Bimekizumab Treatment Resulted in Improvements in MRI Inflammatory and Structural Lesions in the Sacroiliac Joints of Patients with Axial Spondyloarthritis: 52-Week Results and Post Hoc Analyses from Two Phase 3 Studies

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Disclosures

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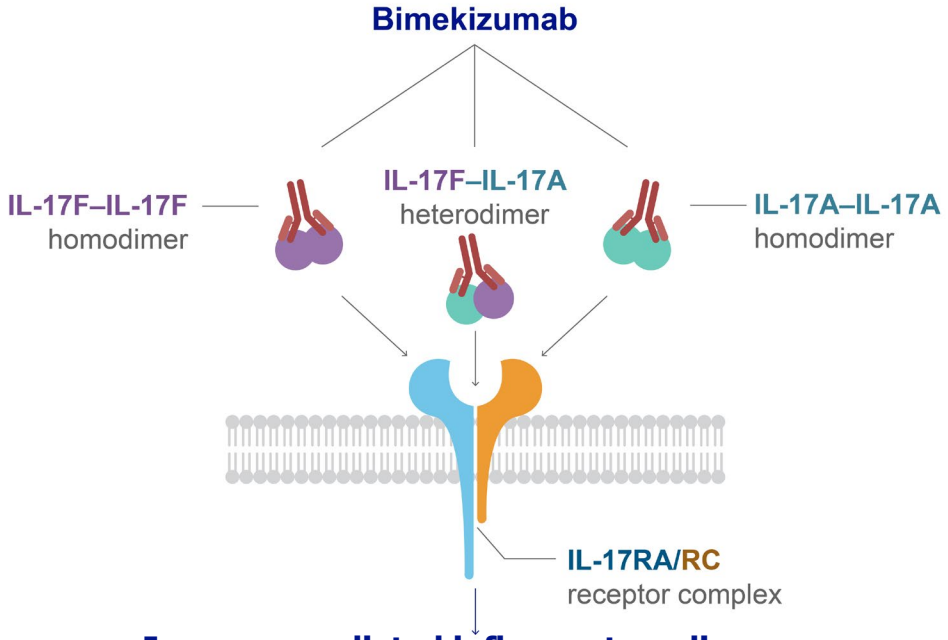
Background and Objective

- **Inflammatory** and **structural lesions** in the **sacroiliac joints** (SIJ) are key characteristics of **axial spondyloarthritis** (axSpA), and can be visualized using MRI assessment[1,2]
- **Bimekizumab** is a monoclonal IgG1 antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A
- Bimekizumab has demonstrated **consistent and sustained efficacy to 2 years** in patients with non-radiographic (nr-) and radiographic (r-)axSpA, in the parallel phase 3 studies BE MOBILE 1 and BE MOBILE 2, respectively, and their combined open-label extension (OLE)[3,4]
- Bimekizumab has also demonstrated **improvements in MRI inflammation scores** in the SIJ and spine of patients with axSpA to 1 year[3]
- However, the impact of bimekizumab on **structural lesions** in the SIJ of patients with axSpA has **not yet been demonstrated**

IL-17A and IL-17F[5]



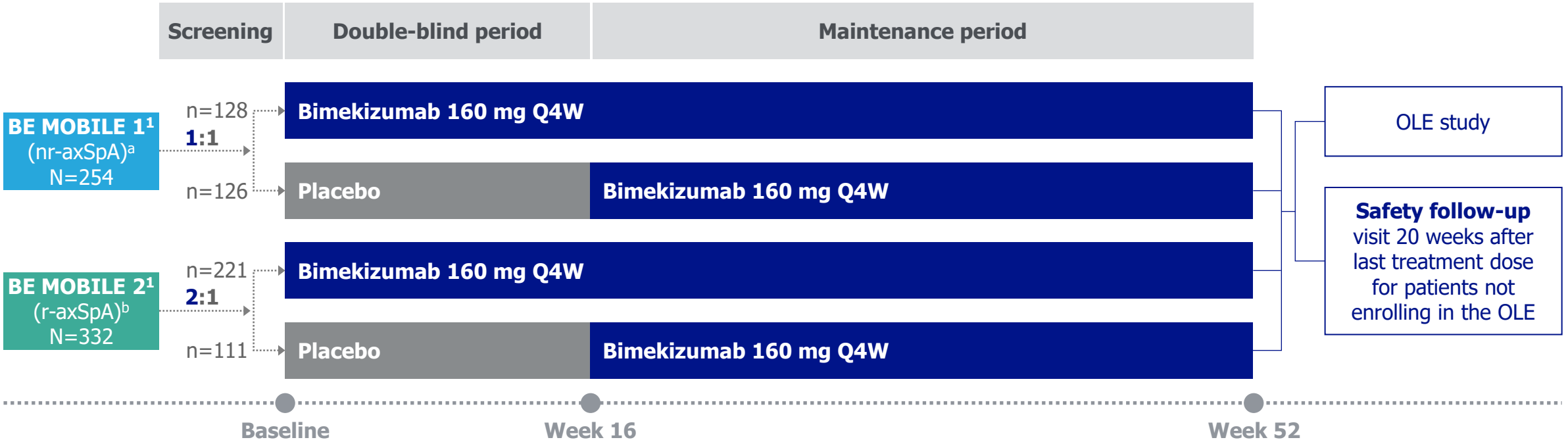
OBJECTIVE: To evaluate the impact of bimekizumab treatment on MRI inflammatory and structural lesions in the SIJ of patients with axSpA to Week 52 in BE MOBILE 1 and BE MOBILE 2

1. Navarro-Compán V. Ann Rheum Dis 2021;80:1511–21; 2. Maksymowych WP. Arthritis Rheum 2009;60:93–102; 3. Baraliakos X. Ann Rheum Dis 2024;83:199–213; 4. Baraliakos X. Presented at EULAR 2024. POS0806; 5. Yang XO. J Exp Med. 2008;1063–75; 6. Glatt S. Ann Rheum Dis. 2018;77:523–32; 7. Navarro-Compán V. Front Immunol 2023;14:1191782. BE MOBILE 1: NCT03928704; BE MOBILE 2: NCT03928743; OLE: NCT04436640. axSpA: axial spondyloarthritis; Ig: immunoglobulin; IL: interleukin; MRI: magnetic resonance imaging; OLE: open-label extension; RA: receptor A; r-axSpA: radiographic axial spondyloarthritis; RC: receptor C; SIJ: sacroiliac joints.

