Achievement of Low Disease Activity Over 52 Weeks in Patients with Active Axial Spondyloarthritis on Bimekizumab Treatment: Results from the Phase 3 Studies BE MOBILE 1 and BE MOBILE 2

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Objective

To report achievement of low disease activity, as assessed by either ASDAS <2.1, BASDAI <4, or both, to Week 52 with bimekizumab across the full disease spectrum of axial spondyloarthritis in two phase 3 studies.

Background

- The recommended treatment target for axial spondyloarthritis (axSpA) is remission or low disease activity (LDA) based on Ankylosing Spondylitis Disease Activity Score (ASDAS) levels.[1]
- The Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) remains commonly used in clinical practice, although limited data exist to validate cut-offs for BASDAI that would indicate remission or LDA.[2,3]
- Bimekizumab (BKZ) is a monoclonal IgG1 antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A.[4]
- BKZ has demonstrated consistent and sustained efficacy to Week 52 in patients with non-radiographic (nr-)axSpA and radiographic (r-)axSpA (i.e., ankylosing spondylitis), indicative of remission or LDA.[4,5]

Methods

- The parallel BE MOBILE 1 (nr-axSpA; NCT03928704) and BE MOBILE 2 (r-axSpA; NCT03928743) studies comprised a 16-week placebo-controlled and 36-week maintenance period (**Figure 1**).[4]
  - Placebo-randomised patients switched to BKZ at Week 16.
- These studies included patients with BASDAI ≥4, but did not specify an inclusion criterion based on ASDAS levels.
- Here, we report the proportion of patients achieving LDA to Week 52, as defined by either ASDAS <2.1, BASDAI <4 or both using multiple imputation (MI) and non-responder imputation (NRI).
- The proportion and baseline characteristics of patients achieving LDA by one measure and/or the other at Week 52 are also reported using NRI.

Results

Patients

- Of the 254 patients with nr-axSpA and 332 with r-axSpA randomised, most completed the 52-week study period:
  - **nr-axSpA:** PBO/BKZ: 85.7%; BKZ: 87.5%
  - **r-axSpA:** PBO/BKZ: 91.9%; BKZ: 88.7%

Achievement of LDA

- In patients with nr-axSpA and r-axSpA, a greater proportion of BKZ vs placebo-treated patients achieved LDA at Week 16 according to ASDAS <2.1, BASDAI <4, and both (**Figure 2**).
- Responses, as measured by achievement of ASDAS <2.1 and/or BASDAI <4, were sustained or improved to Week 52 with BKZ treatment and approached those of BKZ-randomised patients among patients switching to BKZ from placebo at Week 16.

Comparison of ASDAS and BASDAI as Measures of LDA

- The proportion of patients achieving BASDAI <4 was generally higher compared to achievement of ASDAS <2.1, regardless of treatment arm (**Figure 3**).
- A larger majority of patients who achieved ASDAS <2.1 also achieved BASDAI <4 than vice versa (**Figure 3**).
- A higher proportion of patients who achieved both ASDAS <2.1 and BASDAI <4 were younger, male and had experienced their first symptoms of axSpA more recently compared to patients who did not achieve either (**Table 1**).

Conclusions

Across the full disease spectrum of axSpA, dual inhibition of IL-17A and IL-17F with bimekizumab resulted in sustained achievement of LDA vs placebo to Week 16, with the proportion of patients achieving LDA increasing to Week 52.

The larger proportion of patients achieving BASDAI <4 but not ASDAS <2.1 suggests that the latter may be a more stringent criterion for LDA. This is relevant for the consideration of bimekizumab in the context of a potential treat-to-target approach for patients with axSpA in daily practice.

Summary

Treatment with bimekizumab resulted in sustained achievement of low disease activity across the full disease spectrum of axSpA

