.1 (10.2) 28 (59.6)
Berlin MRI spine Mean (SD) >2, n (%)	0.6 (0.8) 0	1.0 (1.7) 4 (12.5)	0.3 (0.5) 0	1.6 (2.5) 9 (28.1)	1.7 (3.1) 11 (22.9)	1.8 (2.8) 11 (26.2)	3.6 (4.3) 17 (47.2)	4.5 (5.6) 22 (46.8)
hs-CRP, (mg/L) Median (Q1, Q3) >5 mg/L, n (%)	3.9 (1.4, 19.8) 4 (36.4)	4.1 (1.5, 10.5) 15 (46.9)	2.1 (1.5, 6.6) 2 (25.0)	5.8 (1.4, 11.9) 18 (56.3)	6.2 (1.9, 14.8) 27 (56.3)	4.6 (0.7, 11.0) 20 (47.6)	7.4 (2.8, 15.0) 24 (66.7)	12.5 (4.5, 30.5) 35 (74.5)
SJC Mean (SD) ≥1, n (%)	0.1 (0.3) 1 (9.1)	0.7 (1.4) 8 (25.0)	0.4 (1.1) 1 (12.5)	0.4 (1.4) 5 (15.6)	1.4 (2.4) 18 (37.5)	1.0 (2.1) 16 (38.1)	0.2 (0.6) 5 (13.9)	1.0 (2.7) 11 (23.4)
ASDAS, mean (SD)	3.5 (0.9)	3.6 (0.8)	3.2 (0.6)	3.6 (0.7)	3.6 (0.7)	3.7 (0.8)	3.7 (0.8)	4.0 (1.0)
BASDAI, mean (SD)	6.5 (1.8)	6.9 (1.2)	6.0 (1.4)	6.5 (1.1)	6.5 (1.1)	6.8 (1.2)	6.5 (1.5)	6.6 (1.6)
BASFI, mean (SD)	4.9 (3.1)	5.3 (2.4)	3.9 (2.5)	5.0 (2.0)	5.4 (2.0)	5.3 (2.3)	5.1 (2.1)	5.5 (2.1)

Figure 1 Achievement of remission in patients with nr-axSpA to Week 52 (OC)



Includes patients enrolled in the MRI sub-study of BE MOBILE 1. PBO-randomized patients were switched to BKZ 160 mg Q4W at Week 16. Remission of OSI is defined as MRI remission of the SIJ (MRI SPARCC SIJ <2) and spine (Berlin MRI spine ≤2), CRP level ≤5 mg/L, and SJC of 0.

Figure 2 Achievement of remission in patients with r-axSpA to Week 52 (OC)



Includes patients enrolled in the MRI sub-study of BE MOBILE 2. PBO-randomized patients were switched to BKZ 160 mg Q4W at Week 16. Remission of OSI is defined as MRI remission of the SIJ (MRI SPARCC SIJ <2) and spine (Berlin MRI spine ≤2), CRP level ≤5 mg/L, and SJC of 0.

ASDAS ID: Axial Spondyloarthritis Disease Activity Score Inactive Disease; **axSpA:** axial spondyloarthritis; **BASDAI:** Bath Ankylosing Spondylitis Disease Activity Index; **BASFI:** Bath Ankylosing Spondylitis Functional Index; **BKZ:** bimekizumab; **CRP:** C-reactive protein; **IL:** interleukin; **MRI:** magnetic resonance imaging; **nr-axSpA:** non-radiographic axSpA; **OC:** observed case; **OSI:** objective signs of inflammation; **PBO:** placebo; **Q4W:** every 4 weeks; **r-axSpA:** radiographic axSpA; **SD:** standard deviation; **SPARCC:** Spondyloarthritis Research Consortium of Canada; **SIJ:** sacroiliac joint; **SJC:** swollen joint count.

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References: [1]Baraliakos X. Ann Rheum Dis 2024;83:199–213; [2]Smolen JS. Ann Rheum Dis 2018;77:3–17; [3]Ramiro S. Ann Rheum Dis 2023;82:19–34. **Author Contributions:** Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: **LSG, HMO, VT, DV, AM, GS, MK, MR**; Drafting of the publication, or reviewing it critically for important intellectual content: **LSG, HMO, VT, DV, AM, GS, MK, MR**; Final approval of the publication: **LSG, HMO, VT, DV, AM, GS, MK, MR**. **Author Disclosures: LSG:** Grants from UCB paid to institution; consulting fees from Acelyrin, Eli Lilly, Janssen, Novartis, Pfizer, and UCB. **HMO:** Speaking honoraria and/or consultancy fees from AbbVie, Amgen, Biogen, Eli Lilly, Janssen, MoonLake, Novartis, Pfizer, Takeda, and UCB; research grants from Janssen, Novartis, Pfizer, and UCB. **VT:** Employee and shareholder of UCB. **DV:** Contractor for UCB and employee of Veramed. **AM, GS, MK:** Employee of UCB. **MR:** Speakers bureau from AbbVie, Boehringer Ingelheim, Chugai, Eli Lilly, Janssen, Novartis, Pfizer, and UCB; consultant of AbbVie, Eli Lilly, Novartis, and UCB. **Acknowledgments:** 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 Mencleberg, PhD, UCB, Breda, the Netherlands, for publication coordination, Sneha Krishnamurthy, MSc, Costello Medical, London, UK for medical writing and editorial assistance, and the Costello Medical Creative team for graphic design assistance. These studies were funded by UCB. All costs associated with development of this presentation were funded by UCB.

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