Methods (1/5)

Study Design

- BE MOBILE 1 (nr-axSpA) and BE MOBILE 2 (r-axSpA) comprised a 16-week double-blind placebo-controlled period followed by a 36-week maintenance period
- In BE MOBILE 1, patients were randomized 1:1 to receive bimekizumab 160 mg every 4 weeks (Q4W) or placebo; in BE MOBILE 2, patients were randomized 2:1 to receive bimekizumab 160 mg Q4W or placebo
- From Weeks 16 to 52, all patients received subcutaneous bimekizumab 160 mg Q4W

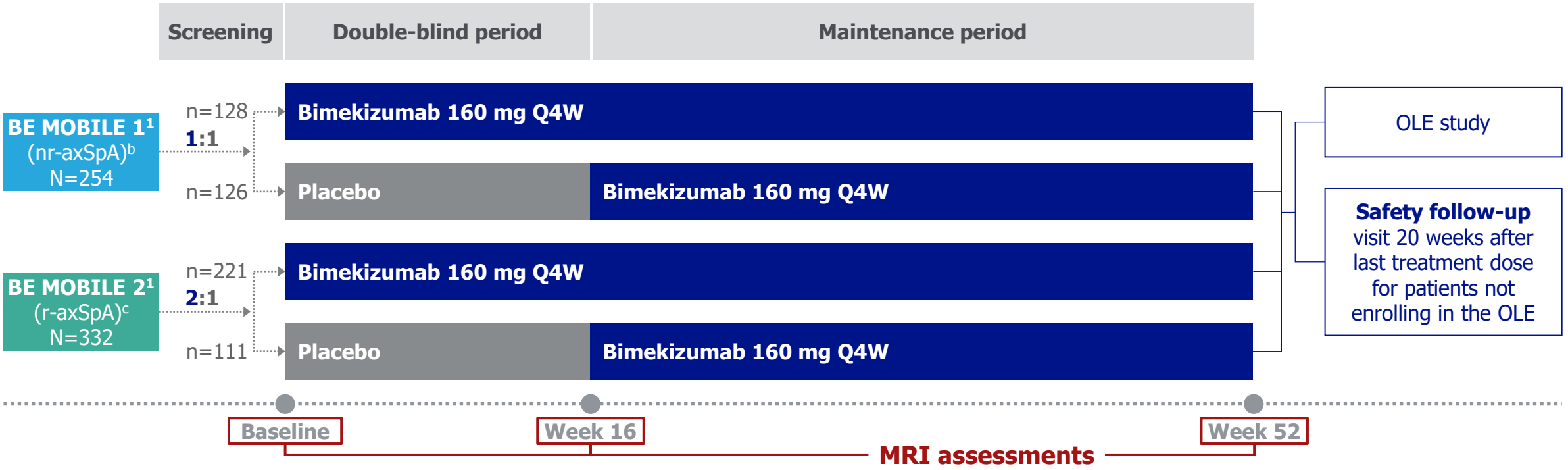


[a] Included patients had adult-onset nr-axSpA fulfilling ASAS classification criteria and objective signs of inflammation (active sacroiliitis on MRI and/or elevated CRP [≥6 mg/L]). [b] Included patients had radiographic evidence of r-axSpA fulfilling modified New York criteria. 1. van der Heijde D, et al. Ann Rheum Dis. 2023;82:515–26. BE MOBILE 1: NCT03928704; BE MOBILE 2: NCT03928743. ASAS: Assessment of SpondyloArthritis international Society; axSpA: axial spondyloarthritis; CRP: C-reactive protein; MRI: magnetic resonance imaging; OLE: open-label extension; nr-axSpA: non-radiographic axSpA; Q4W: every 4 weeks; r-axSpA: radiographic axSpA.

Methods (2/5)

MRI SIJ Assessments

- Spondyloarthritis Research Consortium of Canada (SPARCC) SIJ inflammation scores and SPARCC SIJ Structural Scores (SSS: erosions, backfill, fat lesions, ankylosis) were assessed at baseline, Week 16, and Week 52 in the MRI sub-studies
- MRIs were read centrally by two independent experts (adjudicated in cases of disagreement) in a single reading campaign
- All readers were blinded to timepoint and any clinical data; structural lesions were analyzed post hoc[a]



[a] Inflammatory and structural lesions were assessed independently by different readers, hence the number of MRIs successfully scored could differ. [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]). [c] Included patients had radiographic evidence of r-axSpA fulfilling modified New York criteria. 1. van der Heijde D, et al. Ann Rheum Dis. 2023;82:515–26. BE MOBILE 1: NCT03928704; BE MOBILE 2: NCT03928743. ASAS: Assessment of SpondyloArthritis international Society; axSpA: axial spondyloarthritis; CRP: C-reactive protein; MRI: magnetic resonance imaging; nr-axSpA: non-radiographic axSpA; OLE: open-label extension; Q4W: every 4 weeks; r-axSpA: radiographic axSpA; SPARCC: Spondyloarthritis Research Consortium of Canada; SIJ: sacroiliac joints; SSS: SIJ Structural Score.

Methods (3/5)

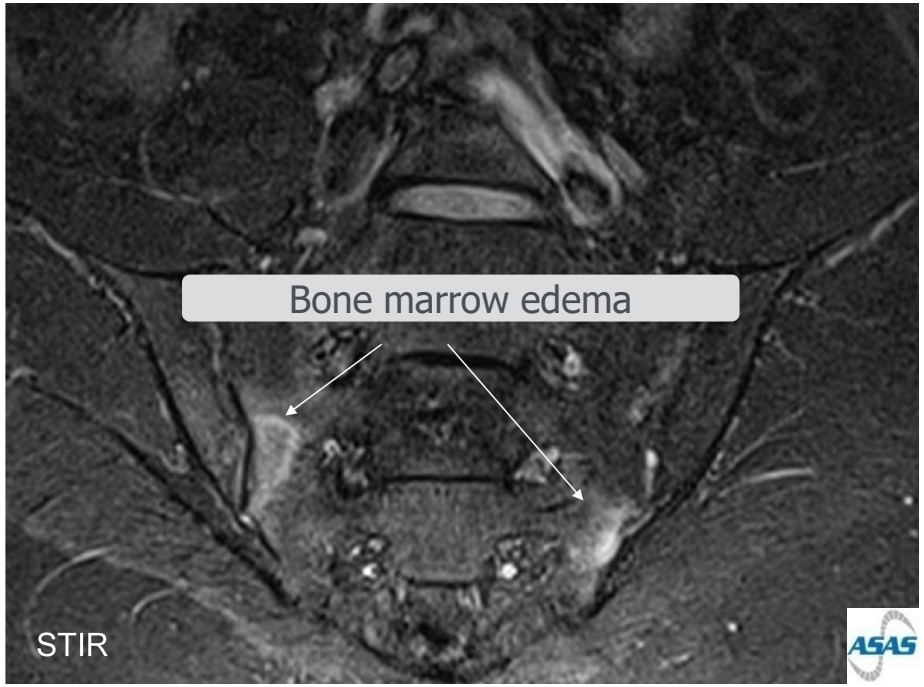
Evaluation of Inflammatory Lesions in the SIJ using MRI SPARCC SIJ Inflammation Scores[1,2]

