Achievement of Remission Defined by Absence of Objective Signs of Inflammation versus ASDAS Inactive Disease in Patients with Active Axial Spondyloarthritis Treated with Bimekizumab: 52-Week Results from Two Phase 3 Trials

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Objective

To report achievement of remission defined using objective signs of inflammation (OSI), including the absence of uveitis flares, compared with an established endpoint, 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).

Introduction

- BKZ, a monoclonal IgG1 antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A, has demonstrated sustained efficacy and safety to 2 years in patients across the full spectrum of axSpA in the phase 3 studies BE MOBILE 1 (non-radiographic [nr-]axSpA) and 2 (radiographic [r-]axSpA) and their open-label extension.[1]
- While achievement of axSpA remission is a key treatment goal and may guide clinical decisions,[2,3] there is no universally accepted definition of remission in axSpA.[4]
  - Assessing remission using OSI may provide clarity on inflammatory disease activity without subjective criteria.
- Previous analyses have shown that higher proportions of patients receiving BKZ in BE MOBILE 1 and 2 achieved OSI remission (MRI remission of the sacroiliac joint [SIJ] and spine, C-reactive protein [CRP] ≤5 mg/L and a swollen joint count [SJC] of 0) compared with an established outcome, ASDAS ID.[5]
- This study compares the achievement of an updated definition of OSI remission, including no uveitis flares, from baseline to Week 52, with ASDAS ID.

Methods

- The study designs of BE MOBILE 1 (NCT03928704) and 2 (NCT03928743) have been reported previously.[6] All patients received subcutaneous BKZ 160 mg every 4 weeks (Q4W) from Week 16.
- Remission of OSI was defined as MRI remission of the SIJ and spine (MRI Spondyloarthritis Research Consortium of Canada [SPARCC] SIJ score <2 and MRI Berlin spine score ≤2), CRP ≤5 mg/L, SJC of 0 and no uveitis flares from baseline to Week 52.
- The proportion of patients from the BE MOBILE 1 and 2 MRI sub-studies achieving these criteria was compared with the proportion achieving ASDAS ID.
- A concordance analysis was conducted to compare the achievement of OSI remission and ASDAS ID.
- No formal statistical analyses were conducted; observed case (OC) data are reported.

Results

Patients

- Of 586 total patients, 152/254 (59.8%) patients in BE MOBILE 1 and 139/332 (41.9%) patients in BE MOBILE 2 enrolled in their respective MRI sub-studies and were included in this analysis (n=291).
- Levels of OSI at baseline were similar across treatment arms in patients with nr-axSpA and r-axSpA, respectively (**Table**).

Achievement of OSI remission vs ASDAS ID

- At Week 16, across BE MOBILE 1 and BE MOBILE 2, a greater proportion of patients treated with BKZ achieved OSI remission (40.5–41.9%) compared with ASDAS ID (15.2–21.6%; **Figures 1A–F**).
- This trend was also observed at Week 52, with 47.4–50.8% of BKZ-randomised patients across the full spectrum of axSpA achieving OSI remission and 23.7–34.9% achieving ASDAS ID (**Figures 1A–F**).
- Upon switching to BKZ at Week 16, a comparable proportion of PBO-randomised patients achieved OSI remission (35.2–46.2%) and ASDAS ID at Week 52 (38.9–46.2%; **Figures 1A–F**).

Concordance between OSI remission and ASDAS ID

- Among BKZ-randomised patients in BE MOBILE 1, BE MOBILE 2 and the pooled population, 10.8–12.7% at Week 16 and 15.8–23.8% at Week 52 achieved both OSI remission and ASDAS ID, with substantial proportions of patients achieving just one outcome but not the other (**Figure 2**).

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, highlighting the potential limitations of using ASDAS ID alone to assess treatment efficacy.

These findings underscore the need for further research on optimal endpoints in axSpA.

Summary

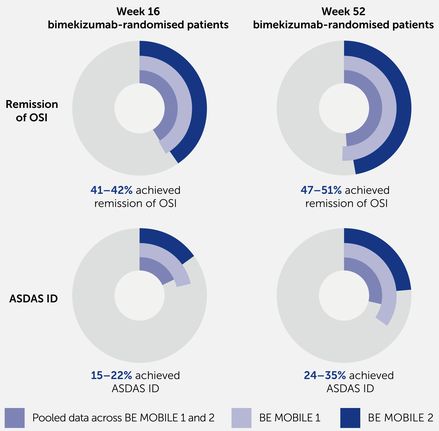
In this analysis, **remission of OSI** in axSpA was defined as the achievement of all of the following criteria:

Remission of MRI inflammation in the SIJ (MRI SPARCC SIJ <2) and spine (MRI Berlin spine ≤2)

