Bimekizumab Reduced MRI Inflammatory Lesions in Patients with Axial Spondyloarthritis: Week 52 Results from the BE MOBILE 1 and 2 Phase 3 Studies

Xenofon Baraliakos,[1] Victoria Navarro-Compán,[2] Denis Poddubnyy,[3] Maureen Dubreuil,[4] Alex Bennett,[5] Lennart Jans,[6] Ute Massow,[7] Carmen Fleurinck,[8] Thomas Vaux,[9] Alicia M. Ellis,[10] Natasha de Peyrecave,[8] Walter P. Maksymowych[11]

Objective

To evaluate the impact of bimekizumab on MRI inflammatory lesions of the sacroiliac joints and spine to Week 52 in two phase 3 studies.

Background

- Inflammatory lesions of the sacroiliac joints (SIJ) and spine are a key feature of axial spondyloarthritis (axSpA).[1,2]
- Bimekizumab (BKZ), a monoclonal IgG1 antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A, has demonstrated consistent and sustained efficacy up to Week 52 across the full disease spectrum of axSpA (non-radiographic axSpA [nr-axSpA] and radiographic axSpA [r-axSpA, i.e. ankylosing spondylitis]).[3–5]

Methods

- BE MOBILE 1 (NCT03928704) and BE MOBILE 2 (NCT03928743) study designs have been reported previously; both comprised a 16-week double-blind placebo (PBO)-controlled period followed by a 36-week maintenance period.[5] From Week 16, all patients received subcutaneous BKZ 160 mg every 4 weeks (Q4W) to Week 52.
- MRIs were performed in the subset of patients in the MRI sub-studies and assessed via central reading by two independent expert readers (scores averaged), with a third adjudicator in cases of disagreement.
- MRI endpoints (Spondyloarthritis Research Consortium of Canada [SPARCC] SIJ and ASspiMRI-a Berlin modification ['Berlin spine'] inflammation scores) and the proportion of patients achieving MRI remission (SPARCC SIJ <2; Berlin spine ≤2)[6] are reported at baseline, Weeks 16 and 52.

Results

Patients

- At baseline, 59.8% of patients with nr-axSpA (152/254) and 41.6% of patients with r-axSpA (138/332) had SPARCC SIJ assessments as part of the MRI sub-studies; 57.4% (146/254) and 41.3% (137/332) of patients had Berlin spine assessments.
- Baseline characteristics in the MRI sub-studies were largely comparable between treatment arms and reflected those of the overall patient population (**Table 1**).

SPARCC SIJ and Berlin Spine Scores

- Improvements in mean MRI scores observed at Week 16 were maintained to Week 52 for patients initially randomised to BKZ. Patients who switched from PBO to BKZ at Week 16 reached similar levels of improvement to BKZ-randomised patients at Week 52 (**Figure 1**).
- Similar patterns of improvement were observed for change from baseline (CfB) in SPARCC SIJ and Berlin spine scores, with patients with higher baseline inflammation scores showing the greatest improvements with BKZ (**Figure 2**).

Achievement of MRI Remission

- Among patients with SIJ inflammation at baseline, a greater proportion of BKZ- vs PBO-randomised patients achieved SPARCC SIJ remission at Week 16. A similar pattern was seen for patients with spine inflammation at baseline and Berlin spine remission at Week 16 (**Figure 3**).
- The proportion of patients achieving MRI remission largely increased to Week 52 (**Figure 3**).

Conclusions

Across the full disease spectrum of axSpA, dual inhibition of IL-17A and IL-17F with bimekizumab resulted in a reduction in MRI inflammatory lesions of the SIJ and spine, with greater improvements observed for patients with higher levels of baseline inflammation, and large proportions of patients achieving MRI remission at Week 52.

Summary

Axial spondyloarthritis is characterised by MRI inflammatory lesions of the sacroiliac joints (SIJ) and spine

To Week 52, bimekizumab treatment led to improvements in inflammation scores, with patients with higher baseline inflammation scores showing greatest improvements

Continuous bimekizumab treatment led to MRI remission at Week 52 in:

76–80% of patients for MRI SPARCC SIJ

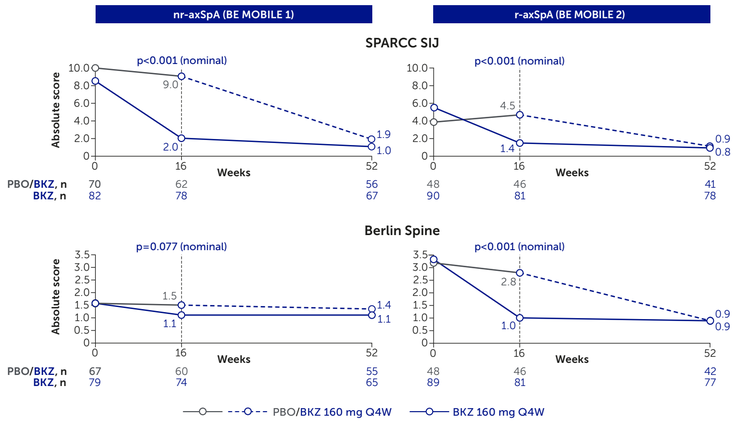
40–77% of patients for MRI Berlin spine

Table 1 Baseline characteristics for MRI sub-study and overall patient populations

n (%), unless stated otherwise	nr-axSpA (BE MOBILE 1)			r-axSpA (BE MOBILE 2)		
	PBO n=70[a]	BKZ 160 mg Q4W n=82[a]	Overall study population N=254[b]	PBO n=48[a]	BKZ 160 mg Q4W n=91[a]	Overall study population N=332[b]
Age, years, mean (SD)	40.0 (12.5)	38.9 (11.6)	39.4 (11.5)	39.7 (12.9)	40.1 (12.2)	40.4 (12.3)
Male	31 (44.3)	50 (61.0)	138 (54.3)	31 (64.6)	68 (74.7)	240 (72.3)
HLA-B27 positive	47 (67.1)	65 (79.3)	197 (77.6)	39 (81.3)	80 (87.9)	284 (85.5)
Symptom duration, years, mean (SD)	8.7 (9.2)	9.0 (8.5)	9.0 (8.8)	12.7 (9.0)	13.7 (11.0)	13.5 (10.3)
ASDAS, mean (SD)	3.6 (0.7)	3.6 (0.7)	3.7 (0.7)	3.6 (0.8)	3.9 (0.8)	3.7 (0.8)[c]
BASDAI, mean (SD)	6.4 (1.3)	6.9 (1.2)	6.8 (1.3)	6.4 (1.4)	6.6 (1.4)	6.5 (1.3)
hs-CRP, mg/L, geometric mean (geometric CV, %)	4.9 (207.5)	3.8 (276.1)	4.8 (261.8)	6.1 (195.1)	7.6 (244.7)	6.6 (246.3)
Prior TNFi exposure	8 (11.4)	5 (6.1)	27 (10.6)	7 (14.6)	13 (14.3)	54 (16.3)
MRI SPARCC SIJ ≥2[d]	46 (65.7)	50 (61.0)	–	21 (43.8)	42 (46.7)	–
MRI Berlin spine >2[e]	13 (19.4)	17 (21.5)	–	20 (41.7)	36 (40.4)	–

Randomised set. SPARCC SIJ and Berlin spine scores range from 0–72 and 0–69, respectively, with lower scores indicating less inflammation; [a]Includes only patients in the MRI sub-study; [b]All patients in the overall study were pooled, regardless of treatment arm; [c]n=331; [d]In patients with SPARCC SIJ assessments: nr-axSpA: BKZ: n=82, PBO: n=70; r-axSpA: BKZ: n=90, PBO: n=48; [e]In patients with Berlin spine assessments: nr-axSpA: BKZ: n=79; PBO: n=67; r-axSpA: BKZ: n=89; PBO: n=48.

Figure 1 Mean MRI inflammation scores to Week 52 (OC)



Randomised set. Includes only patients in the MRI sub-studies. SPARCC SIJ and Berlin spine scores range from 0–72 and 0–69, respectively, with lower scores indicating less inflammation.

Figure 2 Mirror plots for baseline and CfB in MRI inflammation scores at Week 16 (OC)