- Assessment of six consecutive coronal slices of each SIJ (left and right; STIR sequence), with each joint separated into four quadrants
- Overall score comprises three components, individually scored on a dichotomous basis (present=1, absent=0), and summed to give a total maximum score of 72:

Presence of edema assessed in each quadrant (maximum score of 48)

Edema intensity assessed in each joint (maximum score of 12)

Edema depth assessed in each joint (maximum score of 12)



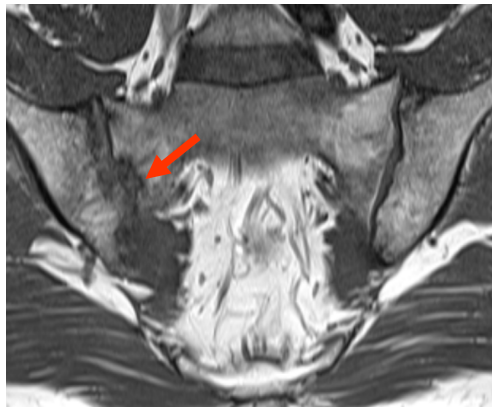
1. Hededal P. J Rheumatol 2018:45:70–7; 2. Image adapted from ASAS Educational Slide Kits. 2013. Available at: https://www.asas-group.org/education/asas-slide-library/ [Accessed September 2024]. MRI: magnetic resonance imaging; SIJ: sacroiliac joints; SPARCC: Spondyloarthritis Research Consortium of Canada; STIR: short tau inversion recovery.

Methods (4/5)

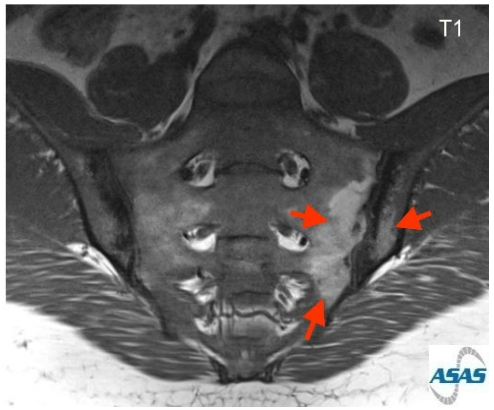
Evaluation of Structural Lesions in the SIJ using MRI SPARCC SSS[1–4]

- SPARCC SSS assesses the structural lesions of erosions, backfill, fat, and ankylosis in the SIJ using MRI T1-weighed image sequences
- Each lesion type is individually scored on a dichotomous basis (present=1, absent=0) on five consecutive slices through the SIJ and summed to give a total score per lesion type

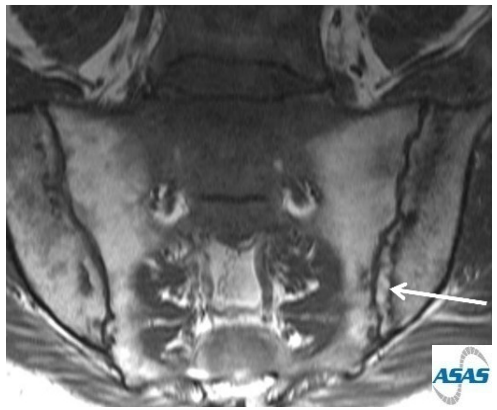
Erosions[3]



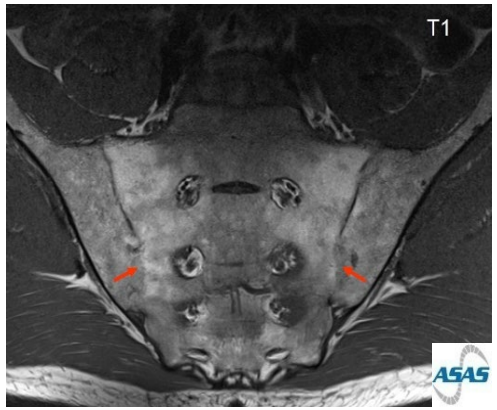
Fat lesions[4]



Backfill[4]



Ankylosis[4]



Presence/absence of erosions and fat lesions are scored in **SIJ quadrants**. Erosions and fat lesions are each scored from 0–8 per slice for five slices (total score range: 0–40)

Presence/absence of backfill and ankylosis are scored in **SIJ halves**. Backfill and ankylosis are each scored from 0–4 per slice for five slices (total score range: 0–20)

1. Maksymowych WP. Arthritis Rheum. 2014;66:2958–67; 2. Maksymowych WP. Ann Rheum Dis 2018;77:78–84; 3. Representative images provided by UCB. Patients consented to the use of these images as part of their participation in the MRI sub-studies; 4. Images adapted from ASAS Educational Slide Kits. 2013. Available at: https://www.asas-group.org/education/asas-slide-library/ [Accessed July 2024]. ASAS: Assessment of SpondyloArthritis international Society; MRI: magnetic resonance imaging; SIJ: sacroiliac joints; SPARCC: Spondyloarthritis Research Consortium of Canada; SSS: SIJ Structural Score.