CRP ≤5 mg/L

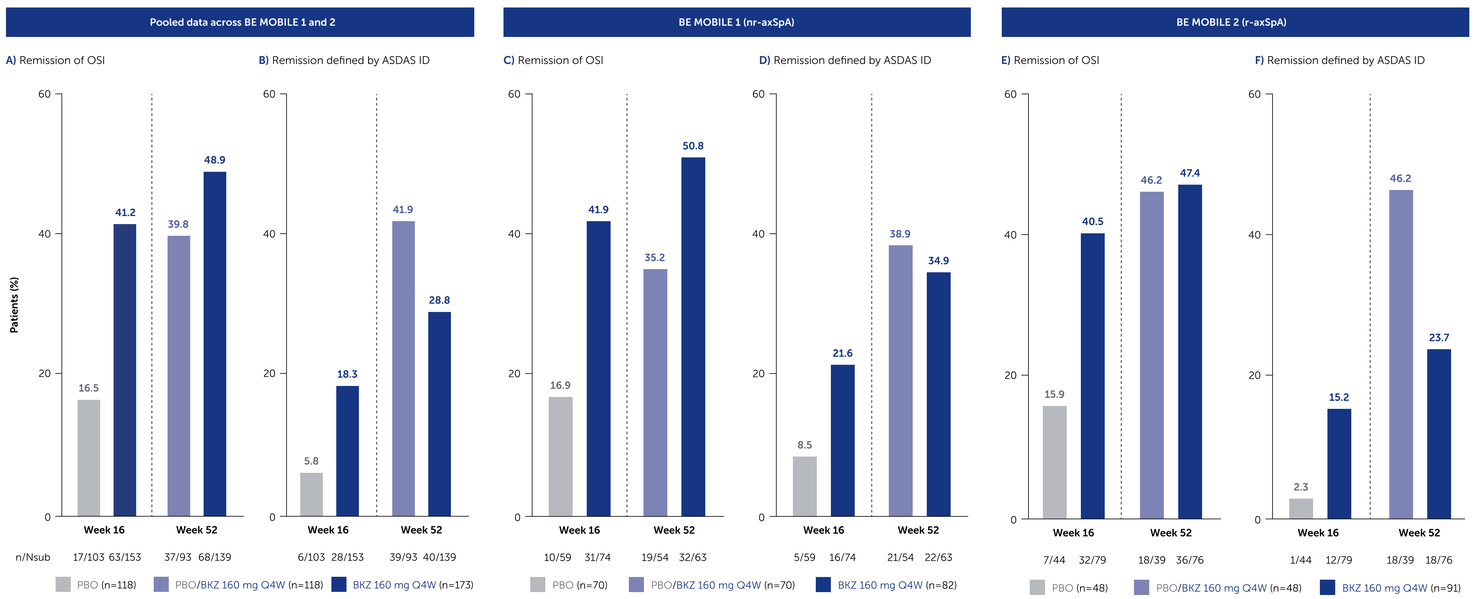
SJC =0

No uveitis flares



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

Figure 1 Achievement of remission in patients with axSpA at Week 16 and Week 52 (OC)



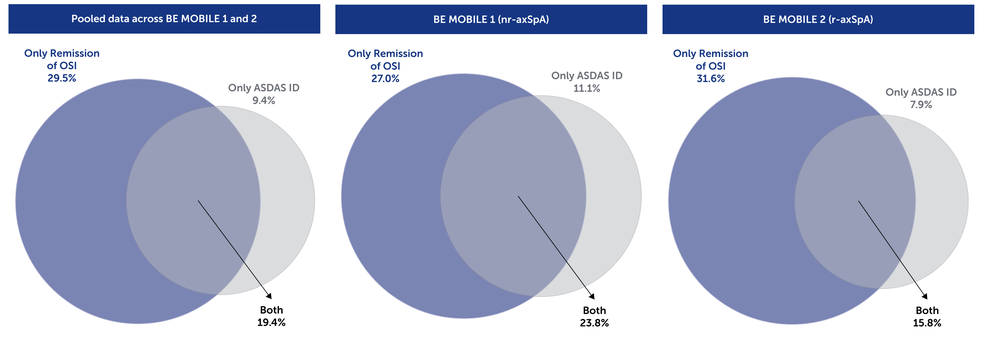
Includes patients enrolled in the MRI sub-studies of BE MOBILE 1 and 2. PBO-randomised patients were switched to BKZ 160 mg Q4W at Week 16. Remission of OSI is defined as MRI remission of the SIJ (MRI SPARCC SIJ <2) and spine (MRI Berlin spine ≤2), CRP level ≤5 mg/L, SJC of 0, and no uveitis flares from baseline to Week 52.

Table Baseline characteristics of patients enrolled in the MRI sub-studies of BE MOBILE 1 and 2

