Resolution of Enthesitis and Peripheral Arthritis with Bimekizumab in Patients with Axial Spondyloarthritis: Week 52 Results from the BE MOBILE 1 and BE MOBILE 2 Phase 3 Studies

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Objective

To evaluate the impact of bimekizumab treatment on the main peripheral manifestations of axial spondyloarthritis, including enthesitis and peripheral arthritis, to Week 52 in two phase 3 studies.

Background

- Peripheral manifestations such as enthesitis and peripheral arthritis are common in patients with axial spondyloarthritis (axSpA),[1] contributing to disease burden and poorer quality of life.[2]
- Bimekizumab (BKZ), a monoclonal IgG1 antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A, has demonstrated efficacy in patients with non-radiographic (nr-)axSpA and radiographic (r-)axSpA (i.e., ankylosing spondylitis) in phase 3 studies, BE MOBILE 1 and BE MOBILE 2.[3,4]

Materials and Methods

- The parallel BE MOBILE 1 (nr-axSpA; NCT03928704) and 2 (r-axSpA; NCT03928743) studies each comprised a 16-week double-blind placebo-controlled period followed by a 36-week maintenance period (**Figure 1**).[3]
- This post-hoc analysis reports the following outcomes over 52 weeks in patients with presence of the corresponding peripheral manifestations at baseline:
  - Mean change from baseline in Maastricht ankylosing spondylitis enthesitis score (MASES), swollen joint count (SJC) and tender joint count (TJC) (multiple imputation [MI]).
  - Complete resolution of enthesitis (MASES=0) or peripheral arthritis (SJC=0) (non-responder imputation [NRI]).
  - Achievement of both SJC=0 and TJC=0 (NRI).
- Assessments of SJC and TJC were performed in 44 joints.

Results

Baseline Characteristics

- Patients with peripheral manifestations of axSpA at baseline:
  - **MASES>0:** 73.2% (186/254) nr-axSpA; 59.9% (199/332) r-axSpA.
  - **SJC>0:** 34.6% (88/254) nr-axSpA; 19.9% (66/332) r-axSpA.
  - **TJC>0:** 64.2% (163/254) nr-axSpA; 53.3% (177/332) r-axSpA.
- Distribution of enthesitis by tendons and swollen joints (observed case [OC]) was largely similar between treatment arms, although patients with nr-axSpA were more likely than those with r-axSpA to have at least one swollen wrist, ankle, interphalangeal or metacarpophalangeal joint, or enthesitis in any assessed tendon (**Figure 2**).

Improvements in Peripheral Manifestations of axSpA

Enthesitis

- Across the full disease spectrum of axSpA, mean change from baseline in MASES was larger in patients receiving BKZ compared with placebo at Week 16 (**Table 1**).
- At the same time point, a greater proportion of patients achieved resolution of enthesitis (MASES=0) with BKZ vs placebo (**Figure 3**).
- Improvements were sustained to Week 52 with BKZ treatment, including in patients switching from BKZ to placebo at Week 16, with ~50% achieving MASES=0 at Week 52.

Peripheral arthritis

- At Week 16, a larger mean change from baseline in SJC or TJC was achieved in patients with nr-axSpA receiving BKZ compared with placebo (**Table 1**).
- By Week 16, over 50% of BKZ-treated patients achieved complete resolution of peripheral arthritis according to SJC=0; ~25% achieved both SJC=0 and TJC=0 (**Figure 3**).
- The proportion of patients achieving either SJC=0 or SJC=0 and TJC=0 increased to Week 52 with BKZ treatment.

Conclusions

Bimekizumab treatment resulted in sustained improvements in peripheral manifestations over 52 weeks. Across the full disease spectrum of axSpA, resolution of enthesitis (MASES=0) was achieved in around half of bimekizumab-treated patients by Week 52. A similar pattern was observed for peripheral arthritis, with more than 60% of patients achieving resolution (SJC=0) by Week 52.