Methods (5/5)

For patients with valid MRI assessments at all 3 timepoints (baseline, Week 16, and Week 52), the following parameters are reported:

Change from baseline in SPARCC SIJ inflammation scores

Proportion of patients with a baseline SPARCC SIJ inflammation score ≥2 achieving MRI SIJ remission, defined as SPARCC SIJ inflammation score <2

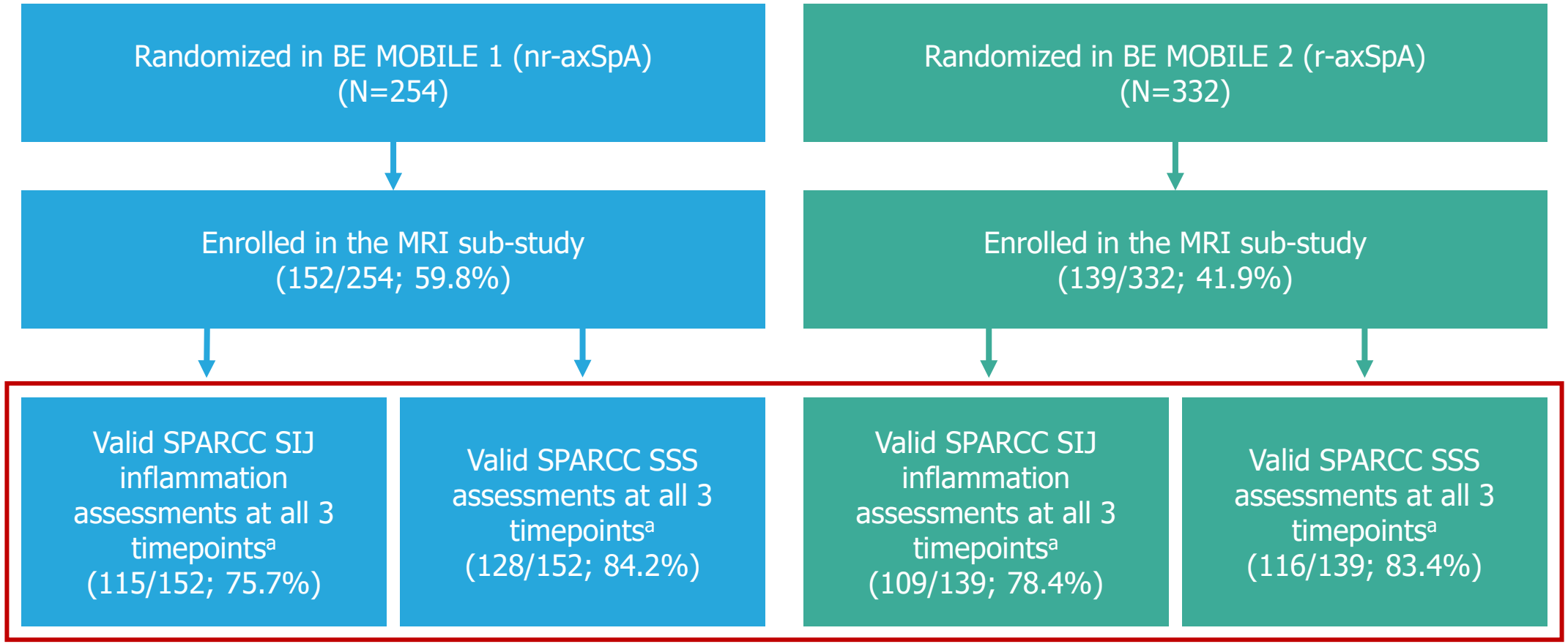
Change from baseline in SPARCC SSS components

Inter-reader agreement data (i.e., smallest detectable change [SDC] and intra-class correlation [ICC]) for inflammatory and structural lesion scores

ICC: intra-class correlation; MRI: magnetic resonance imaging; SPARCC: Spondyloarthritis Research Consortium of Canada; SDC: smallest detectable change; SIJ: sacroiliac joints; SSS: SIJ Structural Score.

Patient Disposition

- Of patients with nr-axSpA or r-axSpA randomized in BE MOBILE 1 and 2, ~60% and ~42% enrolled in the MRI sub-studies, respectively:



[a] Inflammatory and structural lesions were assessed independently by different readers, hence the number of MRIs successfully scored could differ. axSpA: axial spondyloarthritis; MRI: magnetic resonance imaging; nr-axSpA: non-radiographic axSpA; r-axSpA: radiographic axSpA; SPARCC: Spondyloarthritis Research Consortium of Canada; SIJ: sacroiliac joints; SSS: SIJ Structural Score.

Baseline Characteristics: MRI Sub-Studies

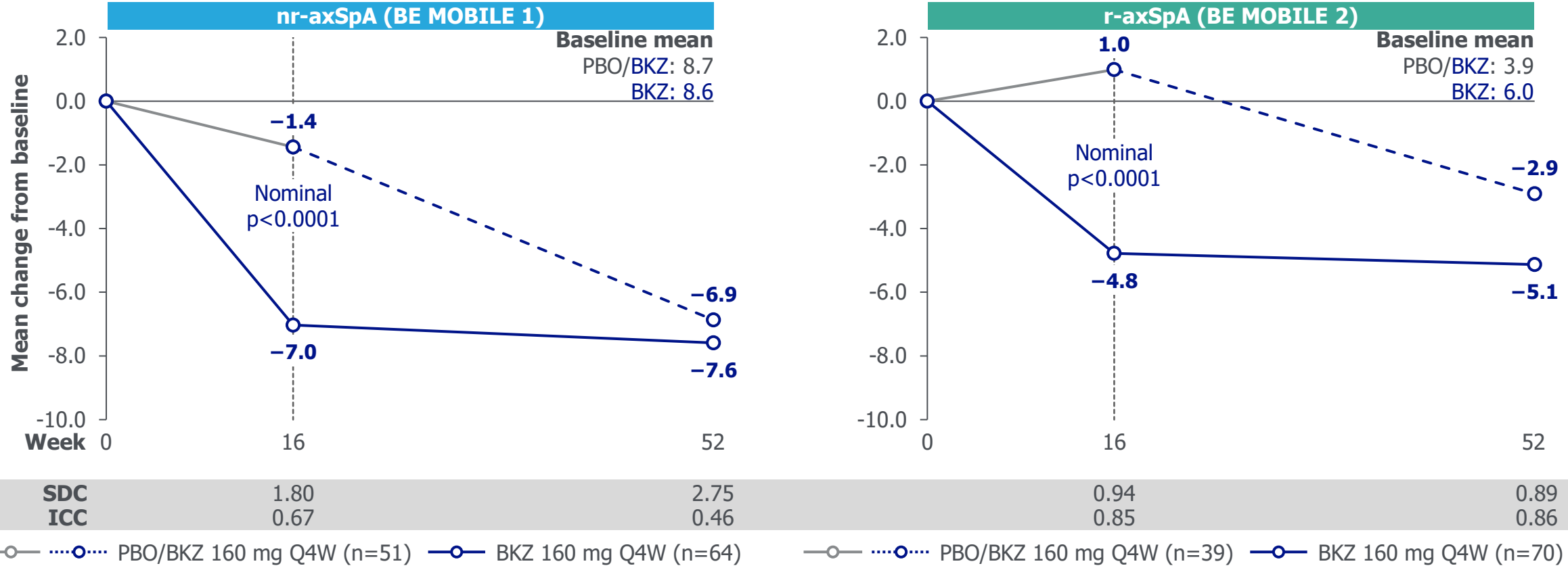
- Baseline characteristics in the MRI sub-studies were largely comparable between treatment arms and reflected those of the overall patient population

