Maintenance of stringent clinical responses with bimekizumab in patients with axial spondyloarthritis: 2-year outcomes from two phase 3 studies

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OBJECTIVES

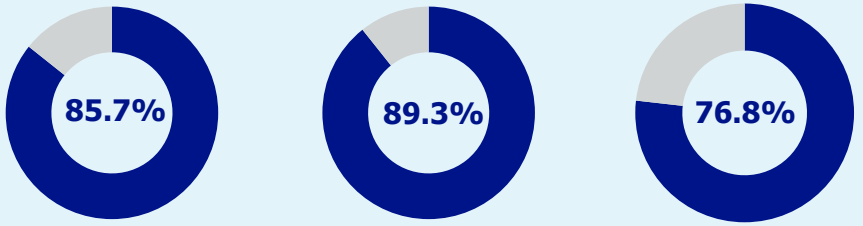
- To assess maintenance of response to bimekizumab (BKZ) over 2 years in patients across the full disease spectrum of axial spondyloarthritis (axSpA), using stringent clinical response criteria.
- To evaluate safety of BKZ through 2 years of treatment in patients with axSpA, in the ongoing open-label extension (OLE) of the phase 3 BE MOBILE 1 and 2 studies.

Background

- AxSpA is a **chronic, inflammatory disease** mainly affecting the **sacroiliac joints and spine.**[1]
- **Maintenance of response** is an internationally recommended axSpA treatment target.[2]
- **BKZ,** a monoclonal IgG1 antibody which selectively inhibits interleukin **(IL)-17F in addition to IL-17A,** has demonstrated sustained clinical efficacy and safety to 2 years in patients across the full disease spectrum of axSpA in the phase 3 studies BE MOBILE 1 and 2, and their combined open-label extension (OLE).[3]
- Here, we report **2-year maintenance of response** to BKZ in these studies for the following outcomes:
  - Assessment of SpondyloArthritis international Society 40% improvement **(ASAS40)**
  - Axial Spondyloarthritis Disease Activity Score low disease activity **(ASDAS LDA [<2.1])**
  - Resolution of enthesitis (Maastricht Ankylosing Spondylitis Enthesitis Score **[MASES]=0)**

Summary

Among patients achieving efficacy outcomes at Week 16, the maintenance of these outcomes at Week 104 was as follows:



Maintained **ASAS40** | Maintained **ASDAS LDA** | Maintained **MASES=0**

Bimekizumab demonstrated sustained **stringent clinical responses.** Patients maintained **low levels of disease activity** over 88 weeks across the full disease spectrum of axSpA.

Missing data imputed using multiple imputation (MI).

1. Navarro-Compán V. et al. Ann Rheum Dis 2021;80:1511–21; **2.** Ramiro S. et al. Ann Rheum Dis 2023;82:19–34; **3.** Baraliakos X. et al. Presented at EULAR 2024, POS0806.

ASAS40: Assessment of SpondyloArthritis international Society 40% improvement; ASDAS LDA: Axial Spondyloarthritis Disease Activity Score low disease activity; axSpA: axial spondyloarthritis; BKZ: bimekizumab; IL: interleukin; MASES: Maastricht Ankylosing Spondylitis Enthesitis Score; MI: multiple imputation; OLE: open-label extension.

