Bimekizumab in Ankylosing Spondylitis & Non-Radiographic Axial Spondyloarthritis

For proactive use by medical affairs personnel

Inspired by **patients.**
Driven by **science.**

Disclaimer

BIMZELX is indicated for the treatment of adult patients with active non-radiographic axial spondyloarthritis with objective signs of inflammation. The recommended dosage is 160 mg by subcutaneous injection every 4 weeks.

BIMZELX is indicated for the treatment of adult patients with active ankylosing spondylitis. The recommended dosage is 160 mg by subcutaneous injection every 4 weeks.

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Publications of BKZ Phase 3 Trials in axSpA

Van der Heijde, et al. (**2023**)
Efficacy and safety of bimekizumab in axial spondyloarthritis: results of two parallel phase 3 randomized controlled trials

US-BK-2400556

Baraliakos, et al. (**2024**)
Bimekizumab treatment in patients with active axial spondyloarthritis: 52-week efficacy and safety from the randomised parallel phase 3 BE MOBILE 1 and BE MOBILE 2 studies

US-BK-2400565

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BE MOBILE 1 and BE MOBILE 2: Phase 3 Studies of Bimekizumab (BKZ) in Patients with Active Axial Spondyloarthritis (axSpA)

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Contents: BE MOBILE 1 and BE MOBILE 2 Combined Results

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BE MOBILE 1: Key Inclusion and Exclusion Criteria

Inclusion[1]

≥18 years of age

nr-axSpA fulfilling ASAS classification criteria

Active nr-axSpA at screening and baseline, determined by:

BASDAI and spinal pain scores ≥4

Objective inflammation, determined by:

Active sacroiliitis on MRI*

AND/OR

Elevated CRP (≥6.0 mg/L)

Failure to respond to at least two different NSAIDs, or history of intolerance or contraindication to NSAIDs

Exclusion[1,2,†]

Failure of >1 TNFi[‡], >2 additional biologic response modifiers[§] or any previous use of IL-17i

Patients with **active, symptomatic** IBD at screening and baseline

Prior history of IBD was **not** an exclusion criterion

Acute anterior uveitis within 6 weeks of baseline visit

Radiographic sacroiliitis meeting mNY criteria (assessed by two central readers)

*MRIs of the sacroiliac joints (SIJ) were assessed as ASAS positive (MRI+) or (MRI–) through central reading by two independent expert readers with an adjudicator; CRP+ defined as ≥6.0mg/L.[1] †Other exclusion criteria included active infection (except common cold), diagnosis of active TB or high risk of acquiring TB, fibromyalgia or osteoarthritis symptoms with potential to interfere with efficacy assessments, and moderately severe or severe major depression indicated by a score ≥15 on the Patient Health Questionnaire (PHQ)-9 at screening; latent TB was permitted provided the patient had received ≥4 weeks of appropriate infection therapy and had no evidence of therapy related hepatotoxicity (ALT/AST remaining ≤3 times upper limit of normal [ULN]) prior to administration of the first treatment dose.[2] ‡ Patients who had previously received a TNFi must have been intolerant/experienced an inadequate response to previous treatment given at an approved dose for at least 12 weeks.[2] §Other than TNFis; including investigational biologics received in prior clinical trials.[2]

1. van der Heijde D et al. Ann Rheum Dis. 2023;82(4):515–526. 2. van der Heijde D et al. Supplementary appendix. Ann Rheum Dis. 2023;82(4):515–526.

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BE MOBILE 2: Key Inclusion and Exclusion Criteria

Inclusion[1]

≥18 years of age

AS fulfilling mNY classification criteria*

Active disease at screening and baseline, determined by:

BASDAI and spinal pain scores ≥4

Failure to respond to at least two different NSAIDs, or history of intolerance or contraindication to NSAIDs

Exclusion[2,†]

Failure of >1 TNFi[‡], >2 additional biologic response modifiers[§] or any previous use of IL-17i

Patients with **active, symptomatic** IBD at screening or baseline

Prior history of IBD was **not** an exclusion criterion

Acute anterior uveitis within 6 weeks of baseline visit

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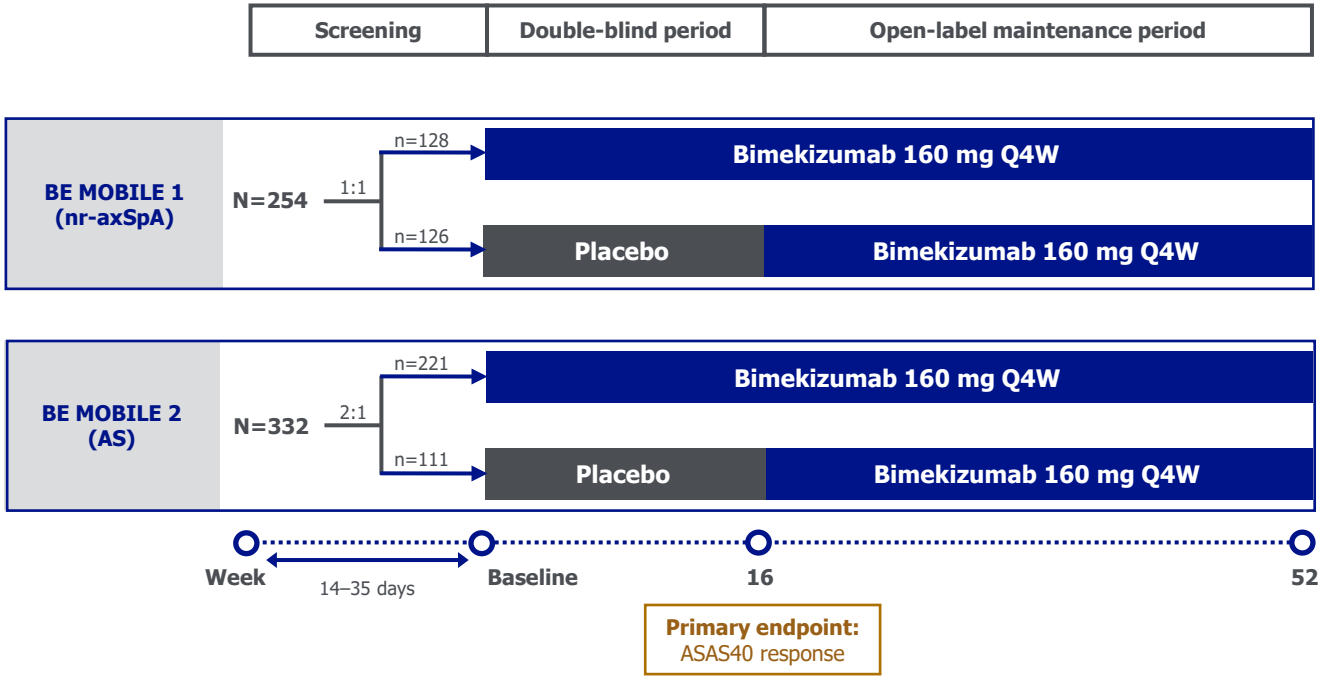
*Including documented radiographic evidence of sacroiliitis (grade ≥2 bilateral or grade ≥3 unilateral). Fulfilment of the ASAS classification criteria was also checked, and all patients met both mNY and ASAS criteria.[1] †Other exclusion criteria included active infection (except common cold), diagnosis of active TB or high risk of acquiring TB, fibromyalgia or osteoarthritis symptoms with potential to interfere with efficacy assessments, and moderately severe or severe major depression indicated by a score ≥15 on the Patient Health Questionnaire (PHQ)-9 at screening. Latent TB was permitted provided the patient had received ≥4 weeks of appropriate infection therapy and had no evidence of therapy related hepatotoxicity (ALT/AST remaining ≤3 times ULN) prior to administration of the first treatment dose.[2] ‡Patients who had previously received a TNFi must have been intolerant/experienced an inadequate response to previous treatment given at an approved dose for at least 12 weeks.[2] §Other than TNFis; including investigational biologics received in prior clinical trials.[2]

1. van der Heijde D et al. Ann Rheum Dis. 2023;82(4):515–526. 2. van der Heijde D et al. Supplementary appendix. Ann Rheum Dis. 2023;82(4):515–526.

BE MOBILE 1 and BE MOBILE 2: Phase 3 Studies Investigating BKZ in Patients with nr-axSpA and AS

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.

Baraliakos X et al. Supplementary appendix. Ann Rheum Dis. 2024;83(2):199–213.

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Statistical Testing Hierarchy

BE MOBILE 1

BKZ 160 mg Q4W α=0.05	Outcome	Test
H_1	**Primary**	ASAS40 response at Week 16 superior to placebo
H_2	Secondary	Change from baseline in BASDAI at Week 16 superior to placebo
H_3	Secondary	ASAS20 response at Week 16 superior to placebo
H_4	Secondary	ASAS-PR at Week 16 superior to placebo
H_5	Secondary	ASDAS-MI at Week 16 superior to placebo
H_6	Secondary	ASAS 5/6 response at Week 16 superior to placebo
H_7	Secondary	Change from baseline in BASFI at Week 16 superior to placebo
H_8	Secondary	Change from baseline in nocturnal spinal pain at Week 16 superior to placebo
H_9	Secondary	Change from baseline in ASQoL at Week 16 superior to placebo
H_{10}	Secondary	Change from baseline in SF-36 PCS at Week 16 superior to placebo

BE MOBILE 2

BKZ 160 mg Q4W α=0.05	Outcome	Test
H_1	**Primary**	ASAS40 response at Week 16 superior to placebo
H_2	Secondary	ASAS40 response at Week 16 superior to placebo (anti-TNF naïve patients)
H_3	Secondary	ASAS20 response at Week 16 superior to placebo
H_4	Secondary	Change from baseline in BASDAI at Week 16 superior to placebo
H_5	Secondary	ASAS-PR at Week 16 superior to placebo
H_6	Secondary	ASDAS-MI response at Week 16 superior to placebo
H_7	Secondary	ASAS 5/6 response at Week 16 superior to placebo
H_8	Secondary	Change from baseline in BASFI at Week 16 superior to placebo
H_9	Secondary	Change from baseline in nocturnal spinal pain at Week 16 superior to placebo
H_{10}	Secondary	Change from baseline in ASQoL at Week 16 superior to placebo
H_{11}	Secondary	Change from baseline in PCS SF-36 at Week 16 superior to placebo
H_{12}	Secondary	Change from baseline in BASMI at Week 16 superior to placebo

Adapted from van der Heijde D et al. Supplementary appendix. Ann Rheum Dis. 2023;82(4):515–526.

Patient Demographics and Baseline Characteristics Were Comparable Between Groups in Both Studies (1/2)

	BE MOBILE 1 (nr-axSpA)		BE MOBILE 2 (AS)	
	PBO (n=126)	BKZ 160 mg Q4W (n=128)	PBO (n=111)	BKZ 160 mg Q4W (n=221)
Sex (male), n (%)	65 (51.6)	73 (57.0)	80 (72.1)	160 (72.4)
Age, years, mean (SD)	39.4 (11.8)	39.5 (11.1)	39.2 (12.6)	41.0 (12.1)
HLA-B27, positive, n (%)	94 (74.6)	103 (80.5)	93 (83.8)	191 (86.4)
Geographical region*, n (%)				
Asia†	13 (10.3)	15 (11.7)	21 (18.9)	40 (18.1)
Eastern Europe‡	71 (56.3)	73 (57.0)	55 (49.5)	108 (48.9)
Western Europe§	33 (26.2)	31 (24.2)	32 (28.8)	67 (30.3)
North America‖	9 (7.1)	9 (7.0)	3 (2.7)	6 (2.7)
BMI, kg/m^2, mean (SD)	27.7 (5.5)	27.2 (6.0)	27.1 (5.8)	26.8 (5.7)
Time since first symptoms of axSpA, years, mean (SD)	9.0 (9.0)	9.1 (8.7)	11.9 (8.6)	14.2 (11.0)
Time since first diagnosis of axSpA, years, mean (SD)	3.6 (5.4)	3.7 (6.2)	5.7 (6.9)	6.7 (8.3)
ASDAS, mean (SD)	3.7 (0.7)	3.7 (0.8)	3.7 (0.8)	3.7 (0.8)¶
hs-CRP, mg/L, geometric mean (geometric CV, %)	5.0 (230.5)	4.6 (297.7)	6.7 (197.4)	6.5 (275.0)
hs-CRP > ULN**, n (%)	71 (56.3)	70 (54.7)	67 (60.4)	137 (62.0)
BASDAI, mean (SD)	6.7 (1.3)	6.9 (1.2)	6.5 (1.3)	6.5 (1.3)
PGADA††, mean (SD)	6.9 (1.9)	7.1 (1.9)	6.7 (1.8)	6.6 (2.0)¶
Total spinal pain††, mean (SD)	7.1 (1.6)	7.3 (1.5)	7.2 (1.2)	7.1 (1.6)
Nocturnal spinal pain, mean (SD)	6.7 (2.1)	6.9 (2.0)	6.8 (1.8)	6.6 (1.9)
Morning stiffness (mean of BASDAI Q5 and 6)††, mean (SD)	6.9 (1.6)	7.0 (1.8)	6.8 (1.6)	6.7 (1.9)
BASFI††, mean (SD)	5.3 (2.3)	5.5 (2.2)	5.2 (2.0)	5.3 (2.2)
BASMI, mean (SD)	3.0 (1.2)	2.9 (1.3)	3.8 (1.6)	3.9 (1.6)
ASQoL, mean (SD)	9.4 (4.4)	9.5 (4.6)	8.5 (4.3)	9.0 (4.7)
SF-36 PCS, mean (SD)	33.6 (8.7)	33.3 (8.3)	34.6 (8.7)	34.3 (8.4)¶

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Randomized set. Patients in BE MOBILE 1 met ASAS criteria and patients in BE MOBILE 2 met mNY and ASAS criteria. *Patients categorized by stratum to which they were randomized. †Includes Turkey, Japan and China. ‡Includes Bulgaria, Czech Republic, Hungary and Poland. §Includes Belgium, France, Germany, Netherlands, Spain and United Kingdom. ‖Includes United States of America only. ¶n=220. **ULN value for hs-CRP is 5 mg/L. ††Part of the primary outcome measure.

Baraliakos X et al. Ann Rheum Dis. 2024;83(2):199–213.

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Patient Demographics and Baseline Characteristics Were Comparable Between Groups in Both Studies (2/2)

	BE MOBILE 1 (nr-axSpA)		BE MOBILE 2 (AS)	
	PBO (n=126)	BKZ 160 mg Q4W (n=128)	PBO (n=111)	BKZ 160 mg Q4W (n=221)
MRI Berlin spine score*, mean (SD)	1.6 (2.9)[†]	1.6 (2.6)[‡]	3.2 (4.1)[§]	3.3 (4.5)[‖]
MRI SPARCC SIJ score*, mean (SD)	9.8 (12.6)[¶]	8.0 (9.9)[**]	3.8 (6.1)[§]	5.4 (8.4)[††]
Current enthesitis (MASES >0), n (%)	92 (73.0)	94 (73.4)	67 (60.4)	132 (59.7)
MASES[‡‡], mean (SE)	4.9 (0.4)	4.8 (0.3)	4.4 (0.3)	4.2 (0.3)
Current peripheral arthritis (SJC >0), n (%)	43 (34.1)	45 (35.2)	22 (19.8)	44 (19.9)
History of IBD[§§], n (%)	1 (0.8)	3 (2.3)	1 (0.9)	3 (1.4)
History of uveitis[§§], n (%)	21 (16.7)	19 (14.8)	24 (21.6)	33 (14.9)
History of psoriasis[§§], n (%)	7 (5.6)	9 (7.0)	10 (9.0)	16 (7.2)
Prior TNFi exposure (TNFi-IR patients)[‖‖], n (%)	17 (13.5)	10 (7.8)	17 (15.3)	37 (16.7)
Concomitant medication use at baseline, n (%)				
NSAIDs	93 (73.8)	96 (75.0)	85 (76.6)	181 (81.9)
Oral glucocorticosteroids	14 (11.1)	7 (5.5)	8 (7.2)	15 (6.8)
csDMARDs[¶¶]	32 (25.4)	29 (22.7)	19 (17.1)	47 (21.3)

Randomized set. Patients in BE MOBILE 1 met ASAS criteria and patients in BE MOBILE 2 met mNY and ASAS criteria. *In patients in MRI sub-study. [†]n=67. [‡]n=79. [§]n=48. [‖]n=89. [¶]n=70. [**]n=82. [††]n=90. [‡‡]In patients with MASES >0 at baseline. [§§]Based on extra-articular assessments at screening or baseline. [‖‖]Defined as patients who were intolerant or experienced an inadequate response to previous TNFi treatment given at an approved dose for at least 12 weeks. [¶¶]Methotrexate in 21 patients with nr-axSpA and 12 patients with AS, sulfasalazine in 33 patients with nr-axSpA and 52 patients with AS.

Baraliakos X et al. Ann Rheum Dis. 2024;83(2):199–213.

Results: Clinical Outcomes

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BE MOBILE 1 Met the Primary and All Ranked Secondary Endpoints at Week 16

	Efficacy endpoint	Placebo (n=126)	BKZ 160 mg Q4W (n=128)	p value‡
1	ASAS40,* n (%)	27 (21.4)	61 (47.7)	<0.001
2	BASDAI CfB,† mean (SE)	-1.5 (0.2)	-3.1 (0.2)	<0.001
3	ASAS20,† n (%)	48 (38.1)	88 (68.8)	<0.001
4	ASAS partial remission,† n (%)	9 (7.1)	33 (25.8)	<0.001
5	ASDAS-MI,† n (%)	9 (7.1)	35 (27.3)	<0.001
6	ASAS 5/6,† n (%)	26 (20.6)	58 (45.3)	<0.001
7	BASFI CfB,† mean (SE)	-1.0 (0.2)	-2.5 (0.2)	<0.001
8	Nocturnal spinal pain CfB,† mean (SE)	-1.7 (0.2)	-3.6 (0.3)	<0.001
9	ASQoL CfB,† mean (SE)	-2.5 (0.4)	-5.2 (0.4)	<0.001
10	SF-36 PCS CfB,† mean (SE)	5.5 (0.7)	9.5 (0.7)	<0.001

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Missing data were imputed using NRI for binary endpoints and RBMI for continuous endpoints (based on data from the PBO group). Randomized set. *Primary endpoint. †Secondary endpoint. ‡All tests performed at a 2-sided alpha level of 0.05. For binary variables, p values were calculated by logistic regression with treatment, MRI/CRP classification and region as factors. For continuous variables, p values were obtained by ANCOVA with treatment, MRI/CRP classification and region as fixed effects, and baseline values as covariates.

van der Heijde D et al. Ann Rheum Dis. 2023;82(4):515–526.

BE MOBILE 2 Met the Primary and All Ranked Secondary Endpoints at Week 16

	Efficacy endpoint	Placebo (n=111)	BKZ 160 mg Q4W (n=221)	p value‡
1	ASAS40,* n (%)	25 (22.5)	99 (44.8)	<0.001
2	ASAS40 (TNFi-naïve patients),† n (%)	22 (23.4)§	84 (45.7)¶	<0.001
3	ASAS20,† n (%)	48 (43.2)	146 (66.1)	<0.001
4	BASDAI CfB,† mean (SE)	-1.9 (0.2)	-2.9 (0.1)	<0.001
5	ASAS partial remission,† n (%)	8 (7.2)	53 (24.0)	<0.001
6	ASDAS-MI,† n (%)	6 (5.4)	57 (25.8)	<0.001
7	ASAS 5/6,† n (%)	21 (18.9)	109 (49.3)	<0.001
8	BASFI CfB,† mean (SE)	-1.1 (0.2)	-2.2 (0.1)	<0.001
9	Nocturnal spinal pain CfB,† mean (SE)	-1.9 (0.2)	-3.3 (0.2)	<0.001
10	ASQoL CfB,† mean (SE)	-3.2 (0.3)	-4.9 (0.3)	<0.001
11	SF-36 PCS CfB,† mean (SE)	5.9 (0.8)	9.3 (0.6)	<0.001
12	BASMI CfB,† mean (SE)	-0.2 (0.1)	-0.5 (0.1)	0.006

Missing data were imputed using NRI for binary endpoints and RBMI for continuous endpoints (based on data from the PBO group). Randomized set.
*Primary endpoint. †Secondary endpoint. ‡All tests performed at a 2-sided alpha level of 0.05. For binary variables, p values, odds ratios, and their 95% CIs were calculated by logistic regression with treatment, prior TNFi exposure and region as factors. For continuous variables, p values, least squares mean differences, and their 95% CIs were obtained by ANCOVA with treatment, prior TNFi exposure and region as fixed effects, and baseline values as covariates. §n=94. ¶n=184.
van der Heijde D et al. Ann Rheum Dis. 2023;82(4):515–526.