Mean (SD), unless otherwise stated	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	40.0 (12.5)	38.9 (11.6)	39.4 (11.5)	39.7 (12.9)	40.1 (12.2)	40.4 (12.3)
Sex, male, n (%)	31 (44.3)	50 (61.0)	138 (54.3)	31 (64.6)	68 (74.7)	240 (72.3)
HLA-B27 positive, n (%)	47 (67.1)	65 (79.3)	197 (77.6)	39 (81.3)	80 (87.9)	284 (85.5)
Symptom duration, years	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	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	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, n (%)	8 (11.4)	5 (6.1)	27 (10.6)	7 (14.6)	13 (14.3)	54 (16.3)
Patients in MRI sub-studies with assessments at all 3 timepoints						
SPARCC SIJ[d]	8.7 (11.6)	8.6 (10.3)	-	3.9 (6.2)	6.0 (9.0)	-
SPARCC SIJ ≥2,[d] n (%)	32 (62.7)	39 (60.9)	-	18 (46.2)	36 (51.4)	-
SPARCC SSS (erosions)[e]	2.7 (4.0)	3.8 (5.3)	-	2.9 (3.4)	3.6 (4.9)	-
SPARCC SSS (backfill)[e]	0.6 (1.3)	0.4 (1.2)	-	0.8 (1.7)	1.8 (3.4)	-
SPARCC SSS (fat lesions)[e]	1.1 (2.9)	1.0 (2.6)	-	3.4 (6.6)	5.6 (7.9)	-
SPARCC SSS (ankylosis)[e]	0.0 (0.1)	0.1 (0.2)	-	5.0 (7.7)	5.9 (8.2)	-

Randomized set. [a] Includes only patients in the MRI sub-study. [b] All patients in the overall study pooled, regardless of treatment arm. [c] n=331. [d] In patients in the MRI sub-studies with valid SPARCC SIJ inflammation assessments at baseline, Week 16, and Week 52: nr-axSpA: PBO: n=51, BKZ: n=64; r-axSpA: PBO: n=39, BKZ: n=70. [e] In patients in the MRI sub-studies with valid SPARCC SSS assessments at baseline, Week 16, and Week 52: nr-axSpA: PBO: n=59; BKZ: n=69, r-axSpA: PBO: n=41; BKZ: n=75. ASDAS: Axial Spondyloarthritis Disease Activity Score; axSpA: axial spondyloarthritis; BASDAI: Bath Ankylosing Spondylitis Disease Activity Index; BKZ: bimekizumab; CV: coefficient of variation; hs-CRP: high-sensitivity C-reactive protein; MRI: magnetic resonance imaging; nr-axSpA: non-radiographic axSpA; PBO: placebo; Q4W; every 4 weeks; r-axSpA: radiographic axSpA; SD: standard deviation; SPARCC: Spondyloarthritis Research Consortium of Canada; SIJ: sacroiliac joint; SSS: SIJ structural score; TNFi: tumor necrosis factor inhibitor.

SPARCC SIJ Inflammation Scores (OC)

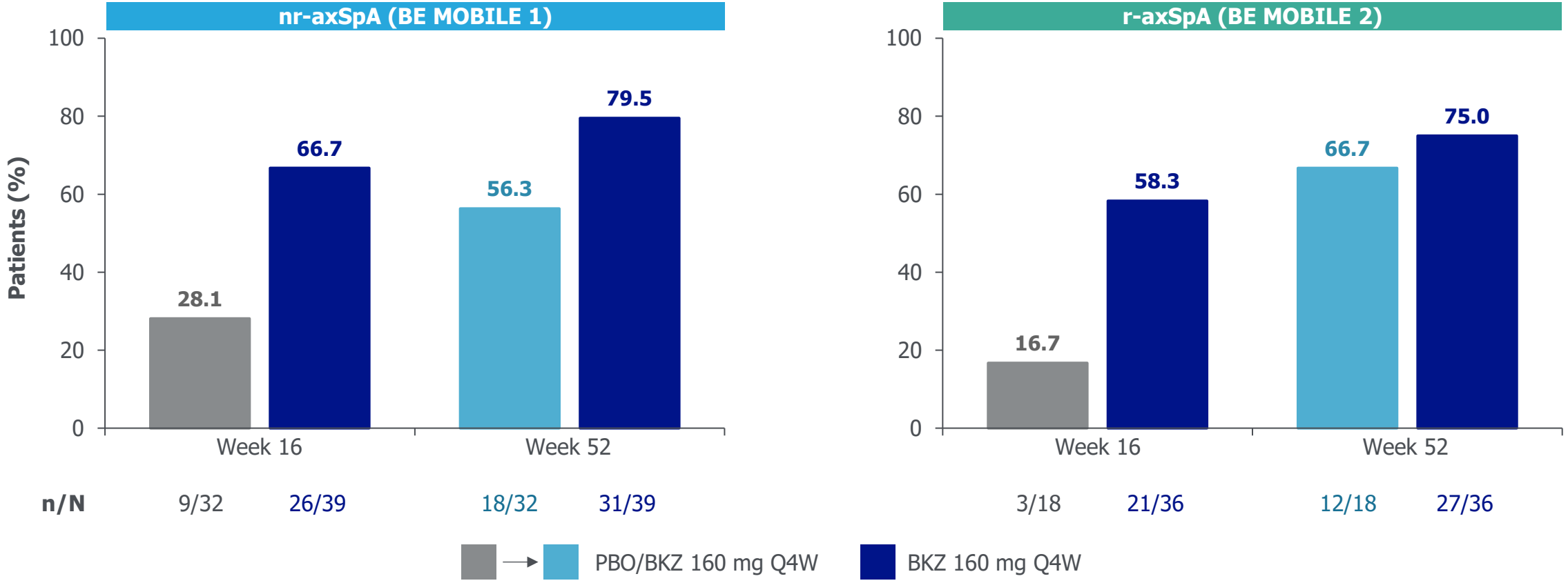
- Across the full disease spectrum of axSpA, bimekizumab demonstrated substantially larger reductions in SPARCC SIJ inflammation scores compared with placebo at Week 16, with marked decreases from baseline
- Patients continuing or switching to bimekizumab showed further decreases at Week 52