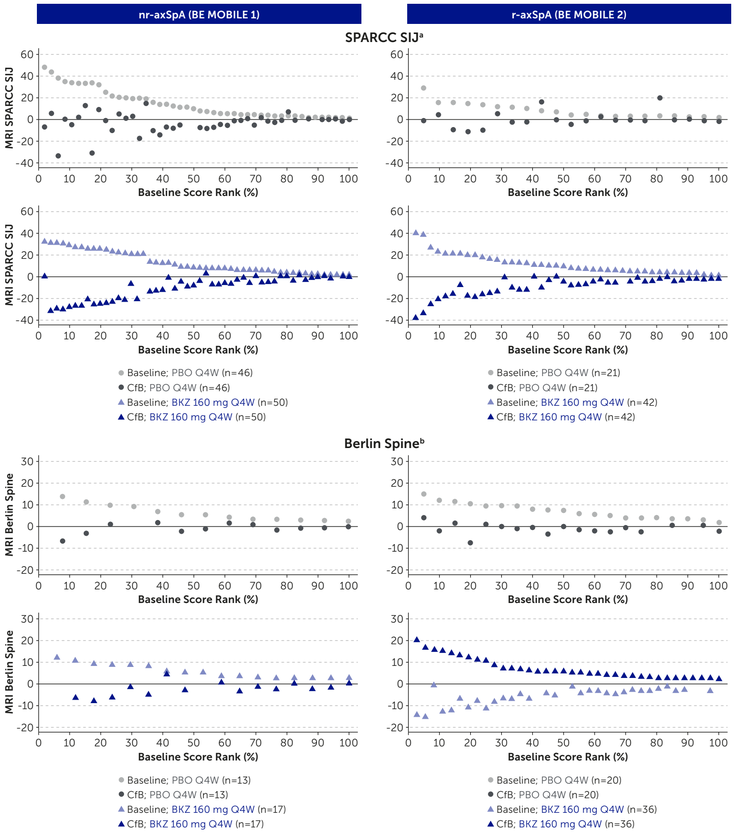
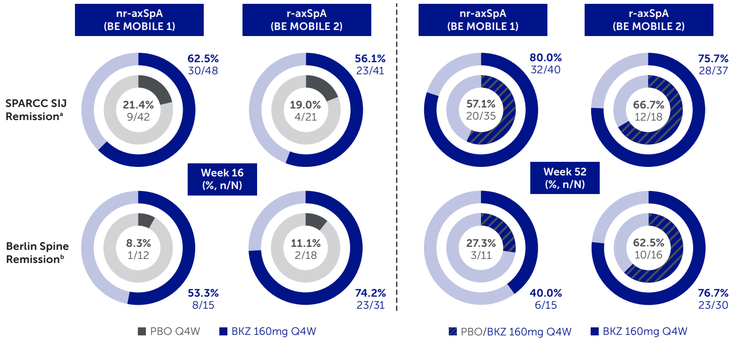


Figure 3 Proportion of patients achieving MRI remission (OC)



Randomised set. Includes only patients in the MRI sub-studies. [a]SPARCC SIJ <2, assessed in the subgroup of patients with SPARCC SIJ ≥2 at baseline; [b]Berlin spine ≤2, assessed in the subgroup of patients with Berlin spine >2 at baseline.

Randomised set. Includes only patients in the MRI sub-studies. [a]SPARCC SIJ assessed in the subgroup of patients with SPARCC SIJ ≥2 at baseline; [b]Berlin spine assessed in the subgroup of patients with Berlin spine >2 at baseline.

ASDAS: Ankylosing Spondylitis Disease Activity Score; **ASspiMRI-a:** Ankylosing Spondylitis spine MRI–activity; **BASDAI:** Bath Ankylosing Spondylitis Disease Activity Index; **BKZ:** bimekizumab; **CfB:** change from baseline; **CV:** coefficient of variation; **HLA-B27:** human leukocyte antigen-B27; **hs-CRP:** high-sensitivity C-reactive protein; **IL:** interleukin; **MRI:** magnetic resonance imaging; **n/N:** number of patients achieving the threshold/number of participants with a non-missing measurement for that timepoint; **nr-axSpA:** non-radiographic axial spondyloarthritis; **OC:** observed case; **PBO:** placebo; **Q4W:** every four weeks; **r-axSpA:** radiographic axial spondyloarthritis; **SD:** standard deviation; **SIJ:** sacroiliac joints; **SPARCC:** Spondyloarthritis Research Consortium of Canada; **TNFi:** tumour necrosis factor inhibitor.

Affiliations: [1]Ruhr-University Bochum, Rheumazentrum Ruhrgebiet Herne, Bochum, Germany; [2]La Paz University Hospital, Department of Rheumatology, IdiPaz, Madrid, Spain; [3]Charité – Universitätsmedizin Berlin, Department of Gastroenterology, Infectious Diseases and Rheumatology, Berlin, Germany; [4]Boston University School of Medicine, Department of Rheumatology, Massachusetts, USA; [5]Defence Medical Rehabilitation Centre, Academic Department of Military Rehabilitation, Stanford Hall, Loughborough, UK; [6]Ghent University Hospital, Department of Radiology, Ghent, Belgium; [7]UCB Pharma, Monheim am Rhein, Germany; [8]UCB Pharma, Brussels, Belgium; [9]UCB Pharma, Slough, UK; [10]UCB Pharma, Raleigh, North Carolina, USA; [11]University of Alberta, Department of Medicine, 568 Heritage Building, Edmonton, Alberta, Canada.

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