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Clinical Responses With BKZ at Week 16 and Week 52 (1/3)

		Baseline		Week 16			Week 52	
		PBO	BKZ 160 mg Q4W	PBO	BKZ 160 mg Q4W	p value*	PBO/BKZ 160 mg Q4W	BKZ 160 mg Q4W
nr-axSpA (BE MOBILE 1) **AS (BE MOBILE 2)**		**n=126** **n=111**	**n=128** **n=221**	**n=126** **n=111**	**n=128** **n=221**		**n=126** **n=111**	**n=128** **n=221**
Clinical response criteria								
ASAS40 [NRI], n (%)[1]	nr-axSpA	–	–	27 (21.4)	61 (47.7)	<0.001	64 (50.8)	78 (60.9)
	AS	–	–	25 (22.5)	99 (44.8)	<0.001	76 (68.5)	129 (58.4)
ASAS20 [NRI], n (%)[1]	nr-axSpA	–	–	48 (38.1)	88 (68.8)	<0.001	88 (69.8)	94 (73.4)
	AS	–	–	48 (43.2)	146 (66.1)	<0.001	89 (80.2)	158 (71.5)
ASAS-PR [NRI], n (%)[1]	nr-axSpA	–	–	9 (7.1)	33 (25.8)	<0.001	38 (30.2)	38 (29.7)
	AS	–	–	8 (7.2)	53 (24.0)	<0.001	41 (36.9)	66 (29.9)
ASAS40 in TNFi-naïve patients[1,†] [NRI], n (%)	nr-axSpA	–	–	25 (22.9)[‡]	55 (46.6)[§]	–	58 (53.2)[‡]	73 (61.9)[§]
	AS	–	–	22 (23.4)[‖]	84 (45.7)[¶]	<0.001	67 (71.3)[‖]	108 (58.7)[¶]
ASAS40 in TNFi-IR patients[2,**] [NRI], n (%)	nr-axSpA	–	–	2 (11.8)[††]	6 (60.0)[‡‡]	–	6 (35.3)[††]	5 (50.0)[‡‡]
	AS	–	–	3 (17.6)[††]	15 (40.5)[§§]	–	9 (52.9)[††]	21 (56.8)[§§]
ASDAS-MI [NRI], n (%)[1]	nr-axSpA	–	–	9 (7.1)	35 (27.3)	<0.001	37 (29.4)	47 (36.7)
	AS	–	–	6 (5.4)	57 (25.8)	<0.001	49 (44.1)	71 (32.1)

Non-responder imputation.[1] Randomized set.[1] Missing data were imputed using NRI for binary endpoints.[1] Week 52 data was collected during the open-label maintenance period.[1] *For binary endpoints, p values were calculated by logistic regression with treatment, MRI/CRP classification and region (BE MOBILE 1) or treatment, prior TNFi exposure and region (BE MOBILE 2) as factors.[1] †Ranked secondary endpoint in BE MOBILE 2.[1] ‡n=109.[1] §n=118.[1] ‖n=94.[1] ¶n=184.[1] **Exploratory endpoint.[1] ††n=17.[2] ‡‡n=10.[2] §§n=37.[2]

1. Baraliakos X et al. Ann Rheum Dis. 2024;83(2):199–213. 2. Baraliakos X et al. Supplementary appendix. Ann Rheum Dis. 2024;83(2):199–213.

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Clinical Responses With BKZ at Week 16 and Week 52 (2/3)

		Baseline		Week 16			Week 52	
		PBO	BKZ 160 mg Q4W	PBO	BKZ 160 mg Q4W	p value*	PBO/BKZ 160 mg Q4W	BKZ 160 mg Q4W
	nr-axSpA (BE MOBILE 1)	n=126	n=128	n=126	n=128		n=126	n=128
	AS (BE MOBILE 2)	n=111	n=221	n=111	n=221		n=111	n=221
Disease activity								
BASDAI CfB [MI], mean (SE)	nr-axSpA	6.7 (0.1)	6.9 (0.1)	-1.5 (0.2)	-3.1 (0.2)	<0.001	-3.5 (0.2)	-3.9 (0.2)
	AS	6.5 (0.1)	6.5 (0.1)	-1.9 (0.2)	-2.9 (0.1)	<0.001	-4.0 (0.2)	-3.6 (0.1)
BASDAI50 [NRI], n (%)	nr-axSpA	–	–	27 (21.4)	60 (46.9)	–	62 (49.2)	69 (53.9)
	AS	–	–	29 (26.1)	103 (46.6)	–	69 (62.2)	119 (53.8)
BASMI CfB† [MI], mean (SE)	nr-axSpA	3.0 (0.1)	2.9 (0.1)	-0.1 (0.1)	-0.4 (0.1)	–	-0.4 (0.1)	-0.6 (0.1)
	AS	3.8 (0.2)	3.9 (0.1)	-0.2 (0.1)	-0.5 (0.1)	0.006	-0.7 (0.1)	-0.7 (0.1)

Non-responder and multiple imputation. Randomized set. Missing data were imputed using NRI for binary endpoints, RBMI for ranked continuous endpoints to Week 16, and MI for continuous non-ranked and ranked (post Week 16) endpoints at Week 52. Week 52 data was collected during the open-label maintenance period. *For continuous endpoints, p values were obtained by ANCOVA with treatment, MRI/CRP classification and region (BE MOBILE 1) or treatment, prior TNFi exposure and region (BE MOBILE 2) as fixed effects, and baseline values as covariates. †Ranked secondary endpoint in BE MOBILE 2.

Adapted from Baraliakos X et al. Ann Rheum Dis. 2024;83(2):199–213.

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Clinical Responses With BKZ at Week 16 and Week 52 (3/3)

		Baseline		Week 16			Week 52	
		PBO	BKZ 160 mg Q4W	PBO	BKZ 160 mg Q4W	p value*	PBO/BKZ 160 mg Q4W	BKZ 160 mg Q4W
nr-axSpA (BE MOBILE 1) **AS (BE MOBILE 2)**		**n=126** **n=111**	**n=128** **n=221**	**n=126** **n=111**	**n=128** **n=221**		**n=126** **n=111**	**n=128** **n=221**
Pain, physical function, and quality of life								
Total spinal pain CfB [MI], mean (SE)	nr-axSpA	7.1 (0.1)	7.3 (0.1)	-1.7 (0.2)	-3.4 (0.2)	–	-3.9 (0.2)	-4.2 (0.2)
	AS	7.2 (0.1)	7.1 (0.1)	-1.9 (0.2)	-3.3 (0.2)	–	-4.5 (0.2)	-4.1 (0.2)
Nocturnal spinal pain CfB [MI], mean (SE)	nr-axSpA	6.7 (0.2)	6.9 (0.2)	-1.7 (0.2)	-3.6 (0.3)	<0.001	-4.1 (0.2)	-4.3 (0.3)
	AS	6.8 (0.2)	6.6 (0.1)	-1.9 (0.2)	-3.3 (0.2)	<0.001	-4.6 (0.3)	-4.1 (0.2)
BASFI CfB [MI], mean (SE)	nr-axSpA	5.3 (0.2)	5.5 (0.2)	-1.0 (0.2)	-2.5 (0.2)	<0.001	-2.6 (0.2)	-3.0 (0.2)
	AS	5.2 (0.2)	5.3 (0.2)	-1.1 (0.2)	-2.2 (0.1)	<0.001	-2.8 (0.2)	-2.8 (0.1)
SF-36 PCS CfB [MI], mean (SE)	nr-axSpA	33.6 (0.8)	33.3 (0.7)	5.5 (0.7)	9.5 (0.7)	<0.001	11.4 (0.9)	12.2 (0.9)
	AS	34.6 (0.8)	34.4 (0.6)	5.9 (0.8)	9.3 (0.6)	<0.001	12.3 (0.9)	12.0 (0.6)
ASQoL CfB [MI], mean (SE)	nr-axSpA	9.4 (0.4)	9.5 (0.4)	-2.5 (0.4)	-5.2 (0.4)	<0.001	-5.3 (0.4)	-5.9 (0.4)
	AS	8.5 (0.4)	9.0 (0.3)	-3.2 (0.3)	-5.0 (0.3)	<0.001	-5.6 (0.4)	-5.7 (0.3)

Multiple imputation. Randomized set. Missing data were imputed using RBMI for ranked continuous endpoints to Week 16, and MI for continuous non-ranked and ranked (post Week 16) endpoints at Week 52. Week 52 data was collected during the open-label maintenance period. *For continuous endpoints, p values were obtained by ANCOVA with treatment, MRI/CRP classification and region (BE MOBILE 1) or treatment, prior TNFi exposure and region (BE MOBILE 2) as fixed effects, and baseline values as covariates.
Adapted from Baraliakos X et al. Ann Rheum Dis. 2024;83(2):199–213.

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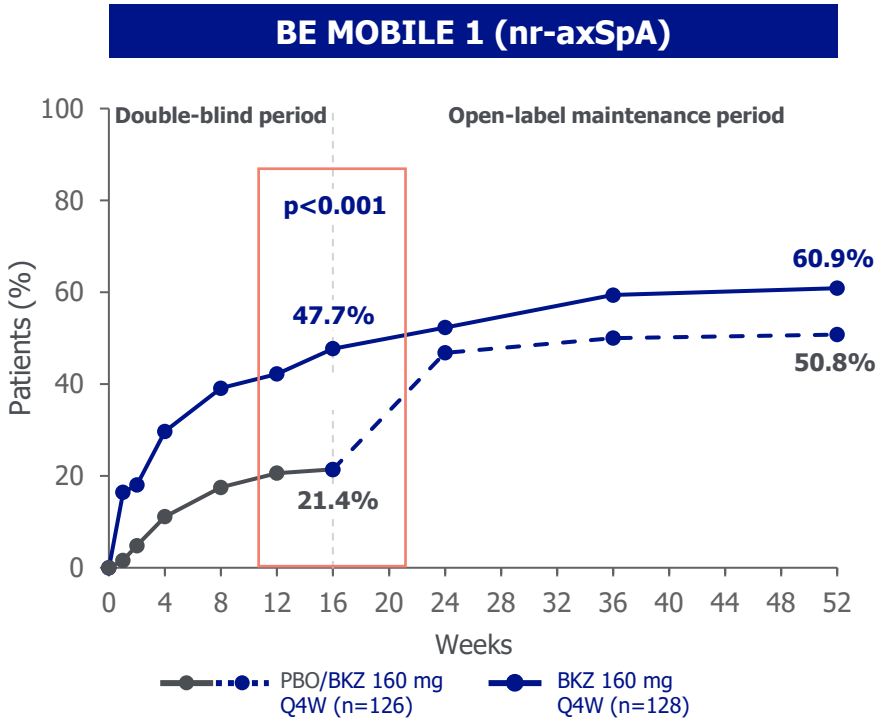
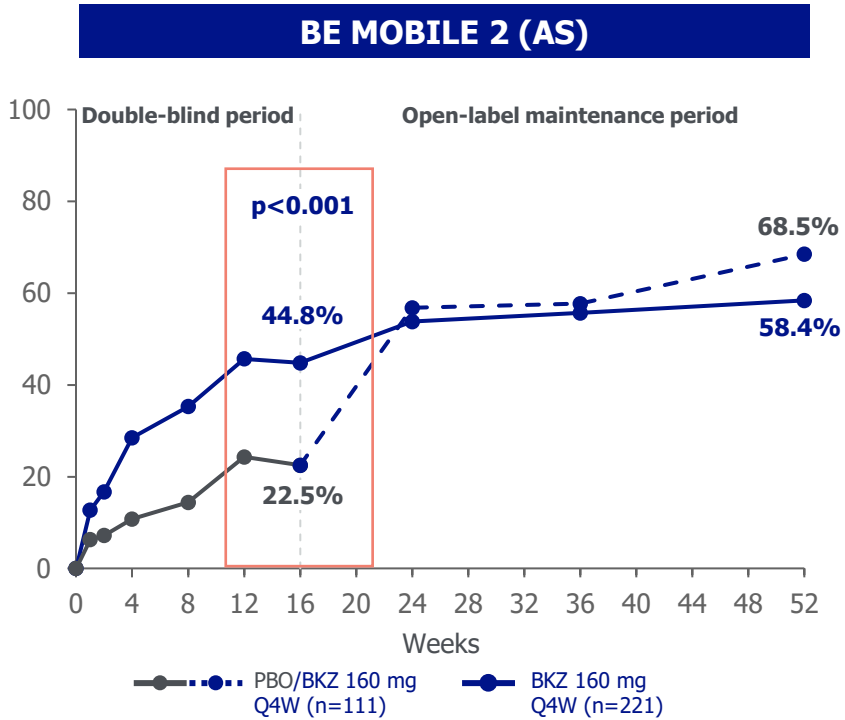
Primary Endpoint: ASAS40 with BKZ to Week 52 (NRI)





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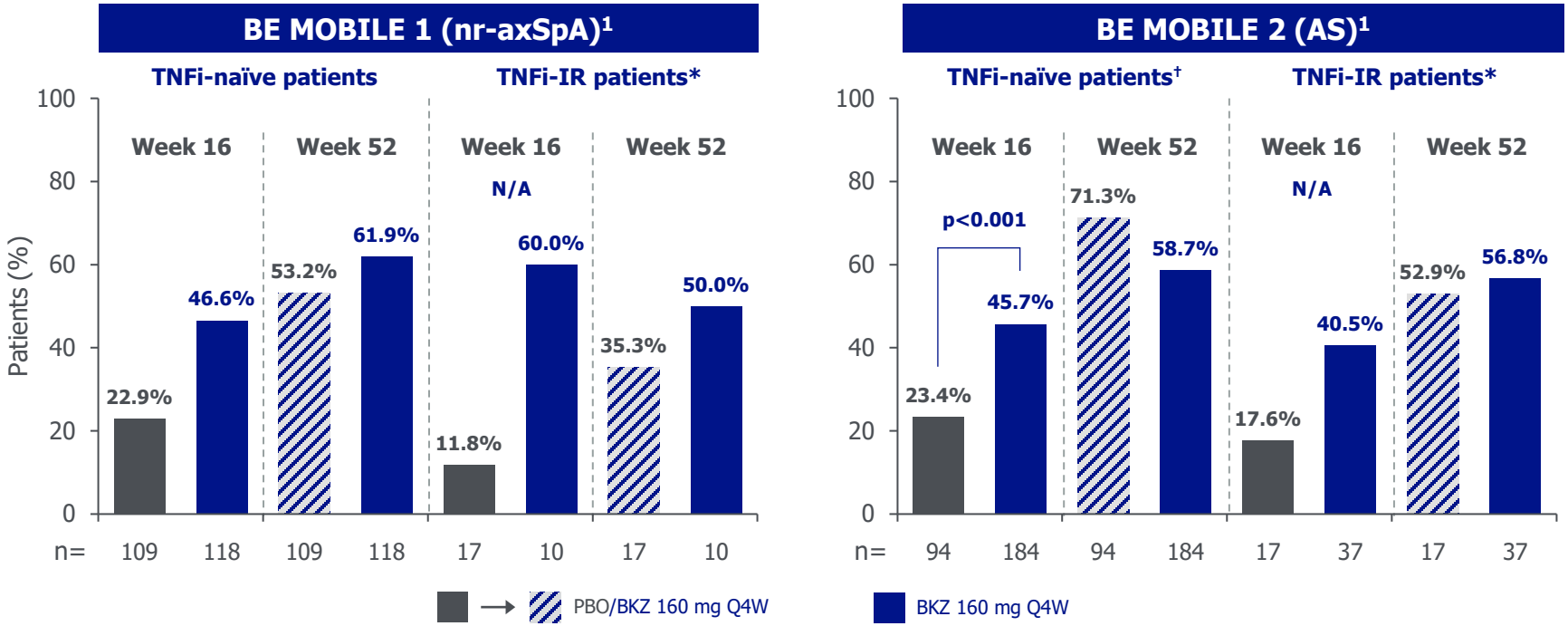
Non-responder imputation. p values were only calculated for the primary endpoints (Week 16). Randomized set. p values calculated by logistic regression with treatment, region, MRI/CRP classification (BE MOBILE 1) and prior TNFi exposure (BE MOBILE 2 only) as factors.

Baraliakos X et al. Ann Rheum Dis. 2024;83(2):199–213.

ASAS40 Responses With BKZ at Week 16 and Week 52 in TNFi-naïve and TNFi-IR patients (NRI)



Non-responder imputation.[1] **p values were only calculated for the ranked secondary endpoint of BE MOBILE 2 (Week 16).**[2] Randomized set.[1] Week 52 data was collected during the open-label maintenance period.[2] *Exploratory endpoint.[1] †Ranked secondary endpoint in BE MOBILE 2 only.[1]

1. Baraliakos X et al. Supplementary appendix. Ann Rheum Dis. 2024;83(2):199–213. 2. Baraliakos X et al. Ann Rheum Dis. 2024;83(2):199–213.

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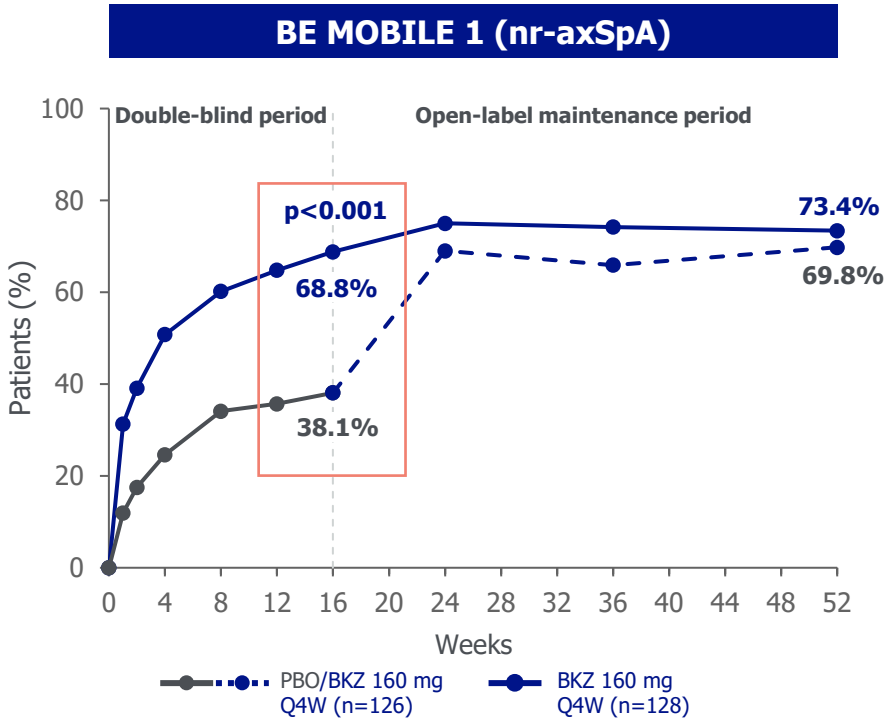
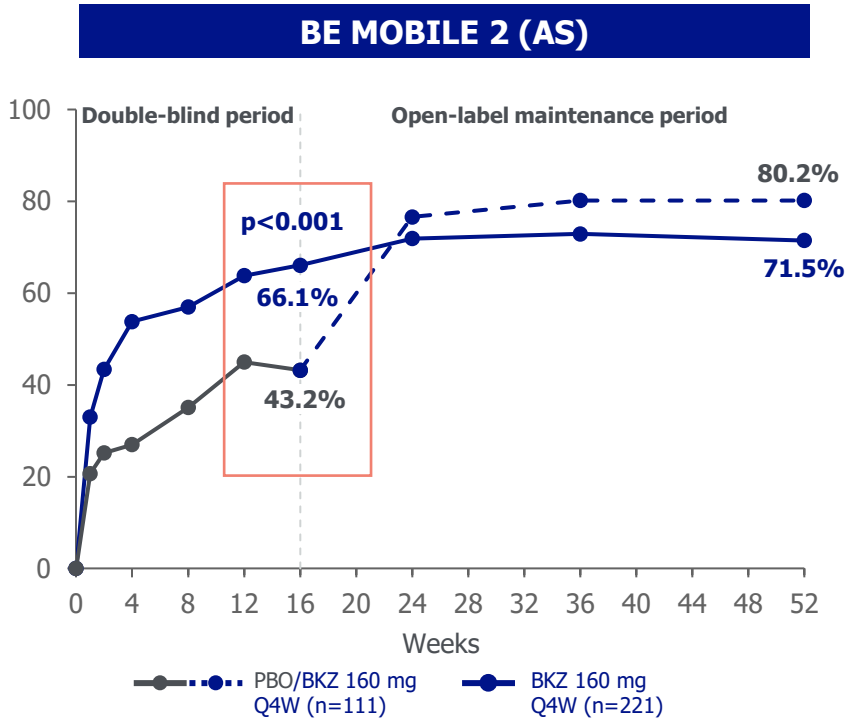
ASAS20 Responses With BKZ to Week 52 (NRI)