Randomized set. Includes only patients in the MRI sub-studies with valid SPARCC SIJ inflammation assessments at baseline, Week 16, and Week 52. SPARCC SIJ inflammation scores range from 0–72, with lower scores indicating less inflammation. SDC was calculated as 1.96 × standard error × √2, where standard error is the difference of the change scores between the two readers (per patient). The ICC assessed the inter-reader reliability using the two-way random effects mixed model for the absolute agreement between single scores from two independent readers. SDC and ICC are calculated based on change from baseline to the week displayed (i.e. baseline to Week 16, and baseline to Week 52, for the respective timepoints shown). axSpA: axial spondyloarthritis; BKZ: bimekizumab; ICC: intra-class correlation; MRI: magnetic resonance imaging; nr-axSpA: non-radiographic axSpA; OC: observed case; PBO: placebo; Q4W; every 4 weeks; r-axSpA: radiographic axSpA; SPARCC: Spondyloarthritis Research Consortium of Canada; SDC: smallest detectable change; SIJ: sacroiliac joints.

Achievement of MRI SIJ Remission (OC)

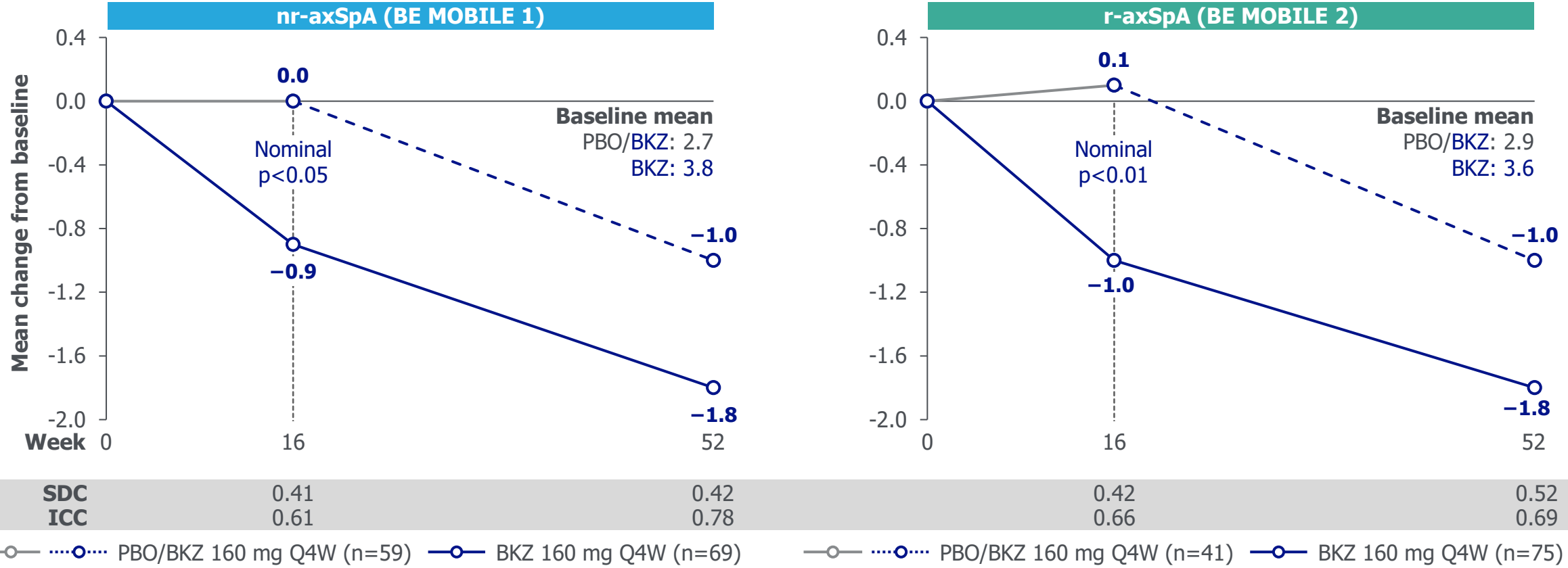
- At Week 16, a larger proportion of bimekizumab- vs placebo-randomized patients with SPARCC SIJ inflammation score ≥2 at baseline achieved MRI SIJ remission (SPARCC SIJ inflammation score <2)
- At Week 52, at least 75% of continuous bimekizumab patients achieved MRI SIJ remission



Randomized set; patients had existing inflammation at baseline (SPARCC SIJ inflammation score ≥2). Includes only patients in the MRI sub-studies with valid SPARCC SIJ inflammation assessments at baseline, Week 16, and Week 52.
axSpA: axial spondyloarthritis; BKZ: bimekizumab; nr-axSpA: non-radiographic axSpA; OC: observed case; MRI: magnetic resonance imaging; PBO: placebo; Q4W; every 4 weeks; r-axSpA: radiographic axSpA; SPARCC: Spondyloarthritis Research Consortium of Canada; SIJ: sacroiliac joints.

SPARCC SSS: Erosions (0–40; OC)

- At Week 16, across the full disease spectrum of axSpA, bimekizumab demonstrated substantially larger reductions in erosion scores compared with placebo
- At Week 52, patients continuing or switching to bimekizumab showed further decreases in erosion scores