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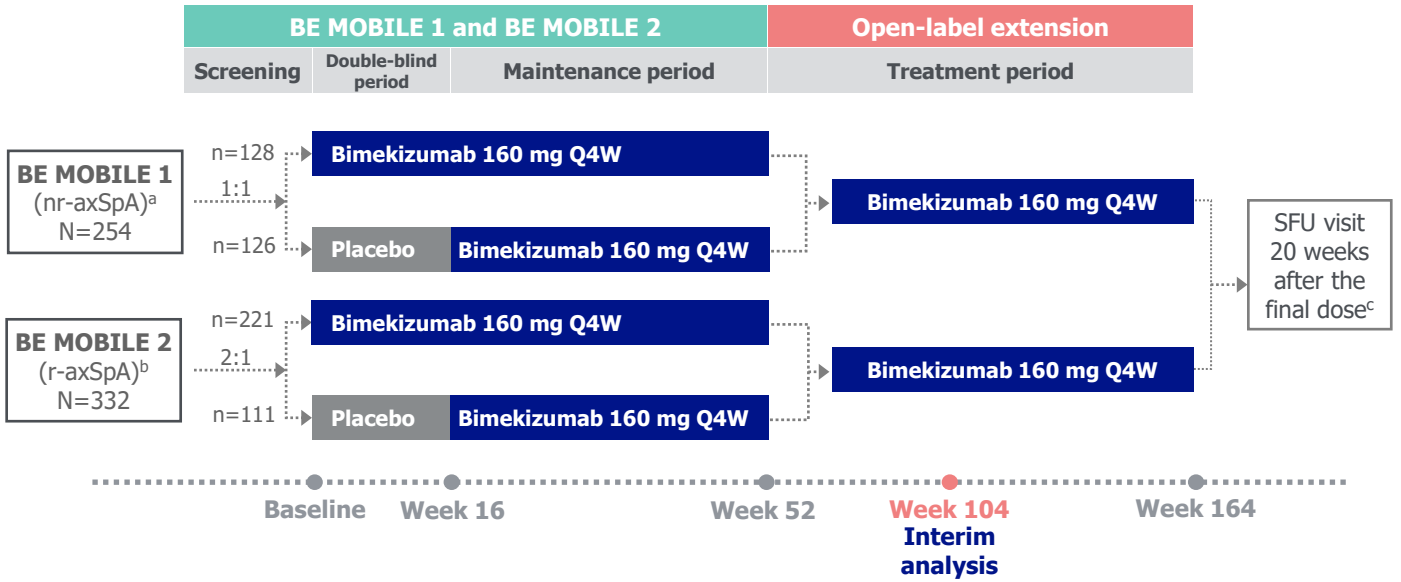
BE MOBILE 1, BE MOBILE 2, and OLE Study Design[1]



Pooled Baseline Characteristics

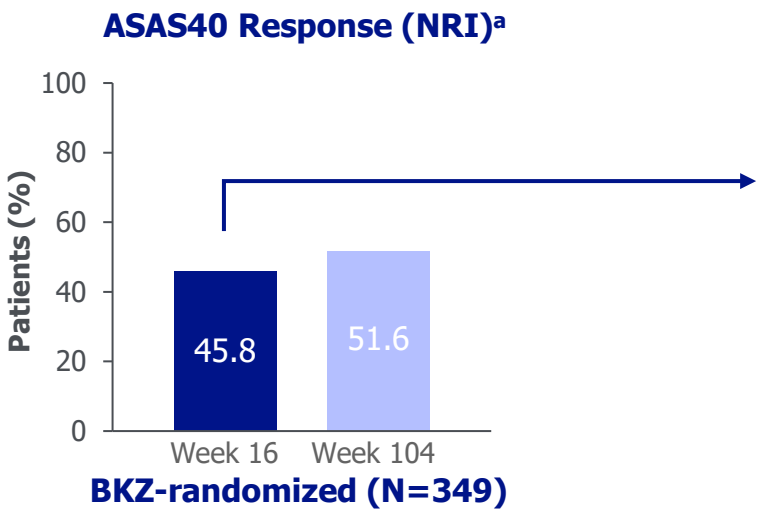
	BKZ 160 mg Q4W N=349
Age (years), mean (SD)	40.0 (11.8)
Sex, male, n (%)	233 (66.8)
BMI (kg/m²), mean (SD)	26.9 (5.9)
Symptom duration (years), mean (SD)	12.4 (10.5)
HLA-B27 positive, n (%)	294 (84.2)
ASDAS, mean (SD)	3.7 (0.8)[d]
BASDAI, mean (SD)	6.6 (1.3)
hs-CRP (mg/L), median (Q1, Q3)	7.2 (2.0, 16.6)
Prior TNFi exposure, n (%)	47 (13.5)
MASES,[e] mean (SE)	4.4 (0.2)[f]