Summary

Peripheral manifestations are common in patients with axSpA, contributing to disease activity and poor quality of life

Bimekizumab treatment led to sustained improvements in peripheral manifestations to Week 52 across the full disease spectrum of axSpA, including:

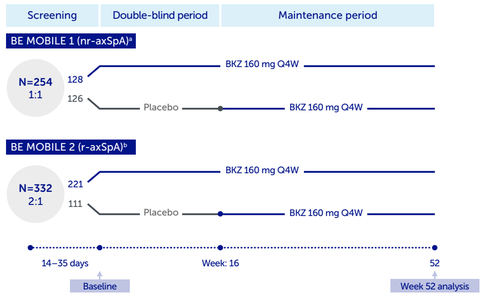
~50% of patients

Resolution of enthesitis (MASES=0 at Week 52)

>60% of patients

Resolution of peripheral arthritis (SJC=0 at Week 52)

Figure 1 BE MOBILE 1 and 2 study designs



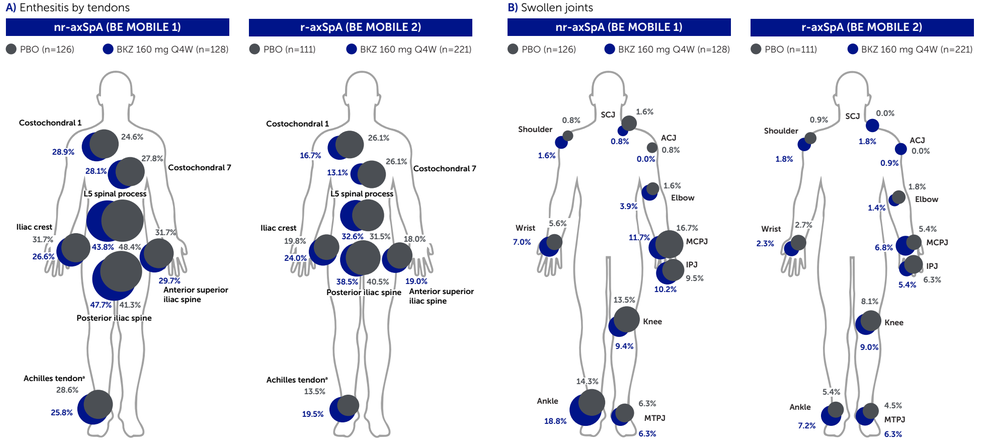
Patients were eligible to receive non-biologic rescue therapy from Week 20 at the discretion of the investigator while continuing to receive BKZ. All patients had active nr-axSpA or r-axSpA at baseline (BASDAI ≥4 and spinal pain ≥4). [a]Included patients had adult-onset nr-axSpA fulfilling ASAS classification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

Table 1 Mean change from baseline in MASES and number of SJC or TJC in patients with MASES>0, SJC>0 or TJC>0 at baseline, respectively (MI)

		n		Baseline		Week 16 change from baseline			Week 52 change from baseline	
Mean (SE)		**PBO**	**BKZ 160 mg Q4W**	**PBO**	**BKZ 160 mg Q4W**	**PBO**	**BKZ 160 mg Q4W**	**Nominal p value**	**PBO/ BKZ 160 mg Q4W**	**BKZ 160 mg Q4W**
MASES	nr-axSpA	92	94	4.9 (0.4)	4.8 (0.3)	−1.3 (0.3)	−2.4 (0.3)	0.013	−2.9 (0.4)	−3.6 (0.3)
	r-axSpA	67	132	4.4 (0.3)	4.2 (0.3)	−1.5 (0.3)	−2.4 (0.3)	0.003	−3.2 (0.3)	−2.9 (0.3)
SJC	nr-axSpA	43	45	3.8 (0.5)	4.2 (0.8)	−1.3 (0.6)	−3.1 (0.7)	0.007	−2.9 (0.4)	−2.5 (0.8)
	r-axSpA	22	44	3.9 (0.7)	4.7 (0.6)	−2.1 (0.5)	−3.6 (0.5)	0.074	−3.6 (0.8)	−4.2 (0.6)
TJC	nr-axSpA	85	78	6.3 (0.6)	6.0 (0.8)	−1.1 (0.5)	−3.0 (0.7)	0.008	−3.5 (0.6)	−4.0 (0.8)
	r-axSpA	61	116	5.4 (0.6)	5.3 (0.6)	−2.9 (0.5)	−2.5 (0.4)	0.401	−4.5 (0.6)	−4.0 (0.5)