US-BK-2401174 | Date of preparation: September 2024

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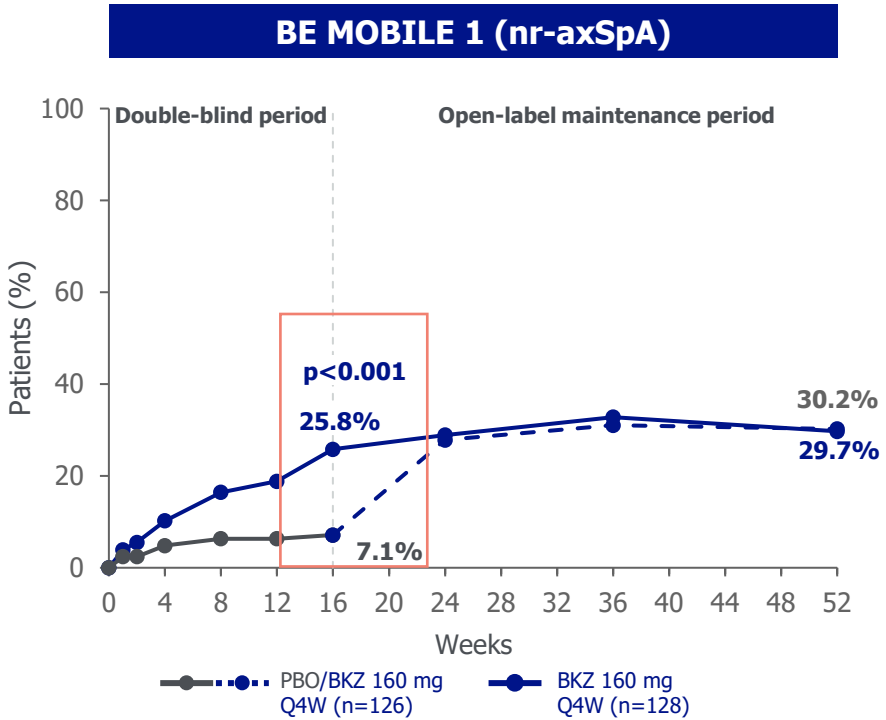
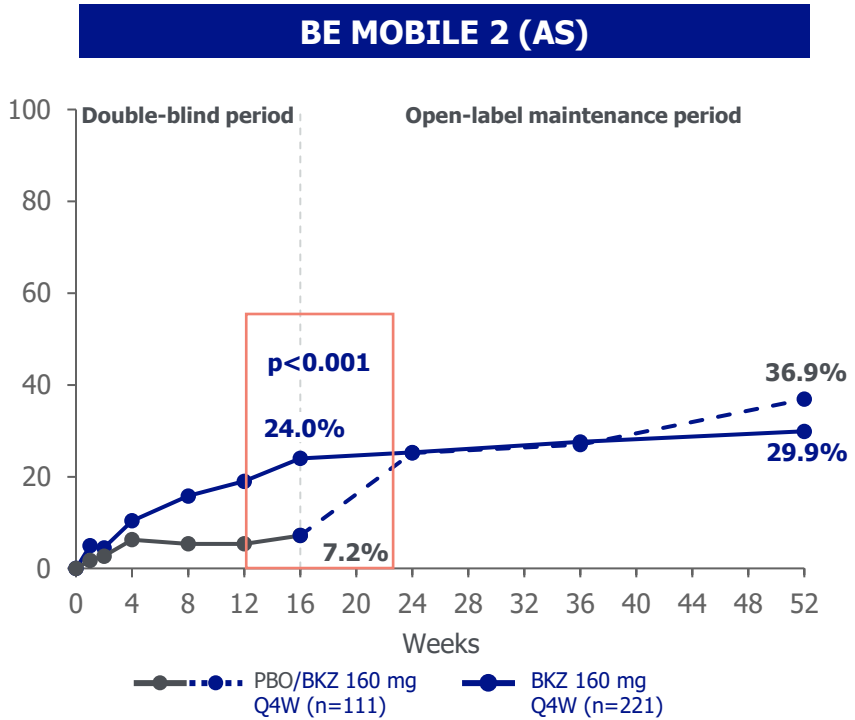
Non-responder imputation. p values were only calculated for the ranked secondary endpoints (Week 16). Randomized set. p values calculated by logistic regression with treatment, region, MRI/CRP classification (BE MOBILE 1 only) and prior TNFi exposure (BE MOBILE 2 only) as factors.

Baraliakos X et al. Ann Rheum Dis. 2024;83(2):199–213.

ASAS-PR Responses With BKZ to Week 52 (NRI)





US-BK-2401174 | Date of preparation: September 2024

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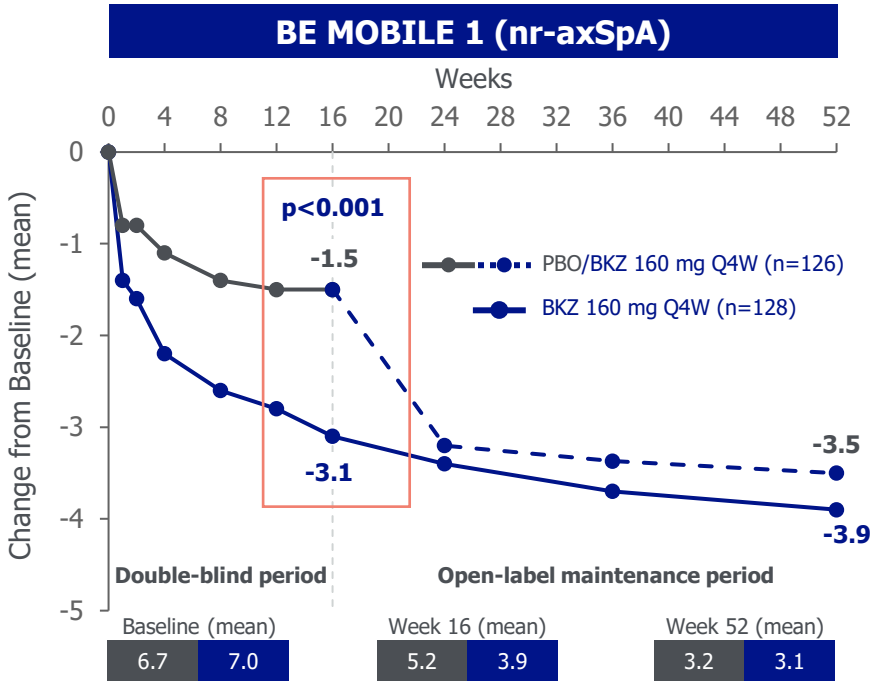
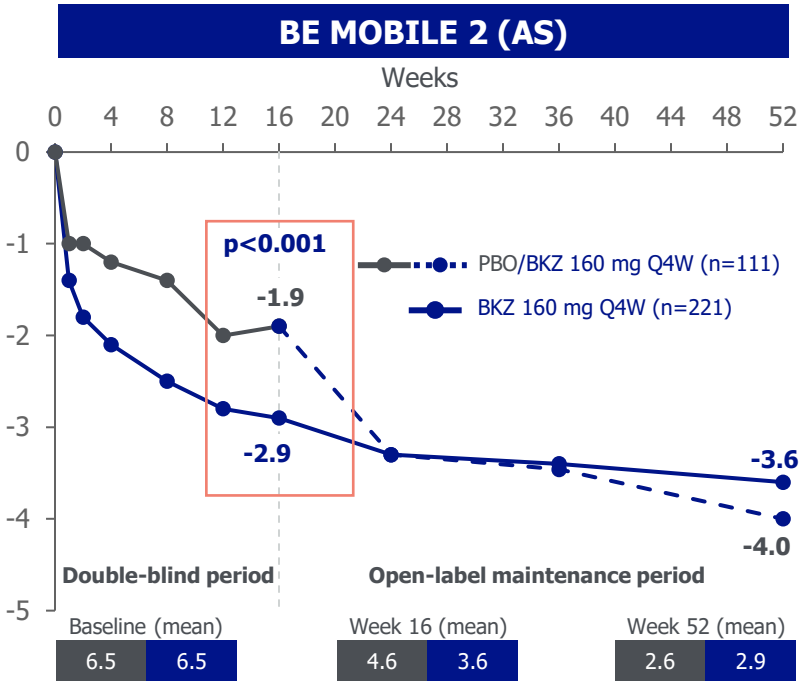
Non-responder imputation. p values were only calculated for the ranked secondary endpoints (Week 16). Randomized set. p values calculated by logistic regression with treatment, region, MRI/CRP classification (BE MOBILE 1 only) and prior TNFi exposure (BE MOBILE 2 only) as factors.

Baraliakos X et al. Ann Rheum Dis. 2024;83(2):199–213.

BASDAI Responses With BKZ to Week 52 (MI)





Multiple imputation. p values were only calculated for the ranked secondary endpoints (Week 16). Randomized set. BASDAI CfB at Week 16 was a ranked secondary endpoint in BE MOBILE 1 and BE MOBILE 2. p value for the comparison of BKZ to PBO were calculated using ANCOVA with treatment, region, MRI/CRP classification (BE MOBILE 1 only), prior TNFi exposure (BE MOBILE 2 only) as fixed effects, and baseline scores as covariate.

Baraliakos X et al. Ann Rheum Dis. 2024;83(2):199–213.

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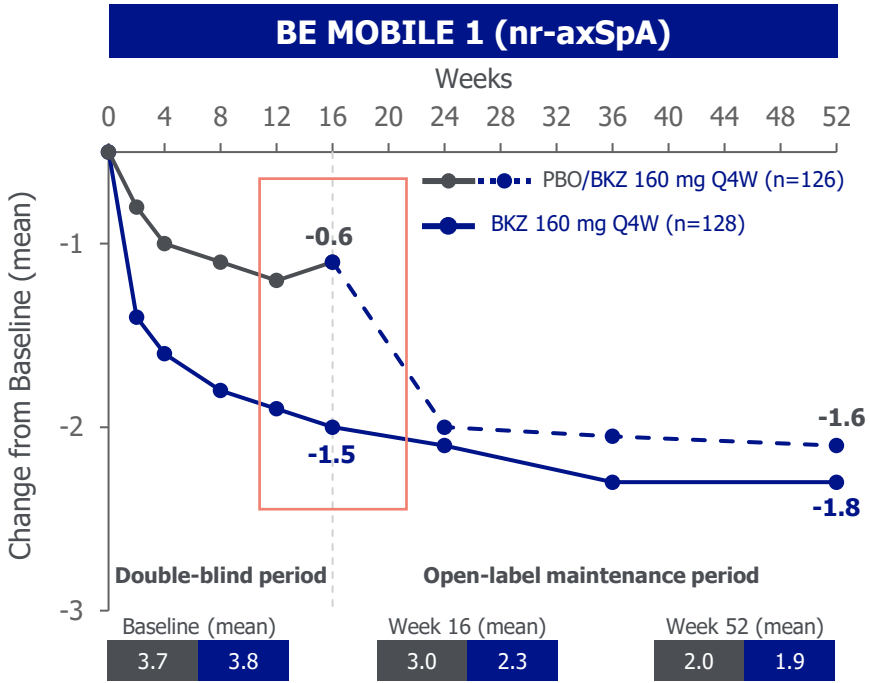
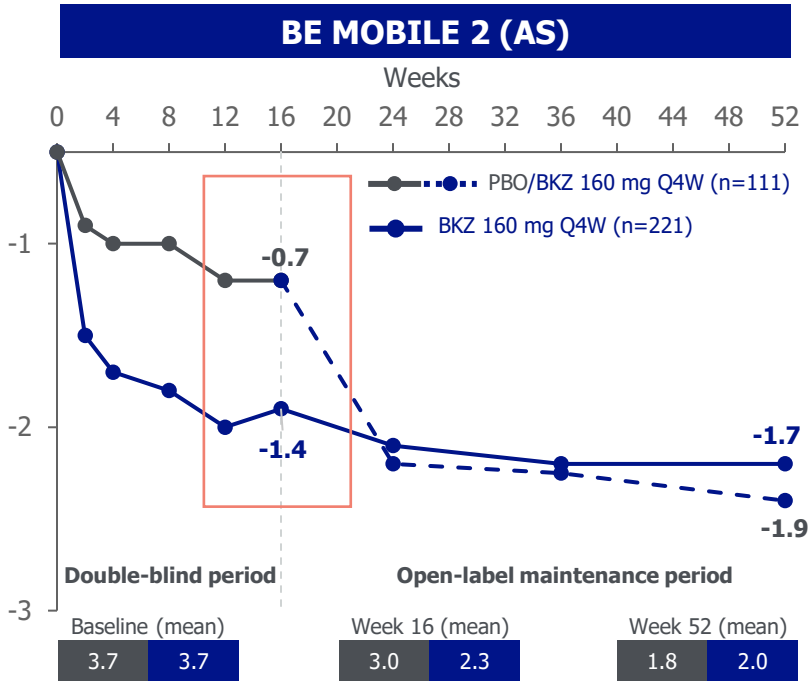
ASDAS Responses With BKZ to Week 52 (MI)

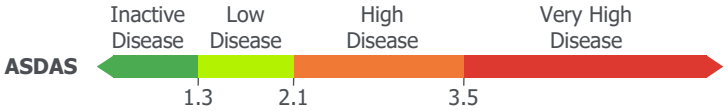




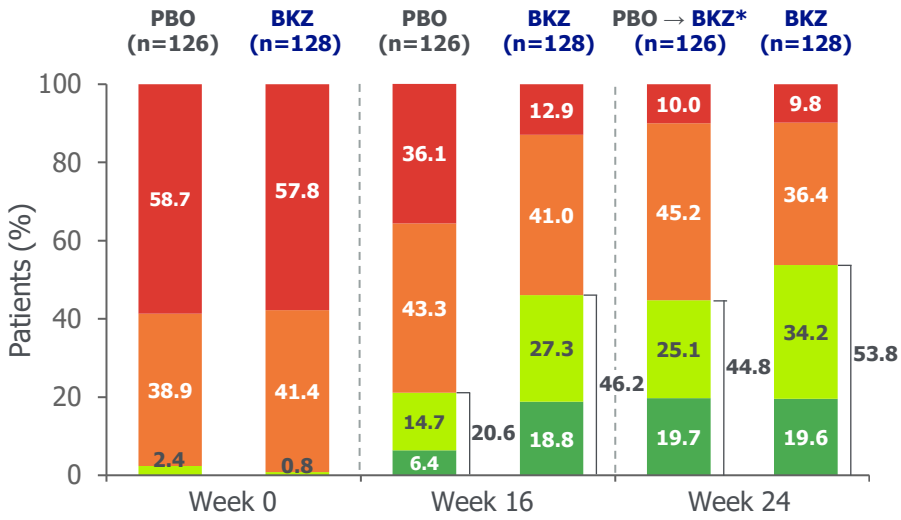
US-BK-2401174 | Date of preparation: September 2024

Multiple imputation. Randomized set. ASDAS was an exploratory endpoint in BE MOBILE 1 and BE MOBILE 2.
Baraliakos X et al. Ann Rheum Dis. 2024;83(2):199–213.

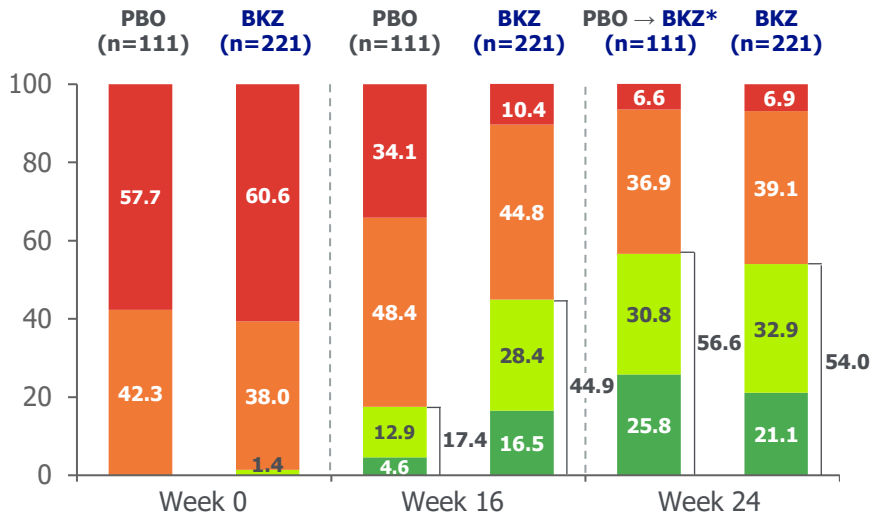
ASDAS States With BKZ at Week 16 and Week 24 (MI)



BE MOBILE 1 (nr-axSpA)[1]



BE MOBILE 2 (AS)[1]



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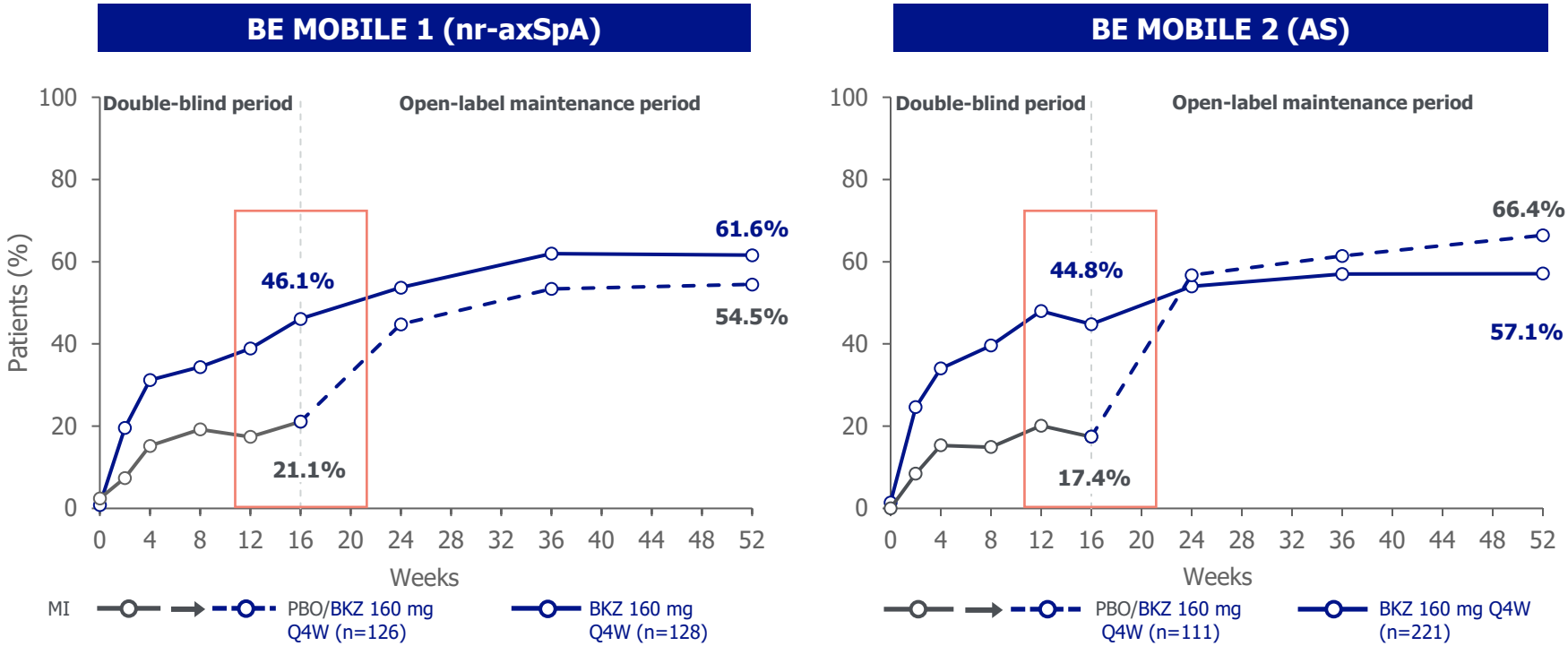
Data reported using multiple imputation where patients that discontinued treatment due to loss of efficacy or safety were considered as non-responders.[1] Randomized set.[1] Exploratory endpoint.[1] Week 24 data was collected during the open-label maintenance period.[2] *At Week 16, patients on PBO switched to BKZ.[1]

1. van der Heijde D et al. Ann Rheum Dis. 2023;82(4):515–526. 2. Baraliakos X et al. Ann Rheum Dis. 2024;83(2):199–213.

ASDAS <2.1 Responses With BKZ to Week 52 (MI)



Multiple imputation. Randomized set. ASDAS LDA when ASDAS <2.1. ASDAS <2.1 was an exploratory endpoint in BE MOBILE 1 and BE MOBILE 2.
Baraliakos X et al. Ann Rheum Dis. 2024;83(2):199–213.