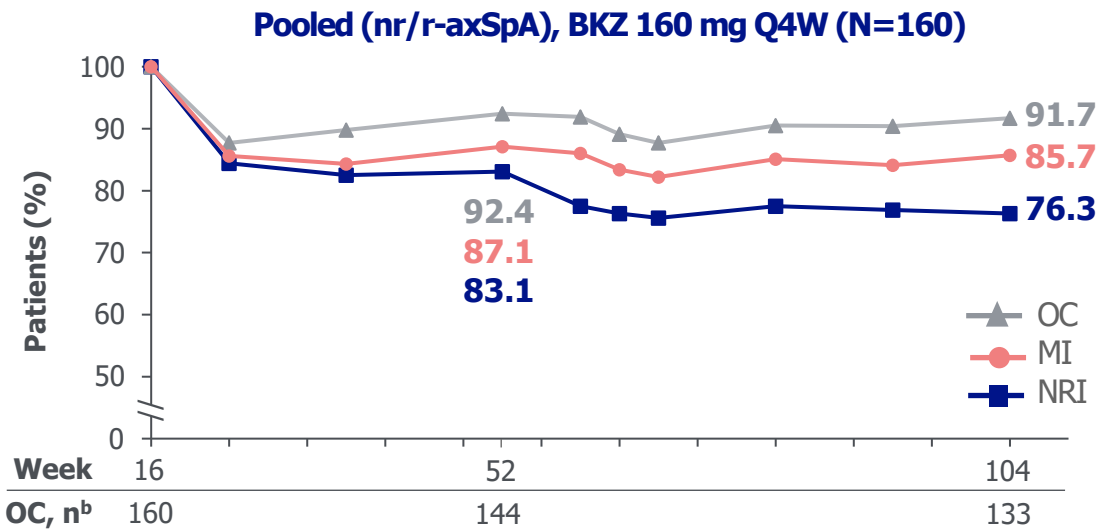
Methods

- **BE MOBILE 1** (NCT03928704) and **BE MOBILE 2** (NCT03928743) comprised a **16-week, double-blinded period** followed by a **36-week maintenance period** in patients with **non-radiographic and radiographic axSpA,** respectively.[1]
- Patients were randomized to receive subcutaneous **BKZ 160 mg every 4 weeks** (Q4W) or **placebo** (PBO); from Week 16, all patients received BKZ 160 mg Q4W. At Week 52, eligible patients could enter the OLE (**BE MOVING;** NCT04436640).
- Pooled Week 104 responder rates are reported for **ASAS40, ASDAS LDA,** and **MASES=0** (in those with MASES >0 at baseline; n=226) among **BKZ-randomized patients** (N=349) who achieved each outcome at Week 16.
- Data use non-responder (NRI), worst category (WCI; ASDAS only), and multiple imputation (MI). Observed case (OC) data are also reported.
- **Treatment-emergent adverse events** (TEAEs) are reported to Week 104 for patients who received ≥1 BKZ dose, including placebo-switchers.