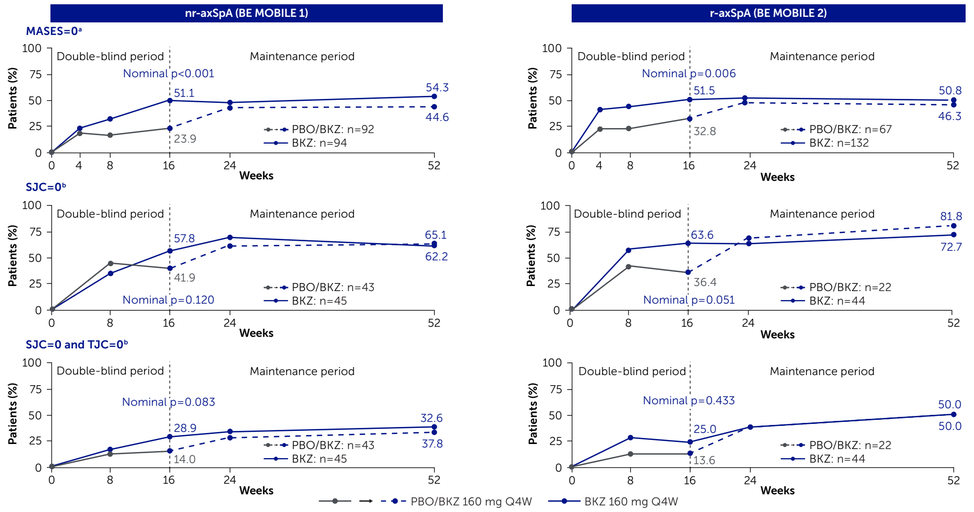
Randomised set. SJC and TJC assessed in 44 joints. P values without any multiplicity adjustment are indicated as nominal p values and should not be used as an indicator of statistical significance.

Figure 2 Distribution of A) enthesitis by tendons and B) swollen joints at baseline in patients with nr-axSpA and r-axSpA (OC)



Randomised set. Labels indicate the percentage of patients with at least one swollen joint or enthesitis in at least one tendon of the mentioned type; shaded circles are approximately proportional in size to the percentages of patients with at least one swollen joint or enthesitis in at least one tendon of the mentioned type. SJC assessed in 44 joints. Left and right joints and tendons are grouped together. [a]Proximal insertion.

Figure 3 Resolution of enthesitis and peripheral arthritis to Week 52 (NRI)



Randomised set. Assessed in patients with: [a]MASES >0 at baseline or [b]SJC >0 at baseline. SJC and TJC assessed in 44 joints. P values without any multiplicity adjustment are indicated as nominal p values and should not be used as an indicator of statistical significance.

ACJ: acromioclavicular joint; **ASAS:** Assessment in SpondyloArthritis International Society; **axSpA:** axial spondyloarthritis; **BKZ:** bimekizumab; **CRP:** C-reactive protein; **IL:** interleukin; **IPJ:** interphalangeal joint; **MASES:** Maastricht ankylosing spondylitis enthesitis score; **MCPJ:** metacarpophalangeal joint; **MI:** multiple imputation; **MRI:** magnetic resonance imaging; **MTPJ:** metatarsophalangeal joint; **nr-axSpA:** non-radiographic axSpA; **NRI:** non-responder imputation; **OC:** observed case; **PBO:** placebo; **Q4W:** every four weeks; **r-axSpA:** radiographic axSpA; **SCJ:** sternoclavicular joint; **SE:** standard error; **SJC:** swollen joint count; **TJC:** tender joint count.

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