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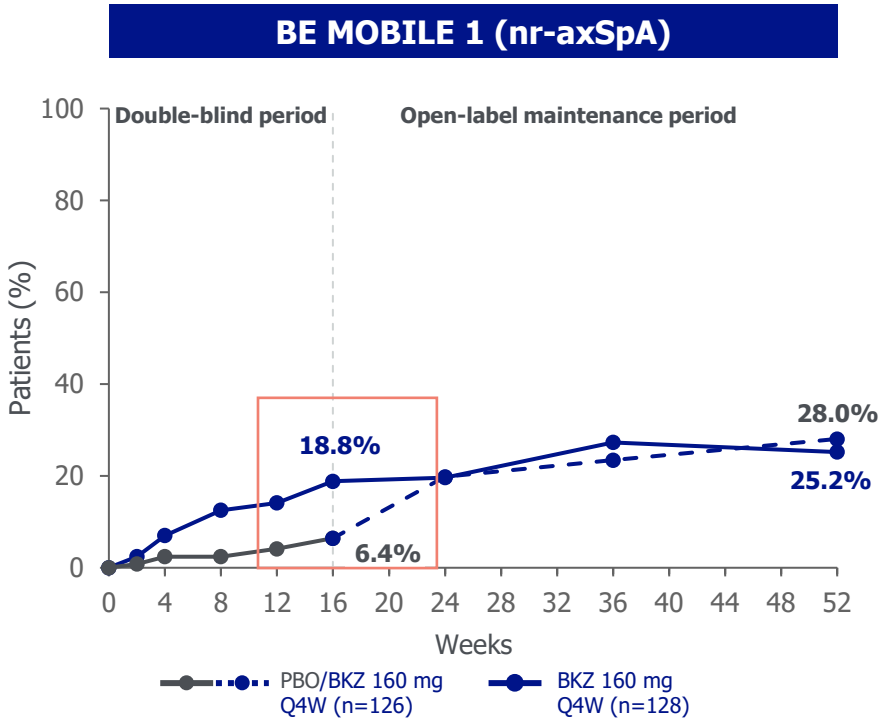
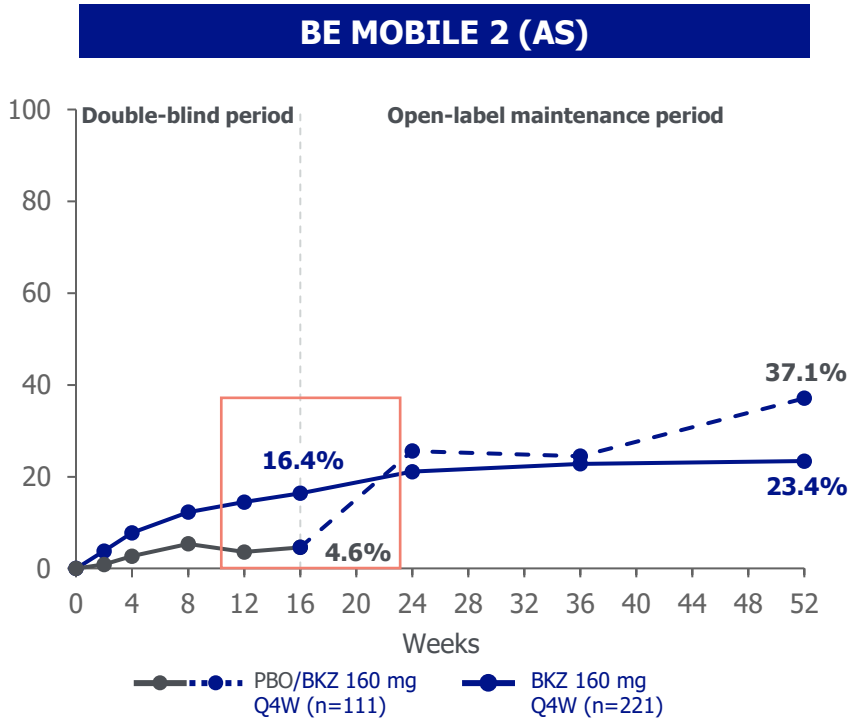
ASDAS <1.3 Responses With BKZ to Week 52 (MI)





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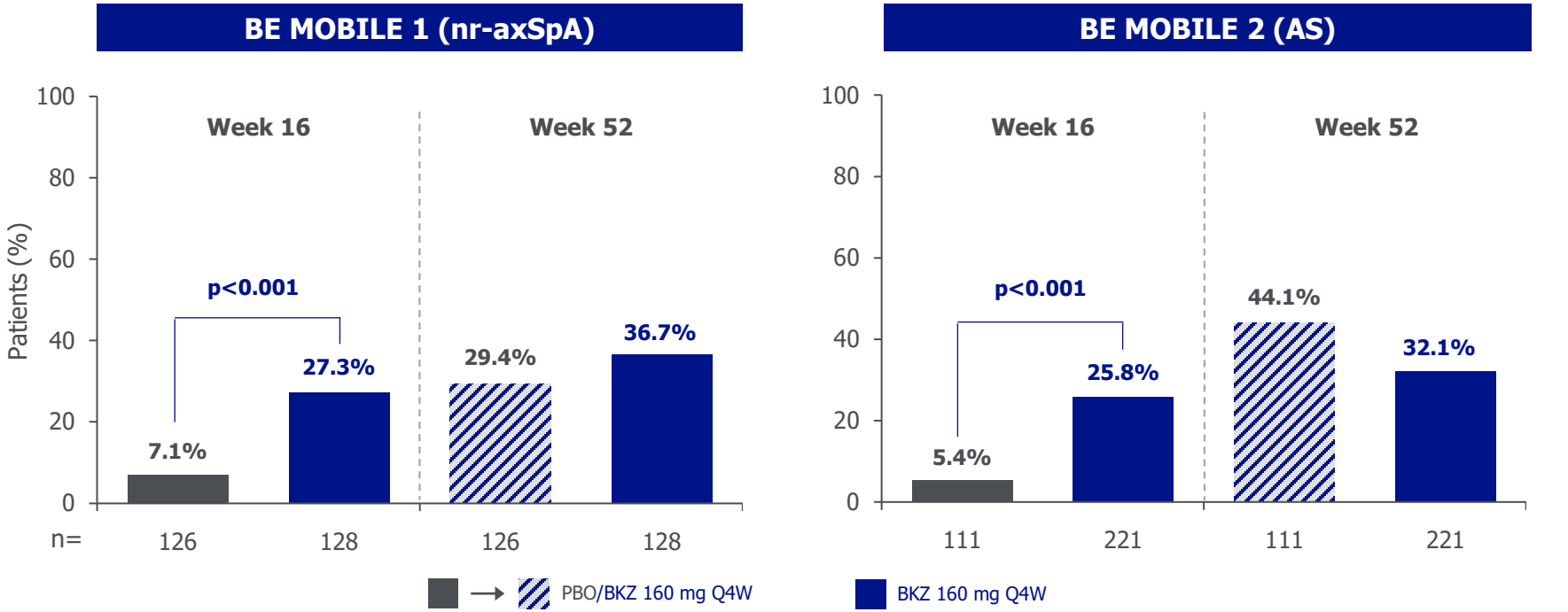
Multiple imputation. Randomized set. ASDAS ID when ASDAS <1.3. ASDAS <1.3 was an exploratory endpoint in BE MOBILE 1 and BE MOBILE 2.

Baraliakos X et al. Ann Rheum Dis. 2024;83(2):199–213.

ASDAS-MI Responses With BKZ at Week 16 and Week 52 (NRI)



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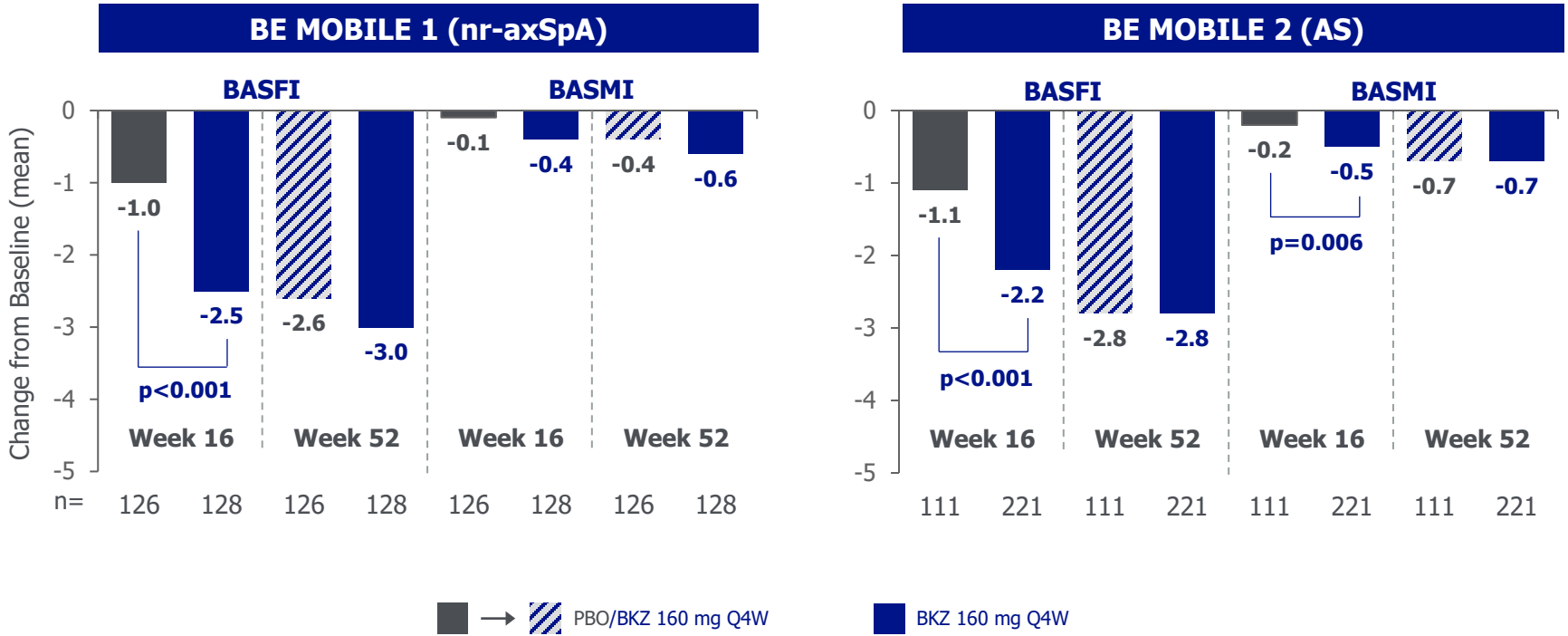
Non-responder imputation. p values were only calculated for the ranked secondary endpoints (Week 16). Randomized set. ASDAS-MI response at Week 16 was a ranked secondary endpoint in BE MOBILE 1 and BE MOBILE 2. Week 52 data was collected during the open-label maintenance period. p values were calculated by logistic regression with treatment, MRI/CRP classification and region (BE MOBILE 1) or treatment, prior TNFi exposure and region (BE MOBILE 2) as factors.

Baraliakos X et al. Ann Rheum Dis. 2024;83(2):199–213.

BASFI and BASMI Responses With BKZ at Week 16 and Week 52 (MI)



Multiple imputation. p values were only calculated for the ranked secondary endpoints (Week 16). Randomized set. BASFI CfB at Week 16 was a ranked secondary endpoint in BE MOBILE 1 and BE MOBILE 2. BASMI CfB at Week 16 was a ranked secondary endpoint in BE MOBILE 2. Week 52 data was collected during the open-label maintenance period. p values were obtained by ANCOVA with treatment, MRI/CRP classification and region (BE MOBILE 1) or treatment, prior TNFi exposure and region (BE MOBILE 2) as fixed effects, and baseline values as covariates.

Baraliakos X et al. Ann Rheum Dis. 2024;83(2):199–213.

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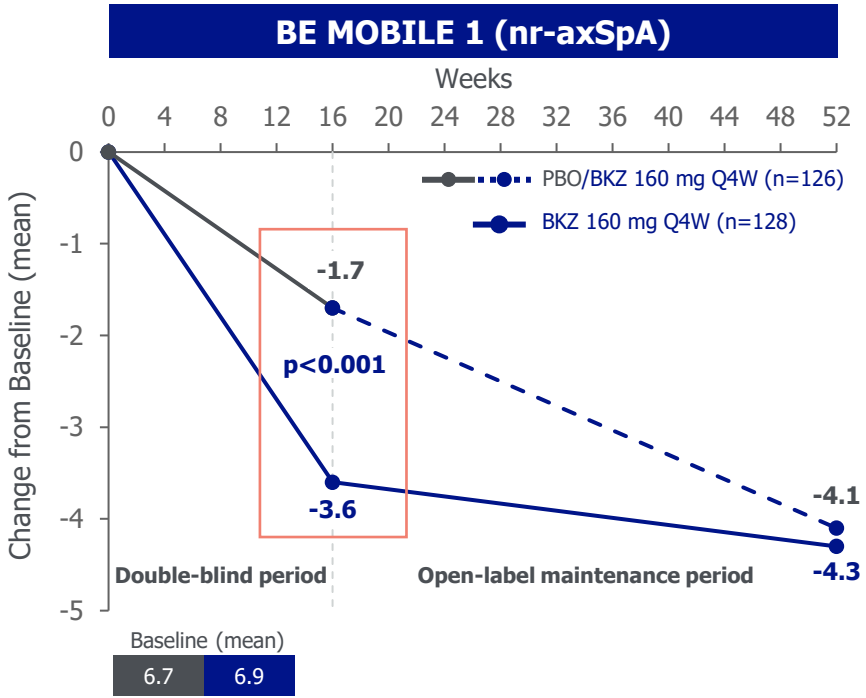
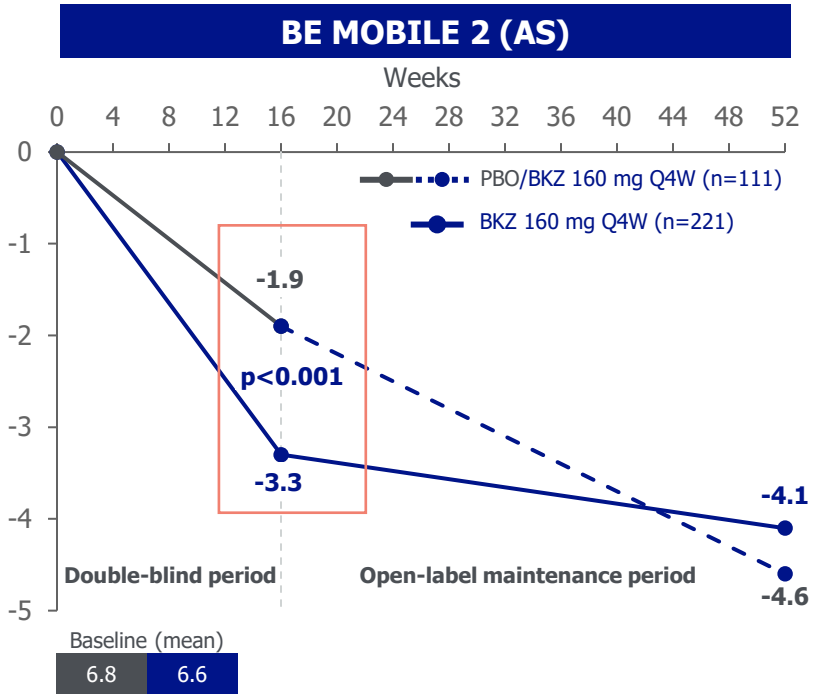
Nocturnal Spinal Pain Responses With BKZ to Week 52 (MI)





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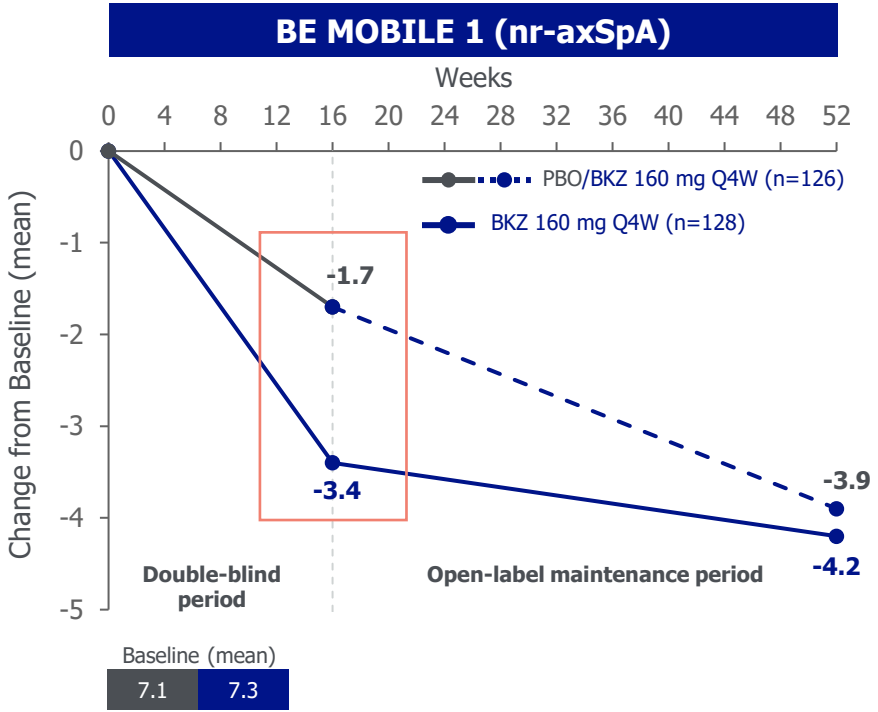
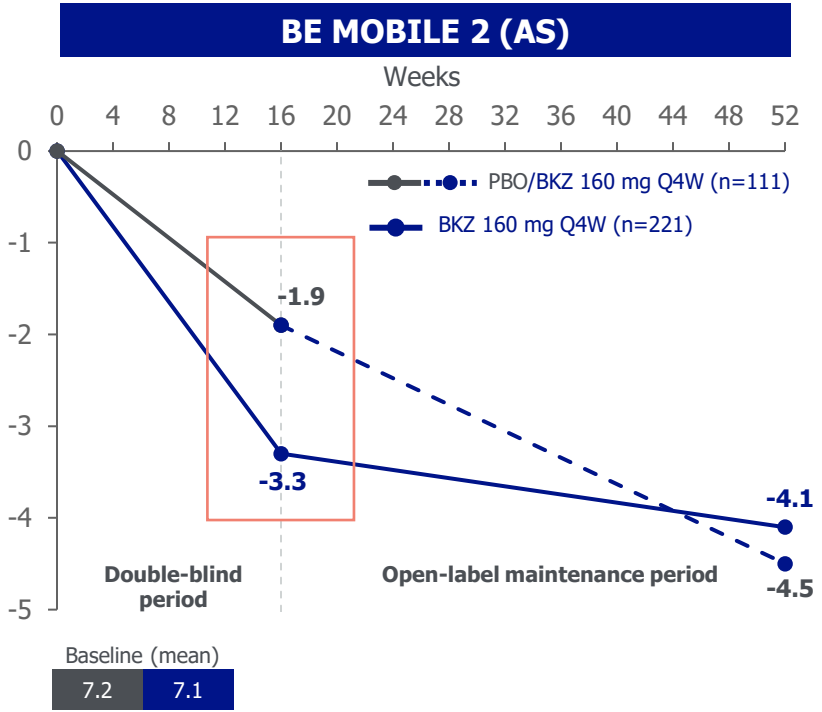
Multiple imputation. p values were only calculated for the ranked secondary endpoints (Week 16). Randomized set. p value was calculated using ANCOVA with treatment, MRI/CRP classification (BE MOBILE 1 only), prior TNFi exposure (BE MOBILE 2 only) and region as fixed effects and baseline values as covariates.

Baraliakos X et al. Ann Rheum Dis. 2024;83(2):199–213.