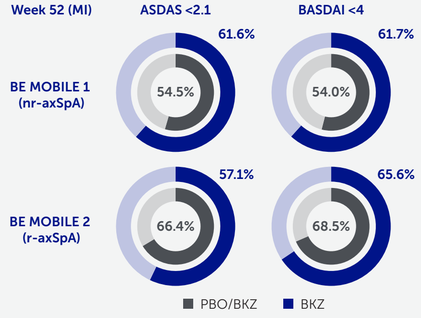
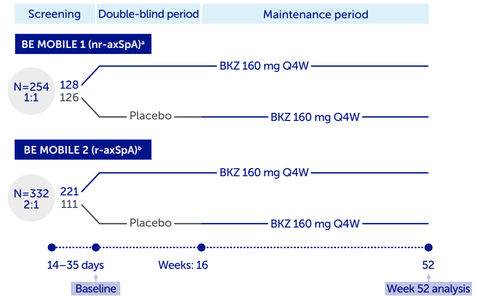
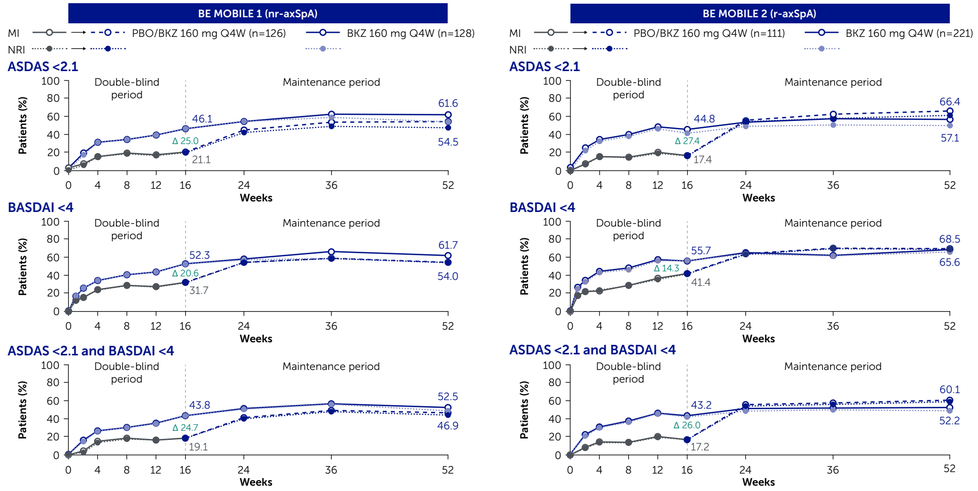


Figure 1 Study design



Patients were eligible to receive non-biologic rescue therapy from Week 20 at the discretion of the investigator, while continuing to receive BKZ. [a]All patients had active nr-axSpA or r-axSpA at baseline (BASDAI ≥4 and spinal pain ≥4). [b]Included patients had adult-onset nr-axSpA fulfilling ASAS classification criteria and objective signs of inflammation (active sacroiliitis on MRI and/or elevated CRP [≥6 mg/L]); [b]Included adult patients had radiographic evidence of axSpA fulfilling both Modified New York criteria and ASAS classification criteria.

Figure 2 Proportion of patients achieving ASDAS <2.1, BASDAI <4, or both, over 52 weeks (NRI and MI)



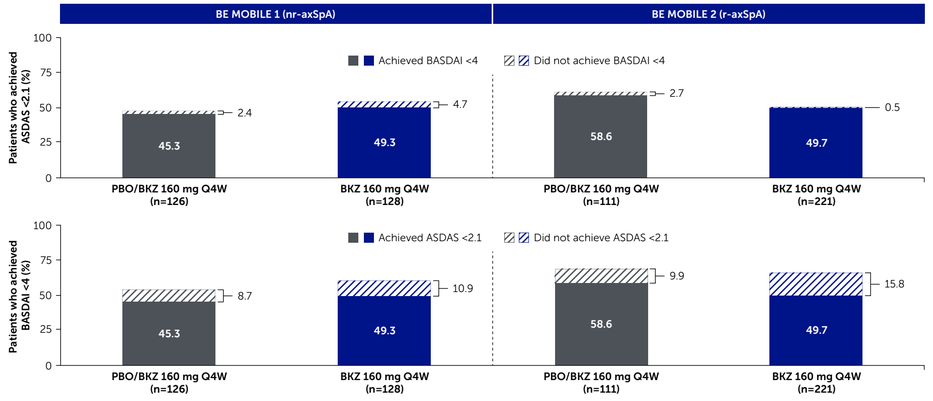
Randomised set. ASDAS <2.1 indicates LDA. Patients randomised to placebo switched to BKZ 160 mg Q4W from Week 16 onwards. Labels, including Week 16 delta values, are given for MI data.

Table 1 Baseline characteristics of patients with nr-axSpA (BE MOBILE 1) and r-axSpA (BE MOBILE 2) who did or did not achieve LDA at Week 52 (NRI)