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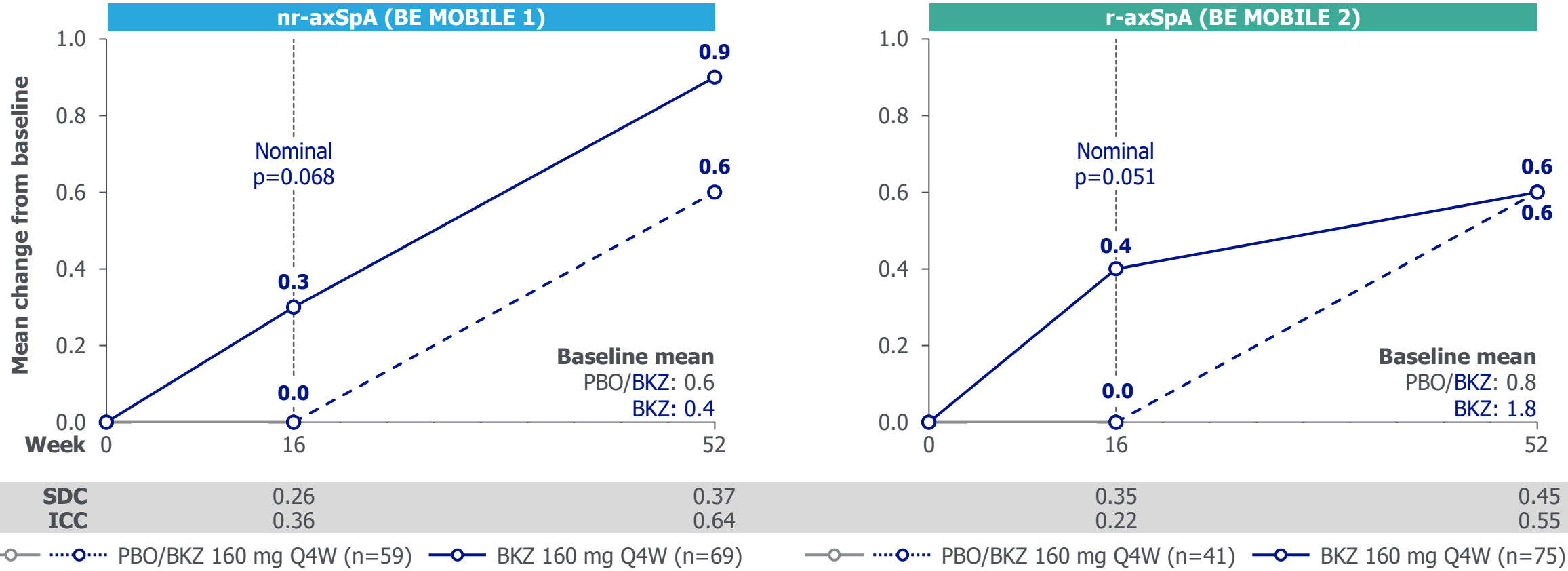
SPARCC SSS: Backfill (0–20; OC)

- At Week 16, bimekizumab showed substantially larger increases in backfill scores vs placebo in patients with nr-axSpA and r-axSpA
- At Week 52, patients continuing or switching to bimekizumab showed further increases in backfill scores



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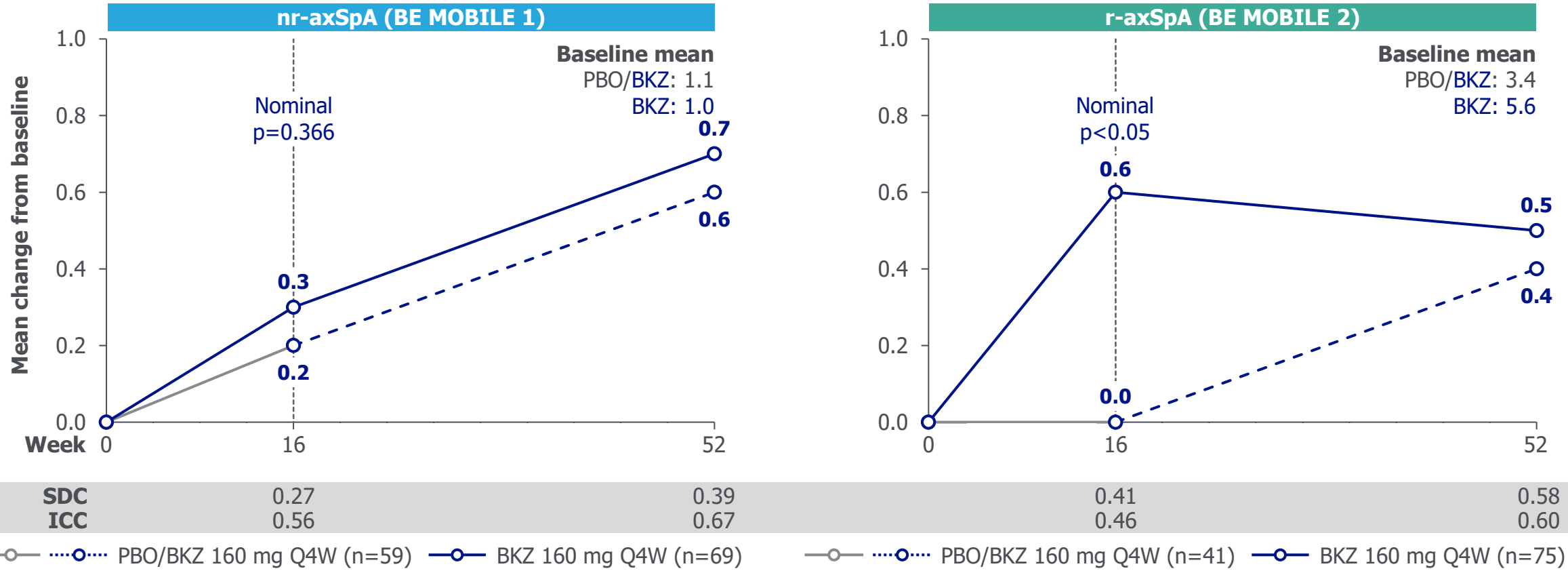
SPARCC SSS: Fat Lesions (0–40; OC)

- At Week 16, fat lesion scores increased with bimekizumab across the full disease spectrum of axSpA
- At Week 52, these scores continued to increase, or were largely sustained, in patients continuing or switching to bimekizumab