Total Spinal Pain Responses With BKZ to Week 52 (MI)





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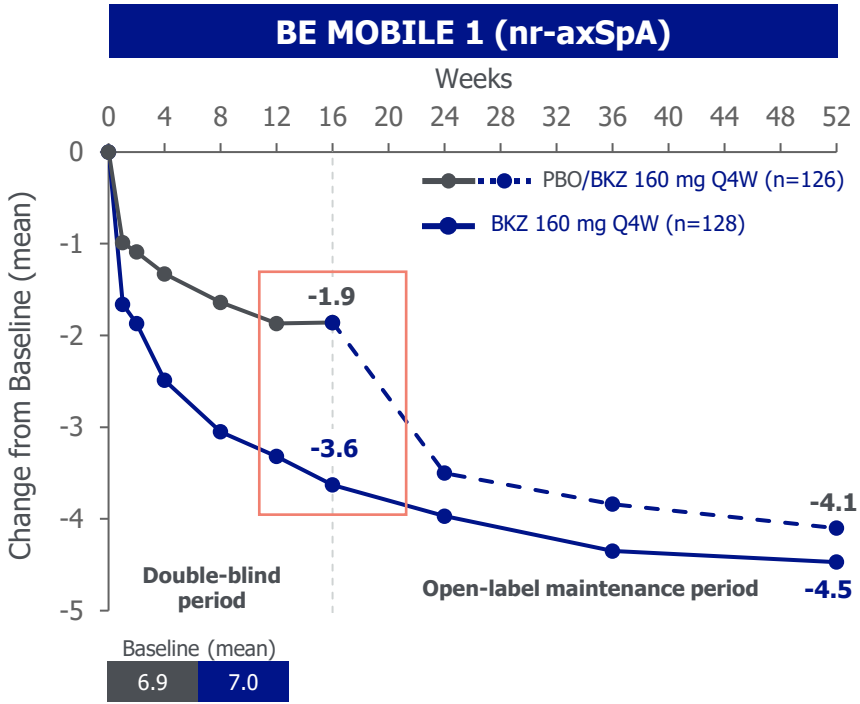
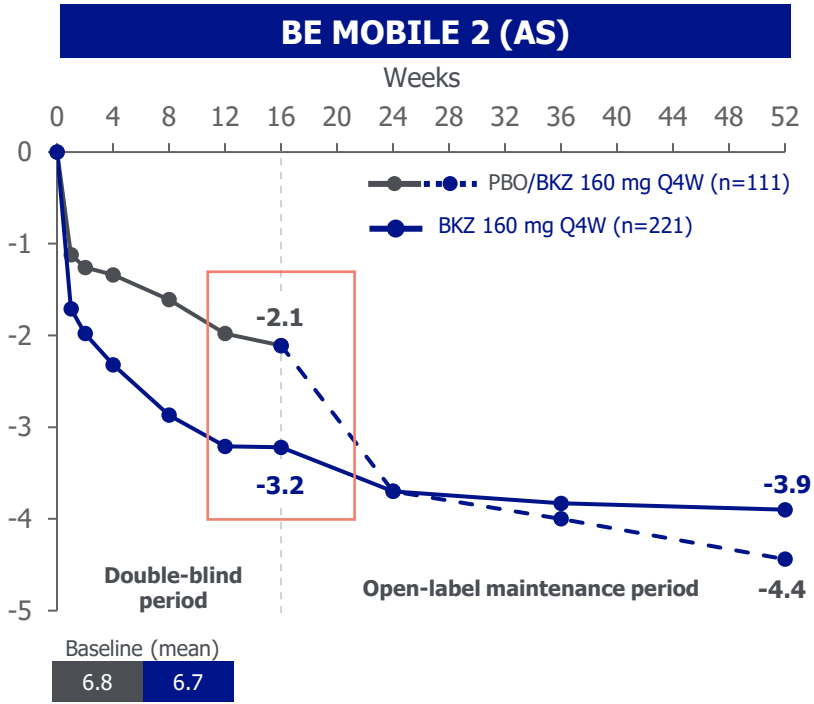
Multiple imputation. Randomized set.

Baraliakos X et al. Ann Rheum Dis. 2024;83(2):199–213.

US-BK-2401174 | Date of preparation: September 2024

BASDAI Morning Stiffness Responses With BKZ to Week 52 (MI)





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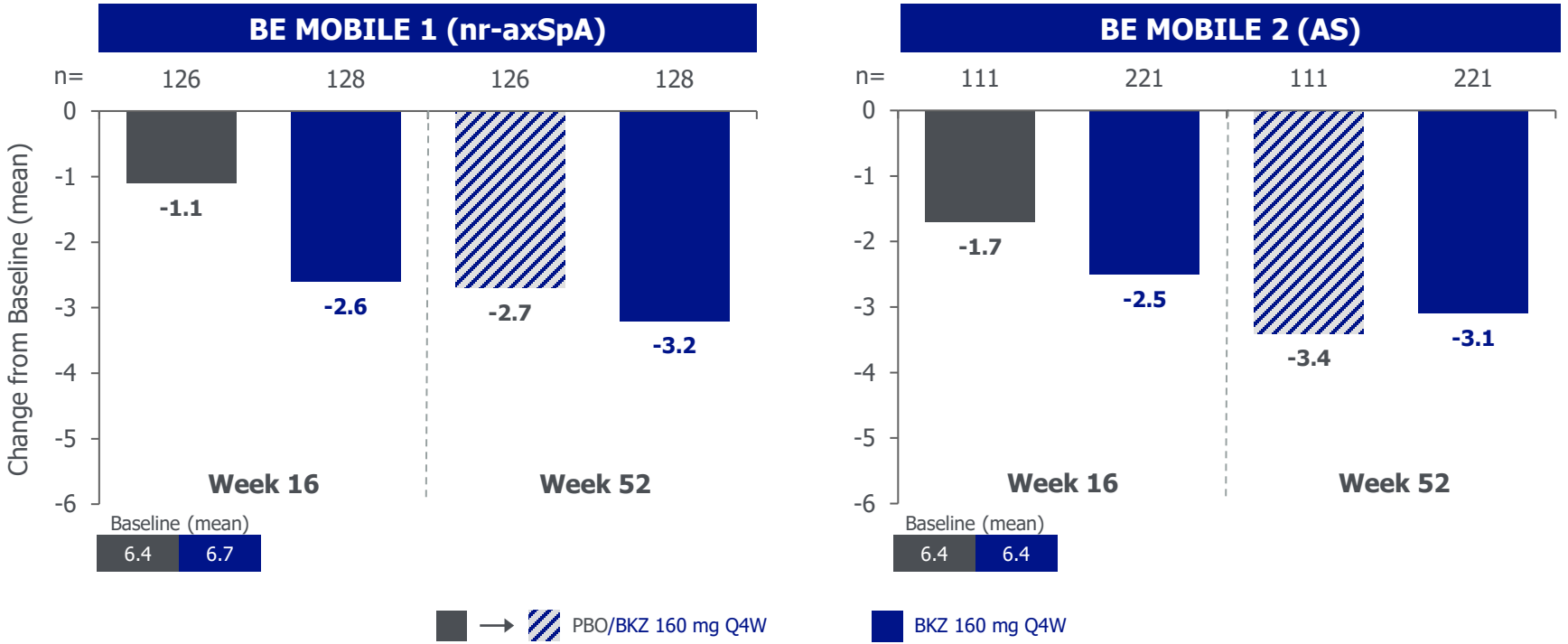
Multiple imputation. Randomized set. BASDAI morning stiffness score assessed as mean of BASDAI questions 5 and 6.

Baraliakos X et al. Ann Rheum Dis. 2024;83(2):199–213.

BASDAI Fatigue Score Responses With BKZ at Week 16 and Week 52 (MI)



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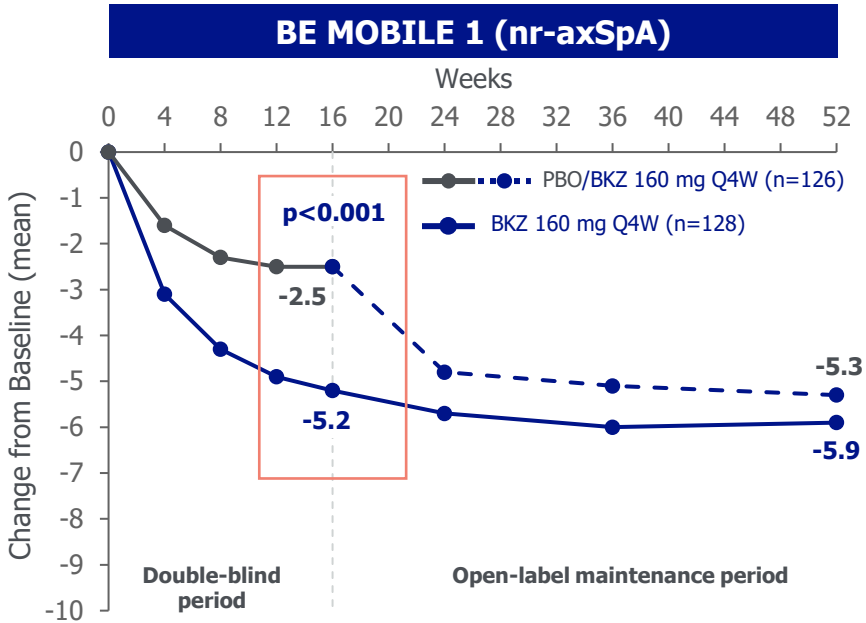
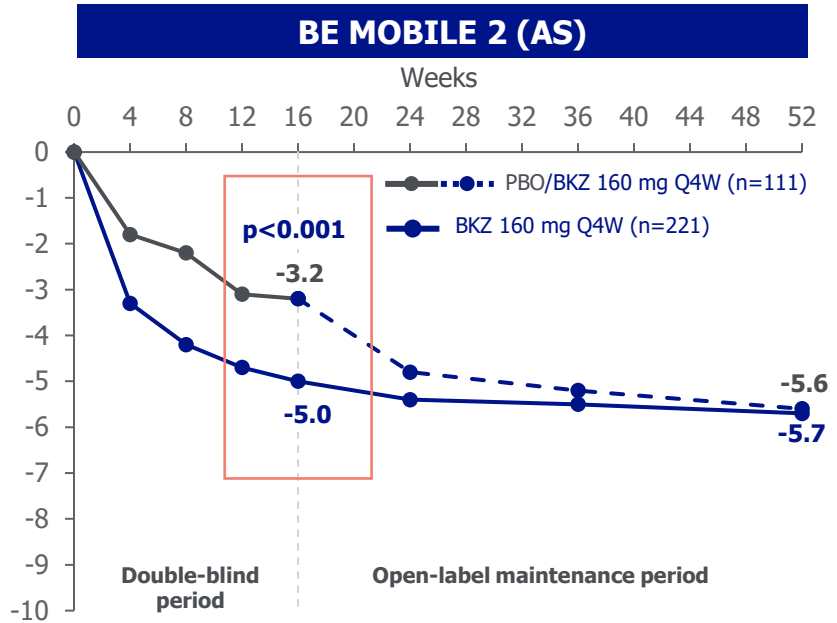
Multiple imputation.[1] Randomized set.[1] Week 52 data was collected during the open-label maintenance period.[2] BASDAI fatigue score assessed as BASDAI question 1.[1]

1. Baraliakos X et al. Supplementary appendix. Ann Rheum Dis. 2024;83(2):199–213. 2. Baraliakos X et al. Ann Rheum Dis. 2024;83(2):199–213.

ASQoL Responses With BKZ to Week 52 (MI)





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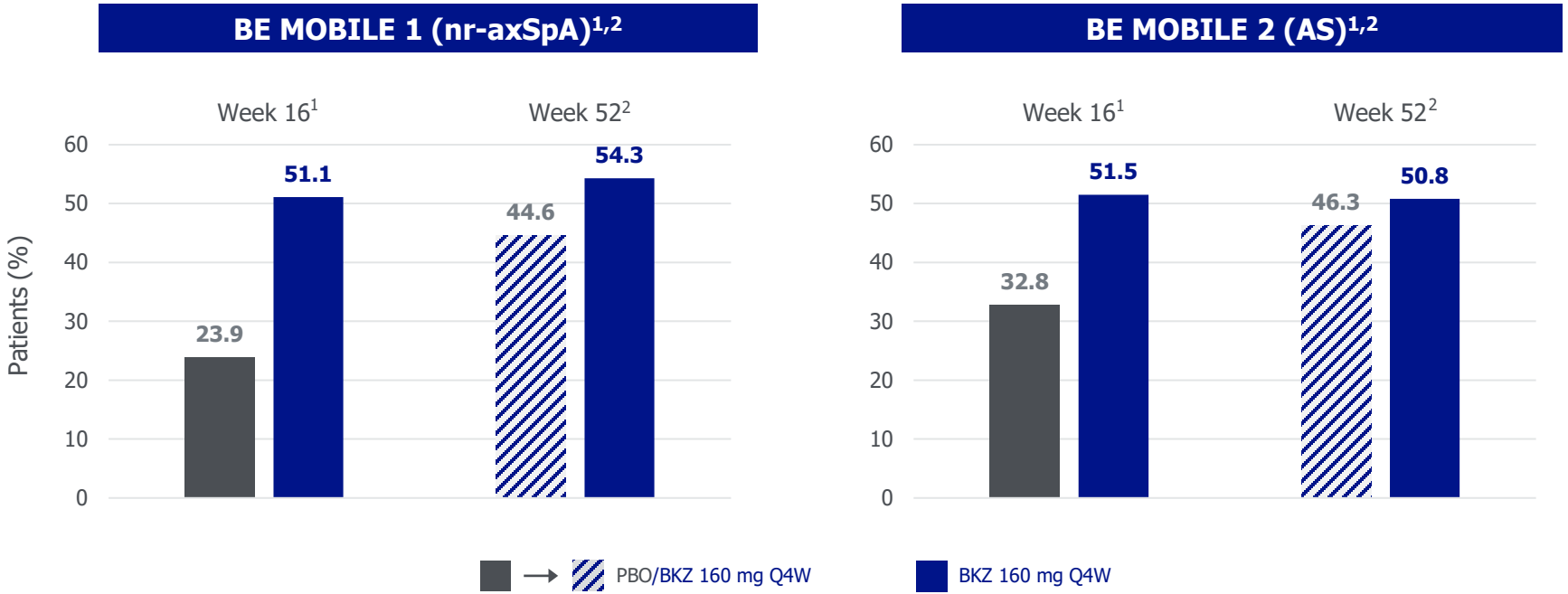
Multiple imputation. p values were only calculated for the ranked secondary endpoints (Week 16). Randomized set. ASQoL was a ranked secondary endpoint. p values for the comparison of BKZ to PBO were calculated using ANCOVA with treatment, region, MRI/CRP classification (BE MOBILE 1 only), prior TNFi exposure (BE MOBILE 2 only) as fixed effects, and baseline scores as covariates.

Baraliakos X et al. Ann Rheum Dis. 2024;83(2):199–213.

Complete Resolution of Enthesitis With BKZ at Week 16 and Week 52 (NRI)



Non-responder imputation.[1,3] Randomized set.[2,3] Data shown for patients who had enthesitis (defined as MASES>0) at baseline (BE MOBILE 1: 186/254; BE MOBILE 2: 199/332).[1,2] Resolution defined as MASES=0.[1,2] Reference 1 reported data at Week 16 only.[1] Reference 2 reported data at Week 52 only.[2] Week 52 data was collected during the open-label maintenance period.[2]

1. van der Heijde D et al. Supplementary appendix. Ann Rheum Dis. 2023;82(4):515–526. 2. Baraliakos X et al. Ann Rheum Dis. 2024;83(2):199–213. 3. van der Heijde D et al. Ann Rheum Dis. 2023;82(4):515–526.

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MASES, SJC and TJC Score Responses With BKZ at Week 16 and Week 52 (MI)

Mean (SE)		Baseline		Week 16 change from baseline		Week 52 change from baseline	
		PBO	BKZ 160 mg Q4W	PBO	BKZ 160 mg Q4W	PBO/BKZ 160 mg Q4W	BKZ 160 mg Q4W
MASES[1,*]	nr-axSpA[†]	4.9 (0.4)	4.8 (0.3)	-1.3 (0.3)	-2.4 (0.3)	-2.9 (0.4)	-3.6 (0.3)
	AS[‡]	4.4 (0.3)	4.2 (0.3)	-1.5 (0.3)	-2.4 (0.3)	-3.2 (0.3)	-2.9 (0.3)
SJC[1,§]	nr-axSpA[‖]	3.8 (0.5)	4.2 (0.8)	-1.3 (0.6)	-3.1 (0.7)	-2.9 (0.4)	-2.5 (0.8)
	AS[¶]	3.9 (0.7)	4.7 (0.6)	-2.1 (0.5)	-3.6 (0.5)	-3.6 (0.8)	-4.2 (0.6)
TJC[1,**]	nr-axSpA[††]	6.3 (0.6)	6.0 (0.8)	-1.1 (0.5)	-3.0 (0.7)	-3.5 (0.6)	-4.0 (0.8)
	AS[‡‡]	5.4 (0.6)	5.3 (0.6)	-2.9 (0.5)	-2.5 (0.4)	-4.5 (0.6)	-4.0 (0.5)

Multiple imputation.[1] Randomized set.[1] Week 52 data was collected during the open-label maintenance period.[2] Assessed in patients with: *MASES >0 at baseline.[1] [†]PBO n=92; BKZ n=94.[1] [‡]PBO n=67; BKZ n=132.[1] [§]SJC >0 at baseline.[1] [‖]PBO n=43; BKZ n=45.[1] [¶]PBO n=22; BKZ n=44.[1] **TJC >0 at baseline.[1] [††]PBO n=85; BKZ n=78.[1] [‡‡]PBO n=61; BKZ n=116.[1]

1. Baraliakos X et al. Supplementary appendix. Ann Rheum Dis. 2024;83(2):199–213. 2. Baraliakos X et al. Ann Rheum Dis. 2024;83(2):199–213.

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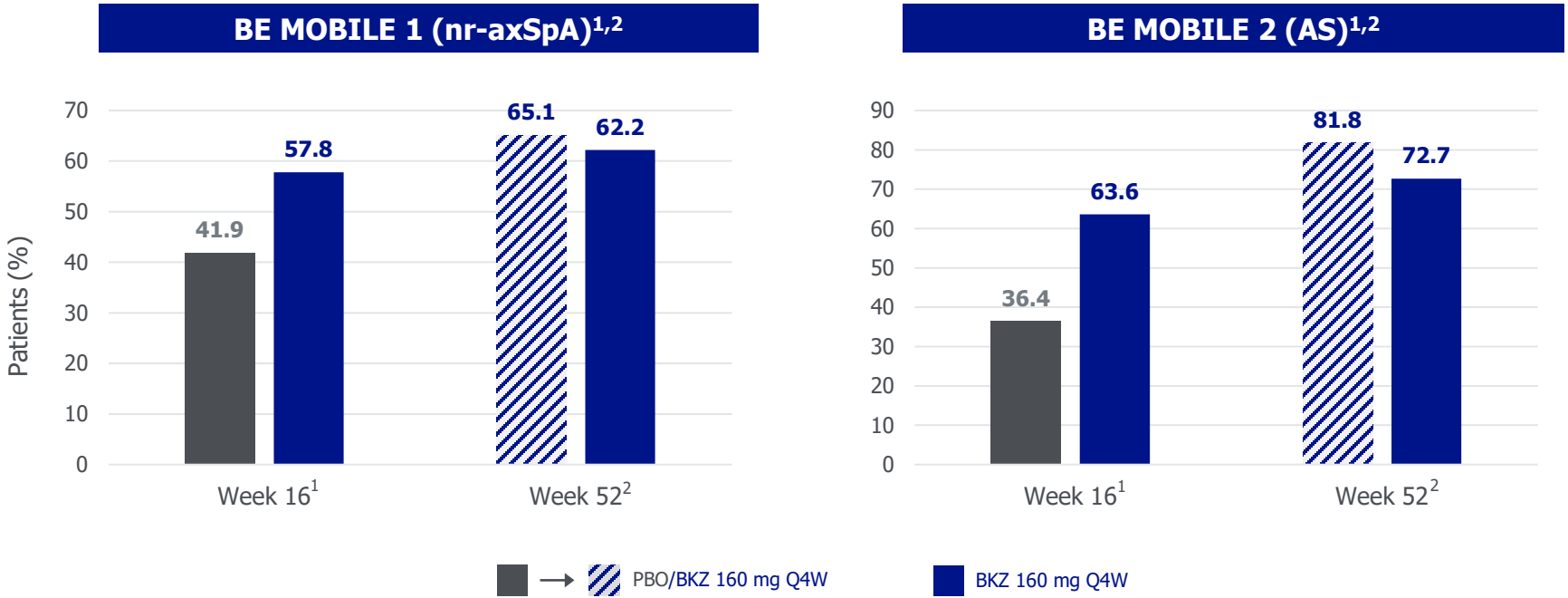
Complete Resolution of Peripheral Arthritis at Week 16 and Week 52 (NRI)



Non-responder imputation.[2,3] Randomized set.[2,3] Assessed in patients with SJC >0 at baseline.[1,2] SJC and TJC assessed in 44 joints.[1,2] Reference 1 reported data at Week 16 only.[1] Reference 2 reported Week 52 data only.[2] Week 52 data was collected during the open-label maintenance period.[2]

1. van der Heijde D et al. Supplementary appendix. Ann Rheum Dis. 2023;82(4):515–526. 2. Baraliakos X et al. Ann Rheum Dis. 2024;83(2):199–213. 3. van der Heijde D et al. Ann Rheum Dis. 2023;82(4):515–526.