	Pooled data across BE MOBILE 1 and 2		BE MOBILE 1 (nr-axSpA)		BE MOBILE 2 (r-axSpA)	
	PBO n=118	BKZ 160 mg Q4W n=173	PBO n=70	BKZ 160 mg Q4W n=82	PBO n=48	BKZ 160 mg Q4W n=91
Age, years, mean (SD)	39.9 (12.6)	39.5 (11.9)	40.0 (12.5)	38.9 (11.6)	39.7 (12.9)	40.1 (12.2)
Male, n (%)	62 (52.5)	118 (68.2)	31 (44.3)	50 (61.0)	31 (64.6)	68 (74.7)
Time since first axSpA symptoms, years, mean (SD)	10.3 (9.3)	11.5 (10.1)	8.7 (9.2)	9.0 (8.5)	12.7 (9.0)	13.7 (11.0)
HLA-B27 positive, n (%)	86 (72.9)	145 (83.8)	47 (67.1)	65 (79.3)	39 (81.3)	80 (87.9)
BASDAI, mean (SD)	6.4 (1.4)	6.7 (1.3)	6.4 (1.3)	6.9 (1.2)	6.4 (1.4)	6.6 (1.4)
BASFI, mean (SD)	5.1 (2.1)	5.3 (2.2)	5.2 (2.2)	5.3 (2.2)	5.0 (2.1)	5.3 (2.1)
History of uveitis, n (%)	18 (15.3)	29 (16.8)	7 (10.0)	14 (17.1)	11 (22.9)	15 (16.5)
SJC						
Mean (SD)	0.7 (1.7)[a]	0.9 (2.2)	1.0 (2.1)	0.8 (1.8)	0.2 (0.7)[b]	0.9 (2.5)
≥1, n (%)	26 (22.0)	43 (24.9)	20 (28.6)	25 (30.5)	6 (12.5)	18 (19.8)
CRP, mg/L						
Median (Q1, Q3)	5.9 (2.2, 14.3)	7.2 (1.9, 15.6)	5.6 (2.2, 14.4)	5.0 (1.4, 11.0)	6.1 (2.3, 13.2)	9.6 (3.5, 21.0)
>5 mg/L, n (%)	65 (55.1)	105 (60.7)	37 (52.9)	41 (50.0)	28 (58.3)	64 (70.3)
MRI SPARCC SIJ						
Mean (SD)	7.4 (10.8)	6.7 (9.2)[c]	9.8 (12.6)	8.0 (9.9)	3.8 (6.1)	5.4 (8.4)[d]
≥2, n (%)	67 (56.8)	92 (53.2)	46 (65.7)	50 (61.0)	21 (43.8)	42 (46.2)
MRI Berlin spine						
Mean (SD)	2.2 (3.5)[e]	2.5 (3.9)[f]	1.6 (2.9)[g]	1.6 (2.6)[h]	3.2 (4.1)	3.3 (4.5)[i]
>2, n (%)	33 (28.0)	53 (30.6)	13 (18.6)	17 (20.7)	20 (41.7)	36 (39.6)
ASDAS, mean (SD)	3.6 (0.7)	3.8 (0.8)	3.6 (0.7)	3.6 (0.7)	3.6 (0.8)	3.9 (0.8)

[a] Nsub=116. **[b]** Nsub=46; **[c]** Nsub=172; **[d]** Nsub=90; **[e]** Nsub=115. **[f]** Nsub=168; **[g]** Nsub=67. **[h]** Nsub=79; **[i]** Nsub=89.

Figure 2 Concordance between the achievement of remission of OSI and the achievement of ASDAS ID at Week 52 in BKZ-randomised patients (OC)



	Only Remission of OSI	Only ASDAS ID	Both
n/Nsub	41/139	13/139	27/139
n/Nsub	17/63	7/63	15/63
n/Nsub	24/76	6/76	12/76

N=173; includes only BKZ-randomised patients enrolled in the pooled MRI sub-studies of BE MOBILE 1 and 2. Remission of OSI is defined as MRI remission of the SIJ (MRI SPARCC SIJ <2) and spine (MRI Berlin spine ≤2), CRP level ≤5 mg/L, SJC of 0, and no uveitis flares from baseline to Week 52.

ASDAS ID: Axial Spondyloarthritis Disease Activity Score <1.3 (Inactive Disease); **axSpA:** axial spondyloarthritis; **BASDAI:** Bath Ankylosing Spondylitis Disease Activity Index; **BASFI:** Bath Ankylosing Spondylitis Functional Index. **BKZ:** bimekizumab; **CRP:** C-reactive protein; **hs-CRP:** high sensitivity CRP; **MRI:** magnetic resonance imaging; **n:** number of patients in each subgroup; **N:** total number of patients in a given treatment group of the randomised set at baseline; **nr-axSpA:** non-radiographic axSpA; **Nsub:** number of patients with non-missing measurements; **OC:** observed case; **OSI:** objective signs of inflammation; **PBO:** placebo; **Q1/3:** quartile 1/3; **Q4W:** every 4 weeks; **r-axSpA:** radiographic axSpA; **SD:** standard deviation; **SIJ:** sacroiliac joint; **SJC:** swollen joint count; **SPARCC:** Spondyloarthritis Research Consortium of Canada; **vs:** versus.

References: [1]Baraliakos X. Rheumatology (Oxford) 2025;kead009: [2]Smolen JS. Ann Rheum Dis 2018;77:3–17; [3]Ramiro S. Ann Rheum Dis 2023;82:19–34; [4]Baraliakos X. J Rheumatol 2018;45:153–7; [5]Gensler LS. Arthritis Rheumatol 2024;76:2362; [6]Baraliakos X. Ann Rheum Dis 2024;83:199–213.

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