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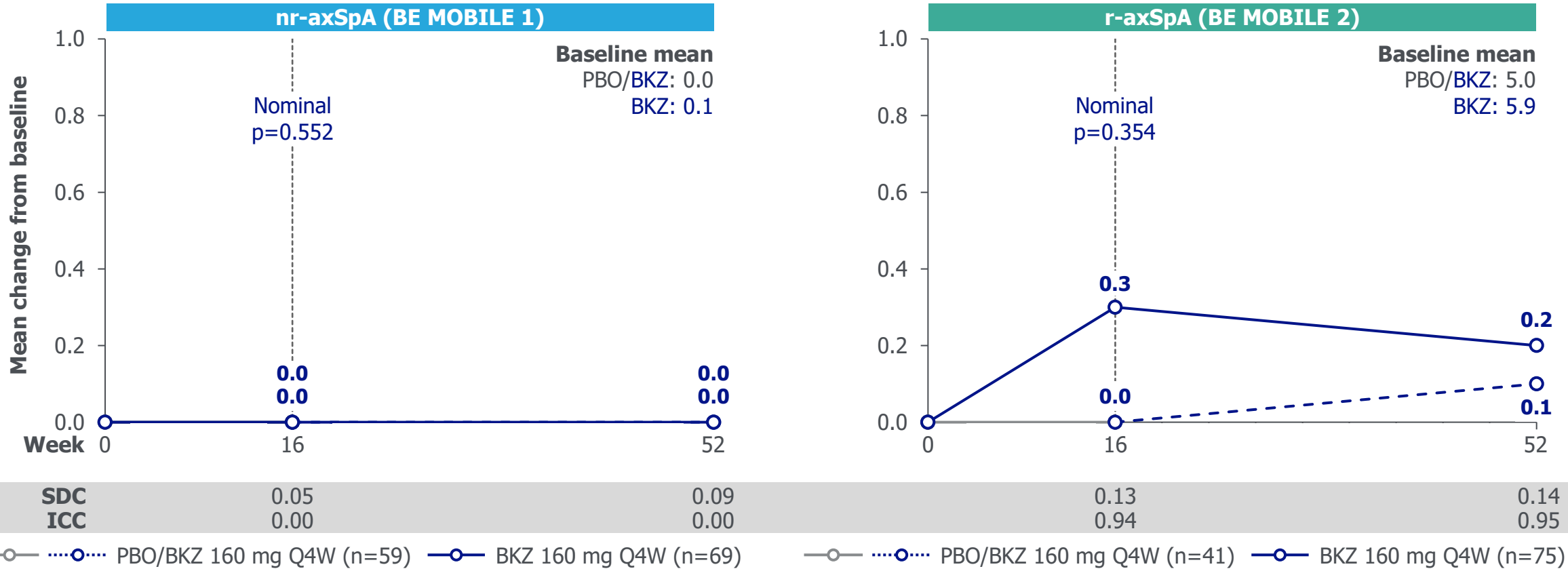
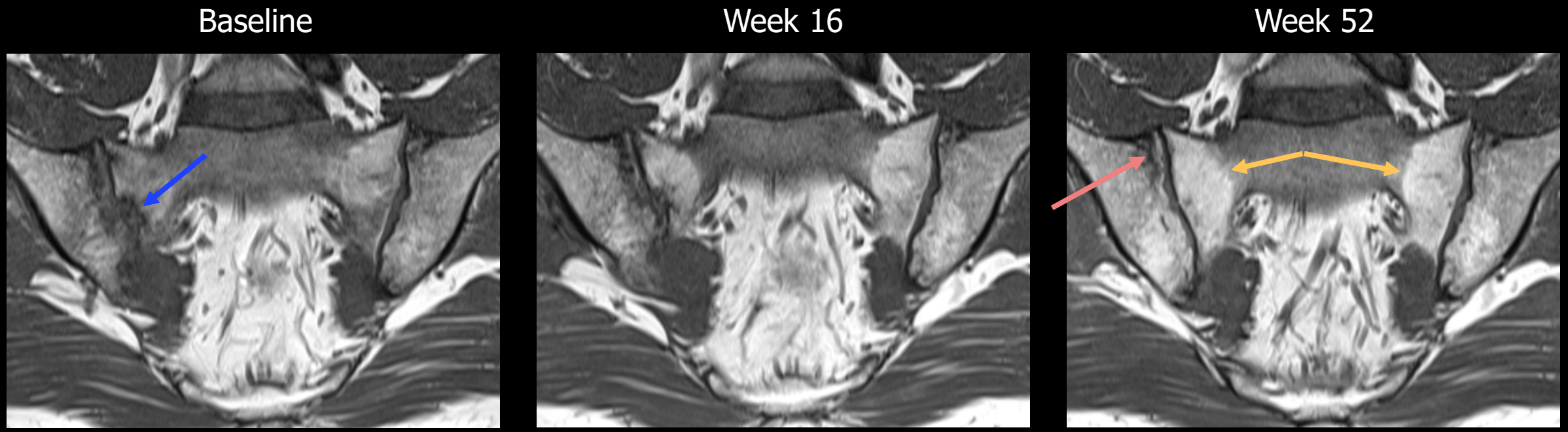
SPARCC SSS: Ankylosis (0–20; OC)

- No or minimal changes in ankylosis score were observed following treatment with bimekizumab in patients with nr-axSpA and r-axSpA, respectively, at Week 16 and Week 52



Randomized set. Includes only patients in the MRI sub-studies with valid SPARCC SSS assessments at baseline, Week 16, and Week 52. SDC was calculated as 1.96 × standard error × √2, where standard error is the difference of the change scores between the two readers (per patient). The ICC assessed the inter-reader reliability using the two-way random effects mixed model for the absolute agreement between single scores from two independent readers. SDC and ICC are calculated based on change from baseline to the week displayed (i.e. baseline to Week 16, and baseline to Week 52, for the respective timepoints shown). axSpA: axial spondyloarthritis; BKZ: bimekizumab; ICC: intra-class correlation; MRI: magnetic resonance imaging; nr-axSpA: non-radiographic axSpA; OC: observed case; PBO: placebo; Q4W; every 4 weeks; r-axSpA: radiographic axSpA; SPARCC: Spondyloarthritis Research Consortium of Canada; SDC: smallest detectable change; SIJ: sacroiliac joints; SSS: SIJ Structural Score.

Changes in Structural Lesions Over Time with Bimekizumab Treatment



Representative images provided by UCB. Patients consented to the use of these images as part of their participation in the MRI sub-studies.

Conclusions

After 52 weeks of bimekizumab treatment, the following were observed consistently across the full disease spectrum of axSpA:

Rapid and substantial reductions in SIJ inflammation, as measured by SPARCC SIJ inflammation scores, at Week 16 and Week 52

Over half of patients achieved **MRI SIJ remission** at Week 16 and Week 52, defined as SPARCC SIJ inflammation score <2

Substantial decreases in **erosions,** and **increases** in **backfill** and **fat lesions** compared with baseline, potentially indicating **tissue response** after only 16 weeks of treatment

Dual inhibition of IL-17A and IL-17F with bimekizumab had a **substantial impact** on **inflammatory and structural lesions** at Week 16; improvements largely continued or were sustained at Week 52 across patients with nr-axSpA and r-axSpA

To access the presentation, scan the QR code or visit:
UCBposters.com/ACR2024
Link expiration: February 17, 2025

axSpA: axial spondyloarthritis; IL: interleukin; MRI: magnetic resonance imaging; nr-axSpA: non-radiographic axSpA; r-axSpA: radiographic axSpA; SPARCC: Spondyloarthritis Research Consortium of Canada; SIJ: sacroiliac joints.