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Results: Clinical Outcomes—Objective Signs of Inflammation

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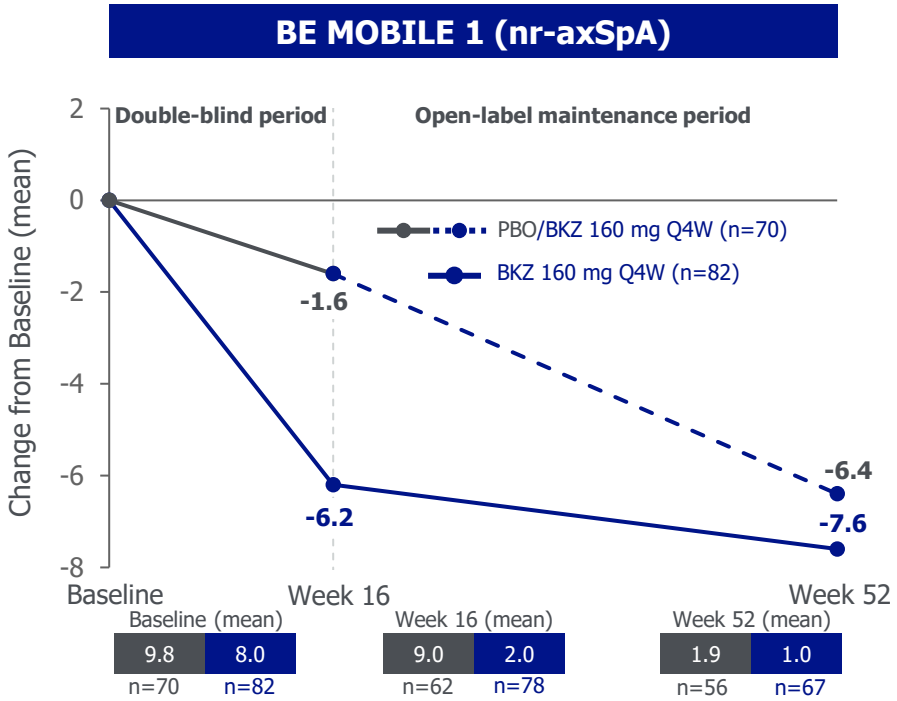
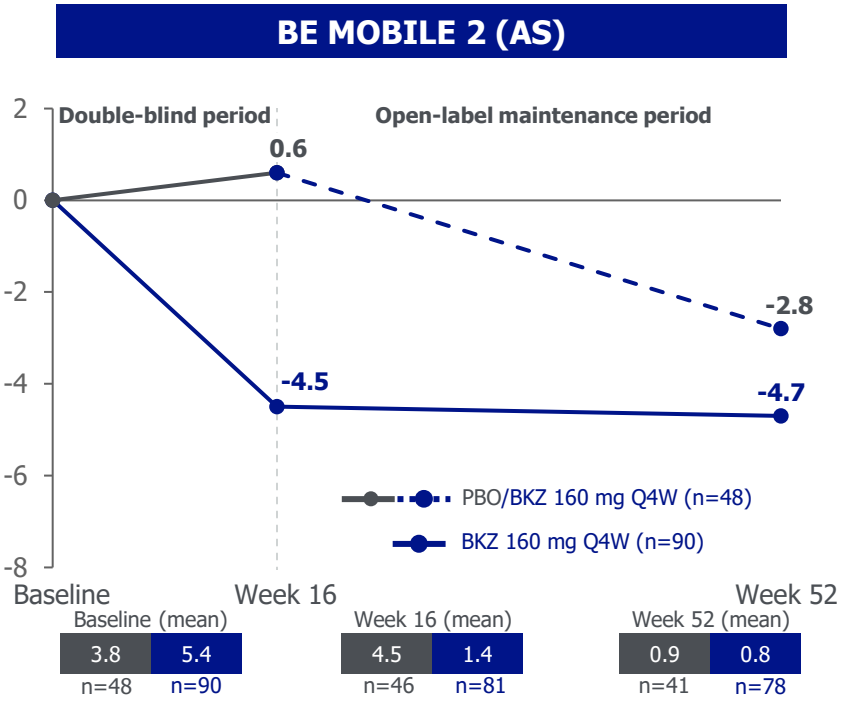
SPARCC SIJ Score Responses With BKZ at Week 16 and Week 52 (OC)





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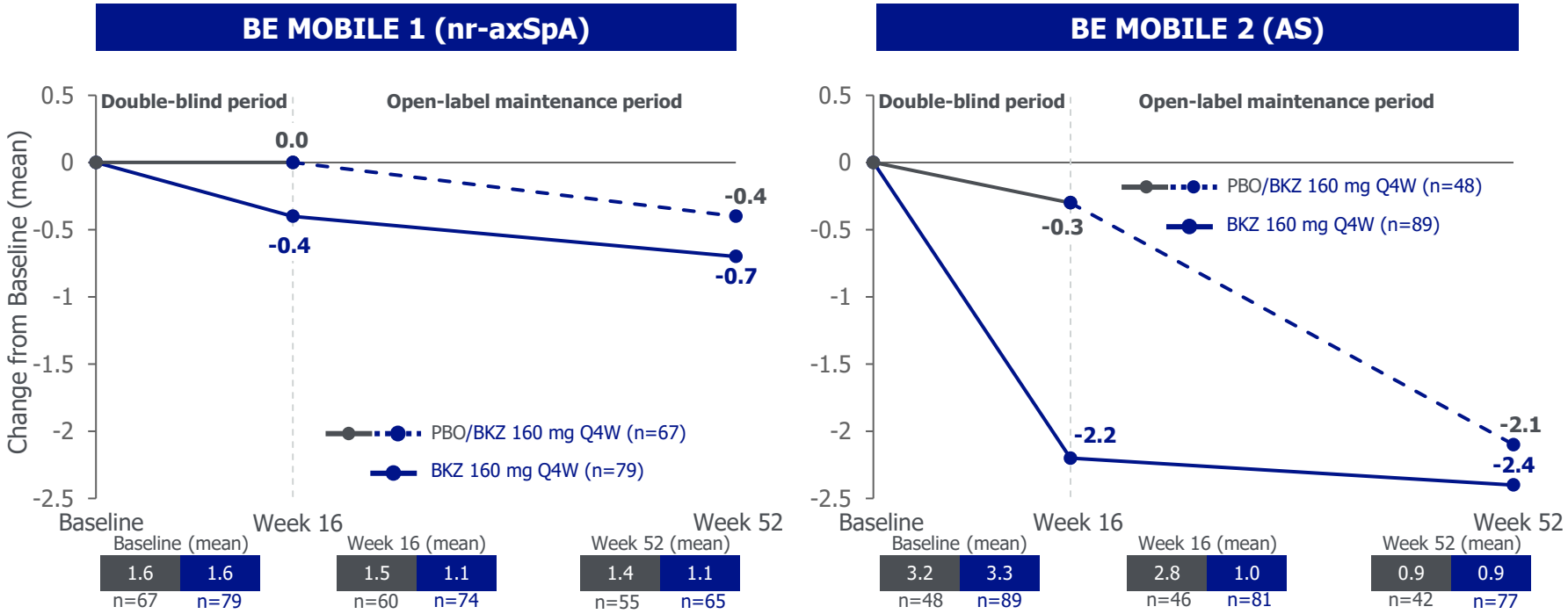
Inspired by patients.
Driven by science.

Data reported using observed case. Randomized set. Tables report mean absolute values. SPARCC SIJ scores reported for only patients in MRI sub-studies. MRI SPARCC SIJ inflammation scores range from 0–72; lower scores indicate less SIJ inflammation and negative changes represent improvements.

Baraliakos X et al. Ann Rheum Dis. 2024;83(2):199–213.

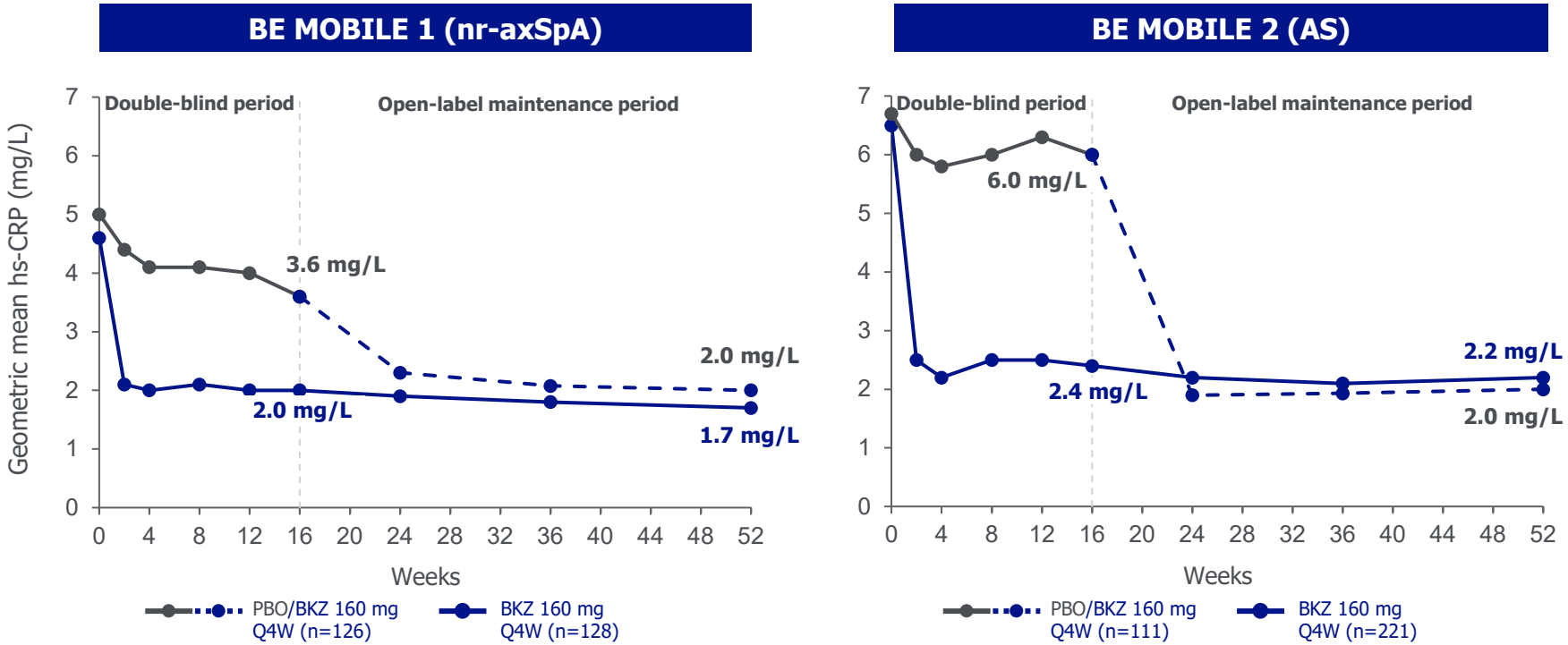
Berlin Spine Score Responses With BKZ at Week 16 and Week 52 (OC)



Data reported using observed case. Randomized set. Tables report mean absolute values. Berlin spine scores reported for only patients in MRI sub-studies. MRI Berlin spine score ranges from 0–69; lower scores indicate less spinal inflammation and negative changes represent improvements.

Adapted from Baraliakos X et al. Ann Rheum Dis. 2024;83(2):199–213.

hs-CRP Responses With BKZ to Week 52 (MI)



Inspired by patients.
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Data reported using multiple imputation. Randomized set. hs-CRP was an exploratory endpoint. Elevated CRP defined as ≥6.0mg/L.
Adapted from Baraliakos X et al. Ann Rheum Dis. 2024;83(2):199–213.

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Results: Adverse Event Data

US-BK-2401174 | Date of preparation: September 2024

Adverse Events Overview (1/4)

n (%), overall period: [EAIR/100 PY]	BE MOBILE 1 (nr-axSpA)				BE MOBILE 2 (AS)			
	Double-Blind Period (Weeks 0–16)		Open-Label Maintenance Period (Weeks 16–52)	Overall (Weeks 0–52)	Double-Blind Period (Weeks 0–16)		Open-Label Maintenance Period (Weeks 16–52)	Overall (Weeks 0–52)
	Placebo (n=126) 38.1 PYAR	BKZ 160 mg Q4W (n=128) 40.4 PYAR	BKZ 160 mg Q4W (n=242) 167.8 PYAR	BKZ 160 mg Q4W (N=244)* 208.2 PYAR	Placebo (n=111) 34.6 PYAR	BKZ 160 mg Q4W (n=221) 68.3 PYAR	BKZ 160 mg Q4W (n=319) 220.0 PYAR	BKZ 160 mg Q4W (N=330)* 290.9 PYAR
Any TEAE	71 (56.3)	80 (62.5)	164 (67.8)	183 (75.0) [202.1]	48 (43.2)	120 (54.3)	217 (68.0)	249 (75.5) [200.8]
Severe TEAEs	1 (0.8)	0	8 (3.3)	8 (3.3) [3.9]	0	4 (1.8)	10 (3.1)	14 (4.2) [4.9]
TEAEs leading to discontinuation from the trial	5 (4.0)	2 (1.6)	4 (1.7)	6 (2.5) [2.9]	0	6 (2.7)	9 (2.8)	15 (4.5) [5.2]
TEAEs leading to discontinuation of study drug	5 (4.0)	2 (1.6)	6 (2.5)	8 (3.3) [3.9]	0	7 (3.2)	9 (2.8)	16 (4.8) [5.6]
Drug-related TEAEs	17 (3.5)	33 (25.8)	67 (27.7)	81 (33.2) [51.3]	19 (17.1)	65 (29.4)	133 (35.4)	135 (40.9) [67.1]
SAEs	1 (0.8)	0	9 (3.7)	9 (3.7) [4.4]	1 (0.9)	5 (2.3)	15 (4.7)	20 (6.1) [7.1]
Deaths	0	0	0	0	0	0	0	0

Safety set. MedDRA (Version 19.0). Overall period includes all data available up to the last Week 52 visit, including data for patients treated beyond Week 24. *Includes patients who switched from PBO to BKZ (events after switch only).
Adapted from Baraliakos X et al. Ann Rheum Dis. 2024;83(2):199–213.

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Adverse Events Overview (2/4)

n (%), overall period: [EAIR/100 PY]	BE MOBILE 1 (nr-axSpA)				BE MOBILE 2 (AS)			
	Double-Blind Period (Weeks 0–16)		Open-Label Maintenance Period (Weeks 16–52)	Overall (Weeks 0–52)	Double-Blind Period (Weeks 0–16)		Open-Label Maintenance Period (Weeks 16–52)	Overall (Weeks 0–52)
	Placebo (n=126) 38.1 PYAR	BKZ 160 mg Q4W (n=128) 40.4 PYAR	BKZ 160 mg Q4W (n=242) 167.8 PYAR	BKZ 160 mg Q4W (N=244)* 208.2 PYAR	Placebo (n=111) 34.6 PYAR	BKZ 160 mg Q4W (n=221) 68.3 PYAR	BKZ 160 mg Q4W (n=319) 220.0 PYAR	BKZ 160 mg Q4W (N=330)* 290.9 PYAR
Most frequently reported TEAEs[†]								
Nasopharyngitis	6 (4.8)	13 (10.2)	18 (17.4)	30 (12.3) [15.7]	4 (3.6)	17 (7.7)	17 (5.3)	30 (9.1) [11.0]
URTI	10 (7.9)	9 (7.0)	15 (6.2)	23 (9.4) [11.9]	8 (7.2)	6 (2.7)	16 (5.0)	21 (6.4) [7.5]
Oral candidiasis[‡]	0	4 (3.1)	17 (7.0)	18 (7.4) [9.0]	0	10 (4.5)	12 (3.8)	20 (6.1) [7.2]
Corona virus infection	1 (0.8)	1 (0.8)	17 (7.0)	17 (7.0) [8.3]	3 (2.7)	1 (0.5)	6 (1.9)	7 (2.1) [2.4]
Headache	2 (1.6)	3 (2.3)	10 (4.1)	13 (5.3) [6.5]	5 (4.5)	9 (4.1)	11 (3.4)	18 (5.5) [6.5]
Pharyngitis	1 (0.8)	4 (3.1)	7 (2.9)	11 (4.5) [5.4]	0	5 (2.3)	7 (2.2)	11 (3.3) [3.9]
Diarrhea	2 (1.6)	3 (2.3)	6 (2.5)	9 (3.7) [4.4]	1 (0.9)	7 (3.2)	12 (3.8)	18 (5.5) [6.5]

Safety set. MedDRA (Version 19.0). Overall period includes all data available up to the last Week 52 visit, including data for patients treated beyond Week 24. *Includes patients who switched from PBO to BKZ (events after switch only). [†]TEAEs >5% in any group are reported by preferred term. [‡]Only one case of oral candidiasis (in BE MOBILE 1) was severe, the remainder were mild or moderate.

Adapted from Baraliakos X et al. Ann Rheum Dis. 2024;83(2):199–213.

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Adverse Events Overview (3/4)

n (%), overall period: [EAIR/100 PY]	BE MOBILE 1 (nr-axSpA)				BE MOBILE 2 (AS)			
	Double-Blind Period (Weeks 0–16)		Open-Label Maintenance Period (Weeks 16–52)	Overall (Weeks 0–52)	Double-Blind Period (Weeks 0–16)		Open-Label Maintenance Period (Weeks 16–52)	Overall (Weeks 0–52)
	Placebo (n=126) 38.1 PYAR	BKZ 160 mg Q4W (n=128) 40.4 PYAR	BKZ 160 mg Q4W (n=242) 167.8 PYAR	BKZ 160 mg Q4W (N=244)* 208.2 PYAR	Placebo (n=111) 34.6 PYAR	BKZ 160 mg Q4W (n=221) 68.3 PYAR	BKZ 160 mg Q4W (n=319) 220.0 PYAR	BKZ 160 mg Q4W (N=330)* 290.9 PYAR
Serious infections	0	0	4 (1.7)	4 (1.6) [1.9]	1 (0.9)	1 (0.5)	5 (1.6)	6 (1.8) [2.1]
Opportunistic infections	0	1 (0.8)	4 (1.7)	5 (2.0) [2.4]	0	0	3 (0.9)	3 (0.9) [1.1]
Any fungal infections	0	9 (7.0)	32 (13.2)	37 (15.2) [19.6]	0	14 (6.3)	31 (9.7)	40 (12.1) [14.9]
Candida infections	0	5 (3.9)	23 (9.5)	25 (10.2) [12.8]	0	11 (5.0)	15 (4.7)	23 (7.0) [8.3]
Fungal infections NEC	0	4 (3.1)	9 (3.7)	13 (5.3) [6.4]	0	5 (2.3)	11 (3.4)	14 (4.2) [5.0]
Tinea infections	0	0	2 (0.8)	2 (0.8) [1.0]	0	1 (0.5)	5 (1.6)	6 (1.8) [2.1]
Neutropenia	0	1 (0.8)	2 (0.8)	2 (0.8) [1.0]	0	1 (0.5)	2 (0.6)	2 (0.6) [0.7]
Hepatic events†	3 (2.4)	7 (5.5)	14 (5.8)	20 (8.2) [10.2]	4 (3.6)	10 (4.5)	24 (7.5)	33 (10.0) [12.1]
Liver enzyme elevations								
>3 x ULN ALT or AST	1 (0.8)	2 (1.6)	4 (1.7)	6 (2.5) [2.9]	2 (1.8)	3 (1.4)	9 (2.8)	12 (3.6) [4.3]
>5 x ULN ALT or AST	0	0	1 (0.4)	1 (0.4) [0.5]	1 (0.9)	3 (1.4)	3 (0.9)	6 (1.8) [2.1]

Safety set. MedDRA (Version 19.0). Overall period includes all data available up to the last Week 52 visit, including data for patients treated beyond Week 24. *Includes patients who switched from PBO to BKZ (events after switch only). †Most reported hepatic events were associated with non-serious abnormal liver function elevations; those that were markedly abnormal were associated with factors other than the trial treatment.

Adapted from Baraliakos X et al. Ann Rheum Dis. 2024;83(2):199–213.