Level of disease activity		PBO/BKZ 160 mg Q4W				BKZ 160 mg Q4W			
		ASDAS <2.1 BASDAI <4	ASDAS <2.1 BASDAI ≥4	ASDAS ≥2.1 BASDAI <4	ASDAS ≥2.1 BASDAI ≥4	ASDAS <2.1 BASDAI <4	ASDAS <2.1 BASDAI ≥4	ASDAS ≥2.1 BASDAI <4	ASDAS ≥2.1 BASDAI ≥4
nr-axSpA (BE MOBILE 1)		n=57	n=3	n=16	n=50	n=63	n=6	n=22	n=37
r-axSpA (BE MOBILE 2)		n=65	n=3	n=15	n=28	n=110	n=1	n=49	n=61
Age, years, mean (SD)	**nr-axSpA**	35.7 (10.0)	41.3 (4.7)	37.9 (11.8)	44.0 (12.6)	37.1 (10.2)	43.0 (13.6)	37.6 (10.8)	44.1 (11.4)
	r-axSpA	36.9 (11.1)	50.3 (9.1)	37.7 (11.4)	44.3 (14.8)	38.8 (11.7)	46.0 (0)	39.4 (11.1)	46.3 (12.4)
Male, n (%)	**nr-axSpA**	38 (66.7)	0	5 (31.3)	22 (44.0)	42 (66.7)	2 (33.3)	13 (59.1)	16 (43.2)
	r-axSpA	48 (73.8)	1 (33.3)	11 (73.3)	20 (71.4)	80 (72.7)	0	38 (77.6)	42 (68.9)
Time since first symptoms of axSpA, years, mean (SD)	**nr-axSpA**	6.3 (5.7)	7.5 (3.5)	6.8 (8.5)	12.7 (11.1)	7.3 (7.7)	15.2 (9.0)	7.5 (7.1)	12.1 (10.1)
	r-axSpA	10.8 (8.2)	12.9 (4.2)	12.5 (9.3)	14.0 (9.3)	13.2 (10.5)	15.3 (0)	12.5 (9.8)	17.6 (12.4)
ASDAS, mean (SD)	**nr-axSpA**	3.5 (0.7)	3.2 (0.2)	3.8 (0.8)	3.8 (0.6)	3.7 (0.8)	3.4 (0.1)	3.7 (0.8)	3.9 (0.7)
	r-axSpA	3.5 (0.8)	3.3 (0.2)	4.0 (0.8)	4.0 (0.6)	3.5 (0.9)	4.4 (0)	3.9 (0.9)	3.9 (0.7)
BASDAI, mean (SD)	**nr-axSpA**	6.5 (1.4)	6.1 (0.4)	6.0 (1.1)	7.1 (1.2)	6.7 (1.2)	7.6 (0.7)	6.5 (1.3)	7.4 (1.2)
	r-axSpA	6.2 (1.4)	6.0 (0.7)	6.7 (1.2)	7.1 (1.2)	6.2 (1.3)	9.2 (0)	6.3 (1.4)	7.0 (1.2)
hs-CRP (mg/L), geometric mean (geometric CV, %)	**nr-axSpA**	4.3 (275.8)	2.0 (146.5)	12.6 (96.4)	4.7 (202.7)	5.5 (240.8)	2.1 (290.2)	6.3 (246.5)	3.3 (435.0)
	r-axSpA	5.7 (183.8)	3.3 (293.1)	10.6 (295.3)	8.4 (167.7)	5.2 (234.0)	5.5 (0)	13.5 (202.9)	5.5 (357.5)
Prior TNFi exposure, n (%)	**nr-axSpA**	6 (10.5)	0	1 (6.3)	10 (20.0)	5 (7.9)	0	4 (18.2)	1 (2.7)
	r-axSpA	6 (9.2)	0	3 (20.0)	8 (28.6)	15 (13.6)	0	12 (24.5)	10 (16.4)

Safety set. ASDAS <2.1 indicates LDA. Patients randomised to placebo switched to BKZ 160 mg Q4W from Week 16 onwards.

Figure 3 Proportion of patients who achieved ASDAS <2.1 and/or BASDAI <4 at Week 52 (NRI)



Randomised set. ASDAS <2.1 indicates LDA. Patients randomised to placebo switched to BKZ 160 mg Q4W from Week 16 onwards.

ASAS: Assessment of Spondyloarthritis International Society; **ASAS40:** ASAS 40% response; **ASDAS:** Ankylosing Spondylitis Disease Activity Score; **axSpA:** axial spondyloarthritis; **BASDAI:** Bath AS Disease Activity Index; **BKZ:** bimekizumab; **CRP:** C-reactive protein; **CV:** coefficient of variation; **hs-CRP:** high-sensitivity CRP; **IL:** interleukin; **LDA:** low disease activity; **MI:** multiple imputation; **MRI:** magnetic resonance imaging; **nr-axSpA:** non-radiographic axSpA; **NRI:** non-responder imputation; **PBO:** placebo; **Q4W:** every four weeks; **r-axSpA:** radiographic axSpA; **SD:** standard deviation; **TNFi**: tumour necrosis factor inhibitor.

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