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Adverse Events Overview (4/4)

n (%), overall period: [EAIR/100 PY]	BE MOBILE 1 (nr-axSpA)				BE MOBILE 2 (AS)			
	Double-Blind Period (Weeks 0–16)		Open-Label Maintenance Period (Weeks 16–52)	Overall (Weeks 0–52)	Double-Blind Period (Weeks 0–16)		Open-Label Maintenance Period (Weeks 16–52)	Overall (Weeks 0–52)
	Placebo (n=126) 38.1 PYAR	BKZ 160 mg Q4W (n=128) 40.4 PYAR	BKZ 160 mg Q4W (n=242) 167.8 PYAR	BKZ 160 mg Q4W (N=244)* 208.2 PYAR	Placebo (n=111) 34.6 PYAR	BKZ 160 mg Q4W (n=221) 68.3 PYAR	BKZ 160 mg Q4W (n=319) 220.0 PYAR	BKZ 160 mg Q4W (N=330)* 290.9 PYAR
Hypersensitivity[†]	3 (2.4)	3 (2.3)	17 (7.0)	18 (7.4) [9.1]	2 (1.8)	17 (7.7)	28 (8.8)	41 (12.4) [15.3]
Anaphylactic reactions	0	0	0	0	0	0	0	0
Injection site reactions	1 (0.8)	0	1 (0.4)	1 (0.4) [0.5]	0	1 (0.5)	0	1 (0.3) [0.3]
Dermatitis and eczema	0	1 (0.8)	7 (2.9)	8 (3.3) [3.9]	1 (0.9)	6 (2.7)	17 (5.3)	19 (5.8) [6.8]
Adjudicated MACE	0	0	0	0	0	0	0	0
Malignancies[‡]	0	0	1 (0.4)	1 (0.4) [0.5]	0	0	1 (0.3)	1 (0.3) [0.3]
Adjudicated SIB[§]	0	0	1 (0.4)	1 (0.4) [0.5]	0	0	1 (0.3)	1 (0.3) [0.3]
Adjudicated IBD[‖]	1 (0.8)	0	2 (0.8)	2 (0.8) [1.0]	0	2 (0.9)	1 (0.3)	3 (0.9) [1.0]
Ulcerative colitis[¶,**]	1 (0.8)	0	1 (0.4)	1 (0.4) [0.5]	0	1 (0.5)	0	1 (0.3) [0.3]
Crohn's disease[¶,††]	0	0	1 (0.4)	1 (0.4) [0.5]	0	1 (0.5)	1 (0.3)	2 (0.6) [0.7]
Uveitis[‡‡,§§]	6 (4.8)	2 (1.6)	3 (1.2)	3 (1.2) [1.5]	5 (4.5)	0	7 (2.2)	7 (2.1) [2.4]

Safety set. MedDRA (Version 19.0). Overall period includes all data available up to the last Week 52 visit, including data for patients treated beyond Week 24. *Includes patients who switched from PBO to BKZ (events after switch only). [†]Identified using the MedDRA standardized medical query 'Hypersensitivity (SMQ)'. [‡]1 clear cell renal carcinoma event in BE MOBILE 1 and 1 superficial spreading melanoma stage I event in BE MOBILE 2, both adjudicated as not related to study drug by investigator. [§]1 intentional self-injury event in BE MOBILE 1 adjudicated as not related to study drug by investigator and 1 suicidal ideation event in BE MOBILE 2, adjudicated as related to study drug by investigator. [‖]Definite or probable IBD. [¶]No patients with nr-axSpA and 1 patient with r-axSpA who had IBD events had a medical history of IBD. **Moderate ulcerative colitis in a patient with nr-axSpA and severe ulcerative colitis in patients with r-axSpA, both of which led to study drug discontinuation. [††]1 case of mild Crohn's disease in a patient with nr-axSpA that did not lead to study drug discontinuation and 2 cases of moderate Crohn's disease that led to study drug discontinuation. [‡‡]In BE MOBILE 1, 1 BKZ-treated patient and 4 PBO-treated patients in Weeks 0–16, and 1 BKZ-treated patient in Weeks 0–52, had a medical history of uveitis at baseline. In BE MOBILE 2, 5 PBO-treated patients in Weeks 0–16, and 5 BKZ-treated patients in Weeks 0–52, had a medical history of uveitis at baseline. [§§]Includes the preferred terms autoimmune uveitis, uveitis, iridocyclitis and iritis.

Adapted from Baraliakos X et al. Ann Rheum Dis. 2024;83(2):199–213.

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TEAEs Leading to Study Drug Discontinuation (1/2)

n (%), overall period: [EAIR/100 PY]	BE MOBILE 1 (nr-axSpA)			BE MOBILE 2 (AS)		
	Double-Blind Period (Weeks 0–16)		Overall (Weeks 0–52)	Double-Blind Period (Weeks 0–16)		Overall (Weeks 0–52)
	Placebo (n=126) 38.1 PYAR	BKZ 160 mg Q4W (n=128) 40.4 PYAR	BKZ 160 mg Q4W (N=244)* 208.2 PYAR	Placebo (n=111) 34.6 PYAR	BKZ 160 mg Q4W (n=221) 68.3 PYAR	BKZ 160 mg Q4W (N=330)* 290.9 PYAR
Any TEAE leading to discontinuation of study drug	5 (4.0)	2 (1.6)	8 (3.3) [3.9]	0	7 (3.2)	16 (4.8) [5.6]
Iridocyclitis	0	0	1 (0.4) [0.5]†	0	0	0
Uveitis	2 (1.6)	0	0	0	0	0
Colitis ulcerative	1 (0.8)	0	0	0	1 (0.5)	1 (0.3) [0.3]
Crohn's disease	0	0	0	0	1 (0.5)	2 (0.6) [0.7]
Cellulitis	0	0	0	0	0	1 (0.3) [0.3]
Psychiatric evaluation abnormal	2 (1.6)	1 (0.8)	1 (0.4) [0.5]	0	2 (0.9)	3 (0.9) [1.0]
Peripheral arthritis	0	0	0	0	0	1 (0.3) [0.3]
Dizziness	0	1 (0.8)	1 (0.4) [0.5]†	0	0	0
Anxiety	0	0	1 (0.4) [0.5]	0	0	0

Safety set. MedDRA (Version 19.0), preferred terms reported. *Includes patients who switched from PBO to BKZ (events after switch only). †Assessed as related to study medication by the investigator.
Adapted from Baraliakos X et al. Supplementary appendix. Ann Rheum Dis. 2024;83(2):199–213.

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TEAEs Leading to Study Drug Discontinuation (2/2)

n (%), overall period: [EAIR/100 PY]	BE MOBILE 1 (nr-axSpA)			BE MOBILE 2 (AS)		
	Double-Blind Period (Weeks 0–16)		Overall (Weeks 0–52)	Double-Blind Period (Weeks 0–16)		Overall (Weeks 0–52)
	Placebo (n=126) 38.1 PYAR	BKZ 160 mg Q4W (n=128) 40.4 PYAR	BKZ 160 mg Q4W (N=244)* 208.2 PYAR	Placebo (n=111) 34.6 PYAR	BKZ 160 mg Q4W (n=221) 68.3 PYAR	BKZ 160 mg Q4W (N=330)* 290.9 PYAR
Hypoesthesia	0	0	0	0	0	1 (0.3) [0.3]
Clear cell renal cell carcinoma	0	0	1 (0.4) [0.5]	0	0	0
Lymphoid tissue hyperplasia†	0	0	0	0	1 (0.5)	1 (0.3) [0.3]
Esophageal candidiasis	0	0	0	0	0	1 (0.3) [0.3]
Oral candidiasis	0	0	3 (1.2) [1.5]‡	0	1 (0.5)	1 (0.3) [0.3]
Dermatitis allergic	0	0	0	0	0	1 (0.3) [0.3]
Rash	0	0	0	0	1 (0.5)	1 (0.3) [0.3]
Suicidal ideation	0	0	0	0	0	1 (0.3) [0.3]
Pleural effusion	0	0	0	0	0	1 (0.3) [0.3]

Safety set. MedDRA (Version 19.0), preferred terms reported. *Includes patients who switched from PBO to BKZ (events after switch only). †Lymphoid tissue hyperplasia was a TEAE related to gastrointestinal disorders and not related to lymphoid blood cells – the TEAE was diagnosed and reported as 'lymphoid nodular hyperplasia'. ‡Assessed as related to study medication by the investigator. Adapted from Baraliakos X et al. Supplementary appendix. Ann Rheum Dis. 2024;83(2):199–213.

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Serious Treatment-Emergent Adverse Events (1/3)

n (%), overall period: [EAIR/100 PY]	BE MOBILE 1 (nr-axSpA)			BE MOBILE 2 (AS)		
	Double-Blind Period (Weeks 0–16)		Overall (Weeks 0–52)	Double-Blind Period (Weeks 0–16)		Overall (Weeks 0–52)
	Placebo (n=126) 38.1 PYAR	BKZ 160 mg Q4W (n=128) 40.4 PYAR	BKZ 160 mg Q4W (N=244)* 208.2 PYAR	Placebo (n=111) 34.6 PYAR	BKZ 160 mg Q4W (n=221) 68.3 PYAR	BKZ 160 mg Q4W (N=330)* 290.9 PYAR
Any SAE	1 (0.8)	0	9 (3.7) [4.4]	1 (0.9)	5 (2.3)	20 (6.1) [7.1]
Sinus node dysfunction	0	0	0	0	0	1 (0.3) [0.3]
Deafness unilateral	0	0	1 (0.4) [0.5]	0	0	0
Goiter	0	0	0	0	1 (0.5)	1 (0.3) [0.3]
Abdominal adhesions	1 (0.8)	0	0	0	0	0
Colitis ulcerative	0	0	0	0	1 (0.5)	1 (0.3) [0.3]
Crohn's disease	0	0	0	0	1 (0.5)	1 (0.3) [0.3]
Hiatus hernia	0	0	0	0	0	1 (0.3) [0.3]
Ileus paralytic	0	0	0	0	0	1 (0.3) [0.3]
Cholelithiasis	0	0	0	0	1 (0.5)	1 (0.3) [0.3]

Safety set. MedDRA (Version 19.0), preferred terms reported. *Includes patients who switched from PBO to BKZ (events after switch only).
Adapted from Baraliakos X et al. Supplementary appendix. Ann Rheum Dis. 2024;83(2):199–213.

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Serious Treatment-Emergent Adverse Events (2/3)

n (%), overall period: [EAIR/100 PY]	BE MOBILE 1 (nr-axSpA)			BE MOBILE 2 (AS)		
	Double-Blind Period (Weeks 0–16)		Overall (Weeks 0–52)	Double-Blind Period (Weeks 0–16)		Overall (Weeks 0–52)
	Placebo (n=126) 38.1 PYAR	BKZ 160 mg Q4W (n=128) 40.4 PYAR	BKZ 160 mg Q4W (N=244)* 208.2 PYAR	Placebo (n=111) 34.6 PYAR	BKZ 160 mg Q4W (n=221) 68.3 PYAR	BKZ 160 mg Q4W (N=330)* 290.9 PYAR
Appendicitis	0	0	2 (0.8) [1.0]†	0	0	0
Diverticulitis	0	0	0	0	0	1 (0.3) [0.3]‡
Cellulitis	0	0	0	0	0	1 (0.3) [0.3]‡
Tonsilitis bacterial	0	0	1 (0.4) [0.5]	0	0	0
Otitis media	0	0	0	0	0	1 (0.3) [0.3]‡
Hepatitis A	0	0	0	0	1 (0.5)	1 (0.3) [0.3]
Infectious pleural effusion	0	0	0	0	0	1 (0.3) [0.3]
Erysipelas	0	0	1 (0.4) [0.5]	0	0	1 (0.3) [0.3]‡
Viral Infection	0	0	0	1 (0.9)‡	0	0
Radius fracture	0	0	0	0	0	1 (0.3) [0.3]

Safety set. MedDRA (Version 19.0), preferred terms reported. *Includes patients who switched from PBO to BKZ (events after switch only). †1 event in one patient assessed as related to study medication by the investigator. ‡Assessed as related to study medication by the investigator.
Adapted from Baraliakos X et al. Supplementary appendix. Ann Rheum Dis. 2024;83(2):199–213.

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Serious Treatment-Emergent Adverse Events (3/3)

n (%), overall period: [EAIR/100 PY]	BE MOBILE 1 (nr-axSpA)			BE MOBILE 2 (AS)		
	Double-Blind Period (Weeks 0–16)		Overall (Weeks 0–52)	Double-Blind Period (Weeks 0–16)		Overall (Weeks 0–52)
	Placebo (n=126) 38.1 PYAR	BKZ 160 mg Q4W (n=128) 40.4 PYAR	BKZ 160 mg Q4W (N=244)* 208.2 PYAR	Placebo (n=111) 34.6 PYAR	BKZ 160 mg Q4W (n=221) 68.3 PYAR	BKZ 160 mg Q4W (N=330)* 290.9 PYAR
Osteoarthritis	0	0	1 (0.4) [0.5]	0	0	0
Clear cell renal cell carcinoma†	0	0	1 (0.4) [0.5]	0	0	0
Superficial spreading melanoma stage I	0	0	0	0	0	1 (0.3) [0.3]
Uterine leiomyoma	0	0	0	0	0	1 (0.3) [0.3]
Syncope	0	0	0	0	0	4 (1.2) [1.4]‡
Depression	0	0	0	1 (0.9)	0	0
Suicidal ideation	0	0	0	0	0	1 (0.3) [0.3]§
Intentional self-injury	0	0	1 (0.4) [0.5]	0	0	0
Nasal crusting	0	0	1 (0.4) [0.5]	0	0	0
Rhinoplasty	0	0	0	0	0	1 (0.3) [0.3]

Inspired by patients. Driven by science.

Safety set. MedDRA (Version 19.0), preferred terms reported. *Includes patients who switched from PBO to BKZ (events after switch only). †SAE occurred 132 days after treatment initiation. ‡1 event assessed as related to study medication by the investigator. §Assessed as related to study medication by the investigator.

Adapted from Baraliakos X et al. Supplementary appendix. Ann Rheum Dis. 2024;83(2):199–213.

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Fungal Infections (1/3)

n (%), overall period: [EAIR/100 PY]	BE MOBILE 1 (nr-axSpA)			BE MOBILE 2 (AS)		
	Double-Blind Period (Weeks 0–16)		Overall (Weeks 0–52)	Double-Blind Period (Weeks 0–16)		Overall (Weeks 0–52)
	Placebo (n=126) 38.1 PYAR	BKZ 160 mg Q4W (n=128) 40.4 PYAR	BKZ 160 mg Q4W (N=244)* 208.2 PYAR	Placebo (n=111) 34.6 PYAR	BKZ 160 mg Q4W (n=221) 68.3 PYAR	BKZ 160 mg Q4W (N=330)* 290.9 PYAR
Fungal infections	0	9 (7.0)	37 (15.2) [19.6]	0	14 (6.3)	40 (12.1) [14.9]
Candida infections	0	5 (3.9)	25 (10.2) [12.8]	0	11 (5.0)	23 (7.0) [8.3]
Oral candidiasis	0	4 (3.1)	18 (7.4) [9.0]	0	10 (4.5)	20 (6.1) [7.2]
Anal candidiasis	0	0	0	0	0	1 (0.3) [0.3]
Genital candidiasis	0	0	0	0	1 (0.5)	1 (0.3) [0.3]
Esophageal candidiasis†	0	0	0	0	0	1 (0.3) [0.3]
Oropharyngeal candidiasis†	0	1 (0.8)	4 (1.6) [1.9]	0	0	1 (0.3) [0.3]
Vulvovaginal candidiasis	0	0	3 (1.2) [1.5]	0	0	0
Skin *candida*	0	0	1 (0.4) [0.5]	0	0	0

Safety set. MedDRA (Version 19.0), preferred terms reported. Overall period includes all data available up to the last Week 52 visit, including data for patients treated beyond Week 24. *Includes patients who switched from PBO to BKZ (events after switch only). †For BE MOBILE 1, 1 oropharyngeal candidiasis event in the Weeks 0–16 period and 4 oropharyngeal candidiasis events and 1 oropharyngitis fungal event in the Weeks 0–52 period were reported as opportunistic infections. For BE MOBILE 2, 1 esophageal candidiasis, 1 oropharyngeal candidiasis and 1 fungal esophagitis event in the Weeks 0–52 period was reported as an opportunistic infection.
Adapted from Baraliakos X et al. Ann Rheum Dis. 2024;83(2):199–213.

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Fungal Infections (2/3)

n (%), overall period: [EAIR/100 PY]	BE MOBILE 1 (nr-axSpA)			BE MOBILE 2 (AS)		
	Double-Blind Period (Weeks 0–16)		Overall (Weeks 0–52)	Double-Blind Period (Weeks 0–16)		Overall (Weeks 0–52)
	Placebo (n=126) 38.1 PYAR	BKZ 160 mg Q4W (n=128) 40.4 PYAR	BKZ 160 mg Q4W (N=244)* 208.2 PYAR	Placebo (n=111) 34.6 PYAR	BKZ 160 mg Q4W (n=221) 68.3 PYAR	BKZ 160 mg Q4W (N=330)* 290.9 PYAR
Fungal infections NEC	0	4 (3.1)	13 (5.3) [6.4]	0	5 (2.3)	14 (4.2) [5.0]
Fungal skin infection	0	2 (1.6)	4 (1.6) [1.9]	0	0	4 (1.2) [1.4]
Tongue fungal infection	0	0	1 (0.4) [0.5]	0	0	0
Oral fungal infection	0	1 (0.8)	3 (1.2) [1.5]	0	0	3 (0.9) [1.0]
Onychomycosis	0	0	2 (0.8) [1.0]	0	0	2 (0.6) [0.7]
Oropharyngitis fungal†	0	0	1 (0.4) [0.5]	0	0	0
Fungal esophagitis	0	0	0	0	0	1 (0.3) [0.3]
Vulvovaginal mycotic infection	0	1 (0.8)	3 (1.2) [1.5]	0	5 (2.3)	7 (2.1) [2.5]

Safety set. MedDRA (Version 19.0), preferred terms reported. Overall period includes all data available up to the last Week 52 visit, including data for patients treated beyond Week 24. *Includes patients who switched from PBO to BKZ (events after switch only). †For BE MOBILE 1, 1 oropharyngeal candidiasis event in the Weeks 0–16 period and 4 oropharyngeal candidiasis events and 1 oropharyngitis fungal event in the Weeks 0–52 period were reported as opportunistic infections. For BE MOBILE 2, 1 esophageal candidiasis, 1 oropharyngeal candidiasis and 1 fungal esophagitis event in the Weeks 0–52 period was reported as an opportunistic infection.

Adapted from Baraliakos X et al. Supplementary appendix. Ann Rheum Dis. 2024;83(2):199–213.

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Fungal Infections (3/3)

n (%), overall period: [EAIR/100 PY]	BE MOBILE 1 (nr-axSpA)			BE MOBILE 2 (AS)		
	Double-Blind Period (Weeks 0–16)		Overall (Weeks 0–52)	Double-Blind Period (Weeks 0–16)		Overall (Weeks 0–52)
	Placebo (n=126) 38.1 PYAR	BKZ 160 mg Q4W (n=128) 40.4 PYAR	BKZ 160 mg Q4W (N=244)* 208.2 PYAR	Placebo (n=111) 34.6 PYAR	BKZ 160 mg Q4W (n=221) 68.3 PYAR	BKZ 160 mg Q4W (N=330)* 290.9 PYAR
Tinea infections	0	0	2 (0.8) [1.0]	0	1 (0.5)	6 (1.8) [2.1]
Tinea pedis	0	0	1 (0.4) [0.5]	0	0	3 (0.9) [1.0]
Tinea versicolor	0	0	0	0	1 (0.5)	2 (0.6) [0.7]
Tinea infection	0	0	1 (0.4) [0.5]	0	0	0
Dermatophytosis of nail	0	0	0	0	0	1 (0.3) [0.3]
Serious *Candida* infections	0	0	0	0	0	0
Systemic fungal infections	0	0	0	0	0	0
Candida infections leading to study discontinuation	0	0	2 (0.8) [1.0]	0	1 (0.5)	2 (0.6) [0.7]

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Safety set. MedDRA (Version 19.0), preferred terms reported. Overall period includes all data available up to the last Week 52 visit, including data for patients treated beyond Week 24. *Includes patients who switched from PBO to BKZ (events after switch only).

Adapted from Baraliakos X, et al. Supplementary appendix. Ann Rheum Dis. 2024;83(2):199–213.

Limitations

Baraliakos X, et al. (2024)
Bimekizumab treatment in patients with active axial spondyloarthritis: 52-week efficacy and safety from the randomised parallel phase 3 **BE MOBILE 1** and **BE MOBILE 2** studies[1]

- There was no placebo comparator after Week 16 and patients were aware they were receiving active treatment from Weeks 16-52
- The absence of an active comparator arm limits any direct comparison between BKZ and inhibitors of IL-17A alone
- The background rates of IBD in the axSpA population make it difficult to interpret the incidence of IBD with BKZ treatment and require larger studies over a longer follow-up period

Van der Heijde D, et al. **(2023)**
Efficacy and safety of bimekizumab in axial spondyloarthritis: results of two parallel phase 3 randomized controlled[2]

- There was no placebo comparator after Week 16 and patients were aware they were receiving active treatment from Weeks 16-24
- Long-term efficacy and safety were difficult to assess since the study duration was 24 weeks
- The absence of an active comparator arm limits any direct comparison between BKZ and inhibitors of IL-17A alone

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1. Baraliakos X et al. Ann Rheum Dis. 2024;83(2):199–213. 2. van der Heijde D et al. Ann Rheum Dis. 2023;82(4):515–526.

Bimekizumab treatment in patients with active axial spondyloarthritis: 52-week efficacy and safety from the randomised parallel phase 3 BE MOBILE 1 and BE MOBILE 2 studies

Xenofon Baraliakos, Atul Deodhar, Désirée van der Heijde, Marina Magrey, Walter P Maksymowych, Tetsuya Tomita, Huji Xu, Ute Massow, Carmen Fleurinck, Alicia M Ellis, Thomas Vaux, Julie Shepherd-Smith, Alexander Marten, Lianne S Gensler

Author Contributions: Substantial contributions to study conception and design: **XB, AAD,DvdH, MM, WPM, TT, HX, UM, CF, AME, TV, JS-S, AM, LSG.** Substantial contributions to analysis and interpretation of the data: **XB, AAD, DvdH, MM, WPM, TT, HX,UM, CF, AME, TV, JS-S, AM, LSG.** Drafting the article or revising it critically for important intellectual content: **XB, AAD, DvdH, MM, WPM, TT, HX, UM, CF, AME, TV, JS-S, AM, LSG.** Final approval of the version of the article to be published: **XB, AAD, DvdH, MM, WPM, TT, HX, UM, CF, AME, TV, JS-S, AM, LSG.** Manuscript guarantor: **XB.**

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UCB Pharma contributed to study design, participated in data collection, completed the data analysis, and participated in data interpretation. UCB Pharma also participated in writing, review, and approval of the manuscript. All authors had full access to the data, reviewed and approved the final version, and were responsible for the decision to submit for publication. A medical writing agency, employed by UCB Pharma, assisted with manuscript preparation under the authors' direction

Efficacy and safety of bimekizumab in axial spondyloarthritis: results of two parallel phase 3 randomized controlled

Désirée van der Heijde, Atul Deodhar, Xenofon Baraliakos, Matthew A Brown, Hiroaki Dobashi, Maxime Dougados, Dirk Elewaut , Alicia M Ellis, Carmen Fleurinck, Karl Gaffney, Lianne S Gensler, Nigil Haroon, Marina Magrey, Walter P Maksymowych, Alexander Marten, Ute Massow, Marga Oortgiesen, Denis Poddubnyy, Martin Rudwaleit, Julie Shepherd-Smith, Tetsuya Tomita, Filip Van den Bosch, Thomas Vaux, Huji Xu

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- Baraliakos X, Deodhar A, van der Heijde D, Magrey M, Maksymowych WP, Tomita T et al. Bimekizumab Treatment in Patients with Active Axial Spondyloarthritis: 52-Week Efficacy and Safety from the Randomised Parallel Phase 3 BE MOBILE 1 and BE MOBILE 2 Studies. Ann Rheum Dis. 2024;83(2):199–213.
- van der Heijde D, Deodhar A, Baraliakos X, Brown MA, Dobashi H, Dougados M, et al. Efficacy and safety of bimekizumab in axial spondyloarthritis: results of two parallel phase 3 randomised controlled trials. Ann Rheum Dis. 2023;82(4):515–526.

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Abbreviations

Abbreviations (1/3)

	Description
ACJ	Acromioclavicular joint
ACR	American College of Rheumatology
ALT	Alanine aminotransferase
AMI	Acute myocardial infarction
ANCOVA	Analysis of covariance
AS	Ankylosing spondylitis
ASAS	Assessment of SpondyloArthritis international Society
ASAS-PR	ASAS partial remission
AST	Aspartate aminotransferase
ASDAS	Ankylosing spondylitis disease activity score
ASDAS-MI	ASDAS Major Improvement
ASQoL	Ankylosing spondylitis quality of life
axSpA	Axial spondyloarthritis
BASDAI	Bath Ankylosing Spondylitis Disease Activity Index
BASFI	Bath Ankylosing Spondylitis Functional Index
BASMI	Bath Ankylosing Spondylitis Metrology Index
bDMARD	Biologic disease-modifying antirheumatic drug

	Description
BKZ	Bimekizumab
BMI	Body mass index
CfB	Change from baseline
CI	Confidence interval
CRP	C-reactive protein
csDMARD	Conventional synthetic disease-modifying antirheumatic drug
CV	Coefficient of variation
DMARD	Disease-modifying antirheumatic drug
EAIR	Exposure-adjusted incidence rate
EULAR	European Alliance of Associations for Rheumatology
FACIT-F	The Functional Assessment of Chronic Illness Therapy - Fatigue
HDA	High disease activity
HLA-B27	Human leukocyte antigen B27
HRQoL	Health-related quality of life
hs-CRP	High sensitivity C-reactive protein
IBD	Inflammatory bowel disease
ID	Inactive disease

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Abbreviations (2/3)

	Description
IL	Interleukin
IL-17R	Interleukin-17 receptor
IPJ	Interphalangeal joint
IR	Inadequate responder
LDA	Low disease activity
LLOQ	Lower limit of quantification
MACE	Major adverse cardiovascular events
MASES	Maastricht Ankylosing Spondylitis Enthesitis Score
MCPJ	Metacarpophalangeal joint
MDA	Minimal disease activity
MI	Multiple imputation
mNY	Modified New York
MRI	Magnetic resonance imaging
MTPJ	Metatarsophalangeal joint
NEC	Not elsewhere classified
nr-axSpA	Non-radiographic axial spondyloarthritis
NRI	Non-responder imputation

	Description
NSAID	Non-steroidal anti-inflammatory drug
OC	Observed case
OLE	Open label extension
PBO	Placebo
PGADA	Patient's Global Assessment of Disease Activity
Pt	Patient
PY	Patient years
PYAR	Patient years at risk
Q4W	Every 4 weeks
RBMI	Reference-based multiple imputation
SAE	Serious adverse event
SCJ	Sternoclavicular joint
SD	Standard deviation
SE	Standard error
SF-36 PCS	36-item short form survey physical component summary
SIB	Suicidal ideation and behavior
SIJ	Sacroiliac joint

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Abbreviations (3/3)

	Description
SJC	Swollen joint count
SpA	Spondyloarthritis
SPARCC	Spondyloarthritis Research Consortium of Canada
TEAE	Treatment emergent adverse event
TJC	Tender joint count
TNFi	Tumor necrosis factor inhibitor
TNFi-IR	Tumor necrosis factor inhibitor inadequate responder
UC	Ulcerative colitis
ULN	Upper limit of normal
URTI	Upper respiratory tract infection
vHDA	Very high disease activity
WPAI	Work Productivity and Activity Impairment
WPAI-SHP	Work Productivity and Activity Impairment Specific Health Problem

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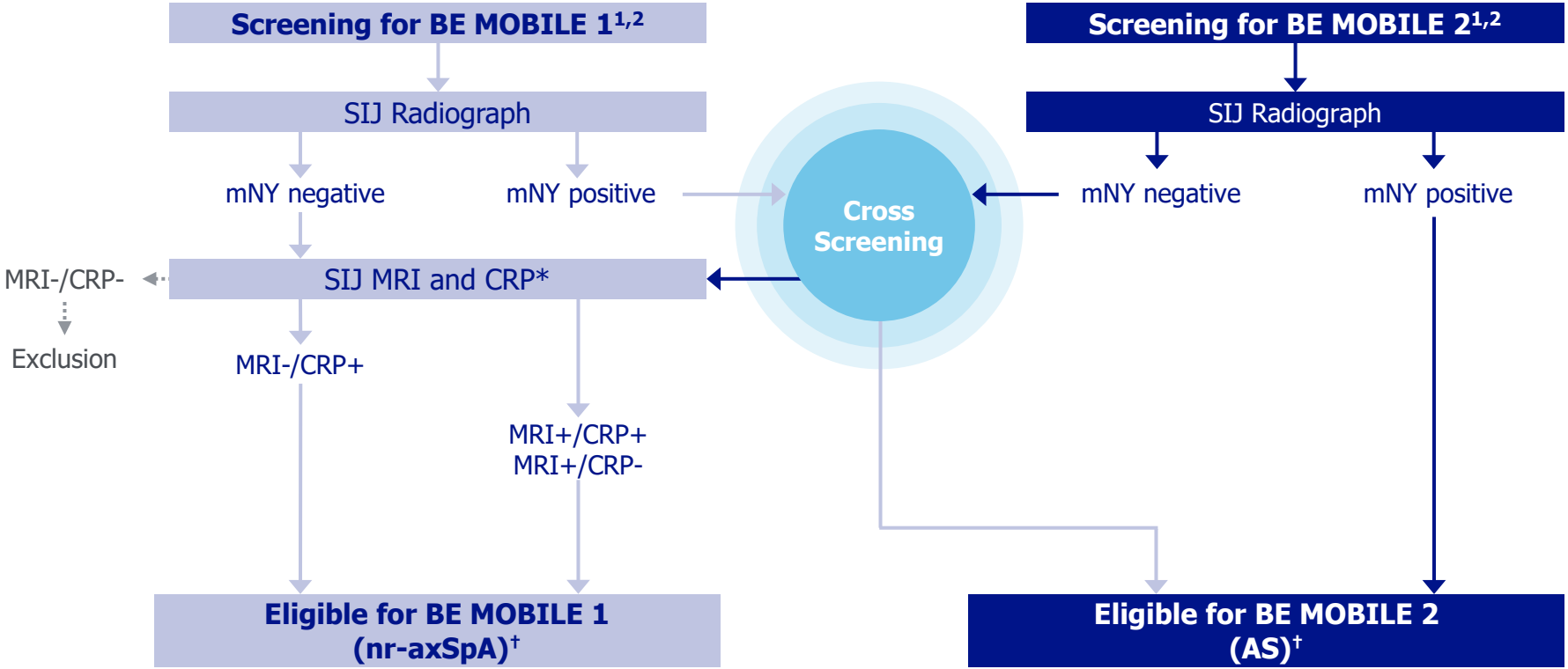
Back-Up

A Cross-Trial Screening Approach Was Utilized in BE MOBILE 1 and BE MOBILE 2



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*MRIs of the sacroiliac joints (SIJ) were assessed as ASAS positive (MRI+) or negative (MRI–) through central reading by two independent expert readers with an adjudicator; CRP+ defined as ≥6.0 mg/L.[2]
†Eligibility also subject to additional inclusion criteria.[1]

1. Adapted from van der Heijde D et al. Ann Rheum Dis. 2023;82(4):515–526. 2. Adapted from van der Heijde D et al. Supplementary appendix. Ann Rheum Dis. 2023;82(4):515–526.

Clinical Responses With BKZ at Week 16 and Week 52 (OC) (1/5)

		Week 16		Week 52	
		PBO	BKZ 160 mg Q4W	PBO/BKZ 160 mg Q4W	BKZ 160 mg Q4W
	nr-axSpA (BE MOBILE 1) AS (BE MOBILE 2)	n=126 n=111	n=128 n=221	n=126 n=111	n=128 n=221
Binary Endpoints					
ASAS40*, n/N (%)	nr-axSpA	27/118 (22.9)	61/127 (48.0)	64/108 (59.3)	78/110 (70.9)
	AS	25/109 (22.9)	99/210 (47.1)	76/102 (74.5)	129/196 (65.8)
ASAS20†, n/N (%)	nr-axSpA	48/118 (40.7)	88/127 (69.3)	88/108 (81.5)	94/110 (85.5)
	AS	48/109 (44.0)	146/210 (69.5)	89/102 (87.3)	158/196 (80.6)
ASAS-PR†, n/N (%)	nr-axSpA	9/118 (7.6)	33/127 (26.0)	38/108 (35.2)	38/108 (35.2)
	AS	8/109 (7.3)	53/210 (25.2)	41/102 (40.2)	66/196 (33.7)
ASAS40 in TNFi-naïve patients‡, n/N (%)	nr-axSpA	25/103 (24.3)	55/117 (47.0)	58/95 (61.1)	73/103 (70.9)
	AS	22/92 (23.9)	84/177 (47.5)	67/85 (78.8)	108/165 (65.5)
ASAS40 in TNFi-IR patients§, n/N (%)	nr-axSpA	2/15 (13.3)	6/10 (60.0)	6/13 (46.2)	5/7 (71.4)
	AS	3/17 (17.6)	15/33 (45.5)	9/17 (52.9)	21/31 (67.7)

Observed case. Randomized set. *Primary endpoint. †Secondary endpoints. ‡Ranked secondary endpoint in BE MOBILE 2. §Exploratory endpoints.
Adapted from Baraliakos X et al. Supplementary appendix. Ann Rheum Dis. 2024;83(2):199–213.

Clinical Responses With BKZ at Week 16 and Week 52 (OC) (2/5)

		Week 16		Week 52	
		PBO	BKZ 160 mg Q4W	PBO/BKZ 160 mg Q4W	BKZ 160 mg Q4W
	nr-axSpA (BE MOBILE 1) AS (BE MOBILE 2)	n=126 n=111	n=128 n=221	n=126 n=111	n=128 n=221
Binary Endpoints					
ASDAS-MI*, n/N (%)	nr-axSpA	9/116 (7.8)	35/127 (27.6)	37/105 (35.2)	47/106 (44.3)
	AS	6/108 (5.6)	57/205 (27.8)	49/99 (49.5)	71/189 (37.6)
ASDAS LDA†, n/N (%)	nr-axSpA	25/116 (21.6)	59/127 (46.5)	60/105 (57.1)	69/106 (65.1)
	AS	19/108 (17.6)	93/206 (45.1)	68/99 (68.7)	111/189 (58.7)
ASDAS ID†, n/N (%)	nr-axSpA	8/116 (6.9)	24/127 (18.9)	32/105 (30.5)	29/106 (27.4)
	AS	5/108 (4.6)	34/206 (16.5)	39/99 (39.4)	45/189 (23.8)
MASES=0†,‡, n/N (%)	nr-axSpA	22/87 (25.3)	48/93 (51.6)	41/79 (51.9)	51/78 (65.4)
	AS	22/65 (33.8)	68/123 (55.3)	31/60 (51.7)	67/111 (60.4)
SJC=0†,§, n/N (%)	nr-axSpA	18/40 (45.0)	26/44 (59.1)	28/34 (82.4)	28/37 (75.7)
	AS	8/22 (36.4)	28/43 (65.1)	18/21 (85.7)	32/41 (78.0)
TJC=0†,‖, n/N (%)	nr-axSpA	21/80 (26.3)	33/76 (43.4)	40/73 (54.8)	38/65 (58.5)
	AS	20/59 (33.9)	48/110 (43.6)	35/55 (63.6)	68/101 (67.3)

Observed case. Randomized set. *Secondary endpoint. †Exploratory endpoints. ‡In patients with MASES >0 at baseline. §In patients with SJC >0 at baseline. ‖In patients with TJC >0 at baseline.
Adapted from Baraliakos X et al. Supplementary appendix. Ann Rheum Dis. 2024;83(2):199–213.

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Clinical Responses With BKZ at Week 16 and Week 52 (OC) (3/5)

		Week 16		Week 52	
		PBO	BKZ 160 mg Q4W	PBO/BKZ 160 mg Q4W	BKZ 160 mg Q4W
	nr-axSpA (BE MOBILE 1) AS (BE MOBILE 2)	n=126 n=111	n=128 n=221	n=126 n=111	n=128 n=221
Binary Endpoints					
BASDAI50*, n/N (%)	nr-axSpA	27/118 (22.9)	60/127 (47.2)	62/108 (57.4)	69/109 (63.3)
	AS	29/109 (26.6)	103/210 (49.0)	69/102 (67.6)	119/196 (60.7)
Continuous Endpoints					
ASDAS CfB*, mean (SD), N	nr-axSpA	-0.6 (0.9), 116	-1.5 (1.1), 127	-1.7 (0.9), 105	-1.9 (1.1), 106
	AS	-0.7 (0.7), 108	-1.4 (1.0), 205	-1.9 (0.9), 99	-1.8 (1.0), 189
hs-CRP*, geometric mean (geometric CV, %), N	nr-axSpA	4.0 (275.3), 116	2.0 (202.4), 128	2.0 (184.3), 105	1.7 (186.5), 109
	AS	6.0 (189.6), 108	2.4 (209.3), 209	2.1 (186.4), 100	2.2 (193.5), 189
BASDAI CfB†, mean (SD), N	nr-axSpA	-1.5 (1.9), 118	-3.1 (2.3), 127	-3.6 (1.9), 108	-4.1 (2.1), 109
	AS	-1.9 (1.9), 109	-2.9 (2.1), 210	-4.0 (2.0), 102	-3.6 (1.9), 196
BASFI CfB†, mean (SD), N	nr-axSpA	-1.0 (2.0), 118	-2.5 (2.4), 127	-2.6 (2.2), 108	-3.2 (2.3), 110
	AS	-1.1 (1.7), 109	-2.2 (2.1), 210	-2.8 (1.8), 102	-2.8 (2.1), 196
BASMI CfB‡, mean (SD), N	nr-axSpA	-0.1 (0.7), 118	-0.4 (0.8), 127	-0.5 (0.8), 106	-0.6 (0.8), 106
	AS	-0.2 (0.7), 104	-0.5 (0.8), 208	-0.8 (0.9), 97	-0.7 (0.9), 187

Observed case. Randomized set. *Exploratory endpoints. †Secondary endpoints. ‡Ranked secondary endpoint in BE MOBILE 2.
Adapted from Baraliakos X et al. Supplementary appendix. Ann Rheum Dis. 2024;83(2):199–213.

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Clinical Responses With BKZ at Week 16 and Week 52 (OC) (4/5)

		Week 16		Week 52	
		PBO	BKZ 160 mg Q4W	PBO/BKZ 160 mg Q4W	BKZ 160 mg Q4W
	nr-axSpA (BE MOBILE 1) AS (BE MOBILE 2)	n=126 n=111	n=128 n=221	n=126 n=111	n=128 n=221
Continuous Endpoints					
Nocturnal spinal pain CfB*, mean (SD), N	nr-axSpA	-1.7 (2.4), 118	-3.6 (3.0), 127	-4.1 (2.5), 108	-4.6 (2.9), 109
	AS	-1.9 (2.4), 109	-3.4 (2.4), 210	-4.5 (2.7), 102	-4.2 (2.2), 196
Total spinal pain CfB†, mean (95% CI), N	nr-axSpA	-1.7 (-2.1, -1.3), 118	-3.4 (-3.9, -2.9), 127	-4.0 (-4.4, -3.6), 108	-4.5 (-4.9, -4.0), 109
	AS	-1.9 (-2.4, -1.5), 109	-3.3 (-3.7, -3.0), 210	-4.5 (-5.0, -4.1), 102	-4.1 (-4.4, -3.8), 196
ASQoL CfB*, mean (SD), N	nr-axSpA	-2.6 (4.2), 118	-5.2 (4.8), 127	-5.5 (4.5), 108	-6.2 (4.8), 110
	AS	-3.2 (3.6), 109	-5.0 (4.4), 210	-5.5 (4.3), 102	-5.8 (4.6), 196
SF-36 PCS CfB*, mean (SD), N	nr-axSpA	5.6 (7.6), 118	9.5 (8.3), 127	11.8 (9.3), 108	12.5 (9.6), 110
	AS	5.8 (7.9), 109	9.4 (8.5), 209	12.1 (9.1), 102	12.3 (9.1), 196
Morning stiffness CfB†, mean (95% CI), N	nr-axSpA	-1.9 (-2.3, -1.5), 118	-3.7 (-4.1, -3.2), 127	-4.2 (-4.6, -3.8), 108	-4.7 (-5.2, -4.2), 109
	AS	-2.1 (-2.5, -1.7), 109	-3.3 (-3.6, -2.9), 210	-4.5 (-4.9, -4.0), 102	-4.0 (-4.3, -3.6), 196

Observed case. Randomized set. *Secondary endpoints. †Exploratory endpoints.
Adapted from Baraliakos X et al. Supplementary appendix. Ann Rheum Dis. 2024;83(2):199–213.

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Clinical Responses With BKZ at Week 16 and Week 52 (OC) (5/5)

		Week 16		Week 52	
		PBO	BKZ 160 mg Q4W	PBO/BKZ 160 mg Q4W	BKZ 160 mg Q4W
	nr-axSpA (BE MOBILE 1) AS (BE MOBILE 2)	n=126 n=111	n=128 n=221	n=126 n=111	n=128 n=221
Continuous Endpoints					
MASES CfB*, mean (SD), N	nr-axSpA	-1.3 (2.7), 87	-2.4 (3.3), 93	-2.9 (3.4), 79	-3.6 (2.9), 78
	AS	-1.5 (2.3), 65	-2.5 (2.8), 123	-3.4 (2.7), 60	-3.0 (2.9), 111
SJC CfB*, mean (SD), N	nr-axSpA	-1.4 (3.9), 40	-3.1 (4.5), 44	-3.0 (2.6), 34	-3.0 (5.5), 38
	AS	-2.1 (2.5), 22	-3.6 (3.6), 43	-3.5 (3.8), 21	-4.3 (4.0), 41
TJC CfB*, mean (SD), N	nr-axSpA	-1.1 (4.9), 80	-3.0 (5.8), 76	-3.5 (5.0), 73	-3.9 (6.8), 66
	AS	-3.0 (4.0), 59	-2.5, (4.5), 111	-4.6 (4.5), 55	-4.2 (5.7), 101

Observed case. Randomized set. *Exploratory endpoints.

Adapted from Baraliakos X et al. Supplementary appendix. Ann Rheum Dis. 2024;83(2):199–213.

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