1. Baraliakos X. et al. Ann Rheum Dis 2024;83:199–213. **[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; **[c]** Study participants will receive their final treatment dose at Week 108; the SFU Visit will be conducted 20 weeks after the final treatment dose; **[d]** n=348; **[e]** MASES is reported in the subgroup of patients with MASES >0 at baseline; **[f]** n=226. axSpA: ASAS40: Assessment of Spondyloarthritis international Society 40% response; ASDAS: Axial Spondyloarthritis Disease Activity Score; axSpA: axial spondyloarthritis; BASDAI: Bath Ankylosing Spondylitis Disease Activity Index; BMI: body mass index; CRP: C-reactive protein; HLA-B27: human leukocyte antigen B27; hs-CRP: high-sensitivity C-reactive protein; LDA: low disease activity; MASES: Maastricht Ankylosing Spondylitis Enthesitis Score; MI: multiple imputation; nr-axSpA: non-radiographic axSpA; NRI: non-responder imputation; OC: observed case; OLE: open-label extension; PBO: placebo; Q1: quartile 1; Q3: quartile 3; Q4W: every 4 weeks; r-axSpA: radiographic axSpA; SD: standard deviation; SE: standard error; SFU: safety follow-up; TEAE: treatment-emergent adverse event; TNFi: tumor necrosis factor inhibitor; WCI: worst category imputation.

Maintenance of ASAS40 to Week 104 among patients who achieved ASAS40 at Week 16 (OC, MI, NRI)

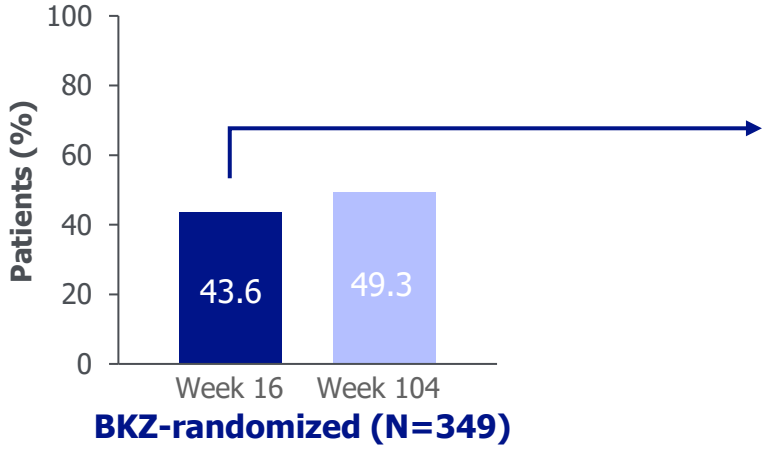


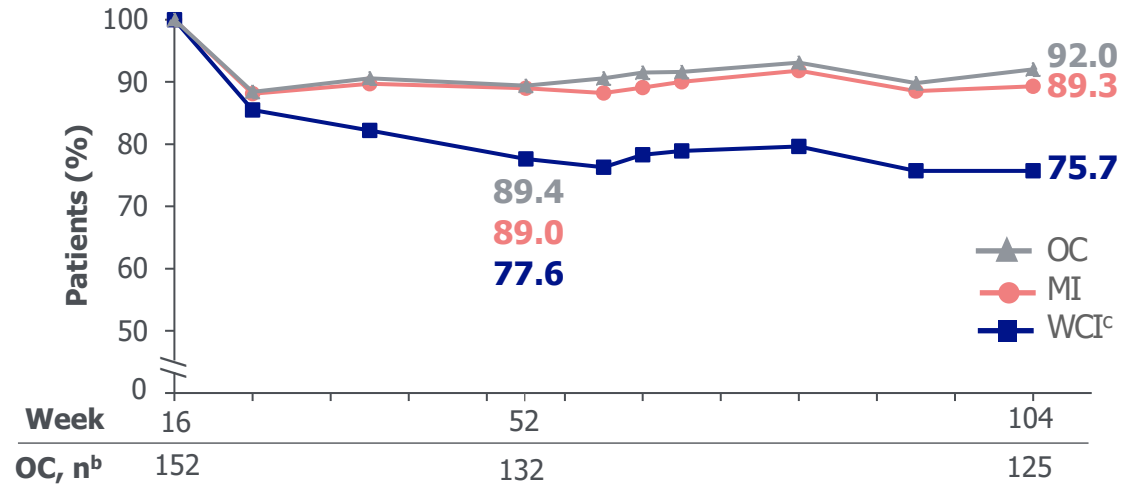


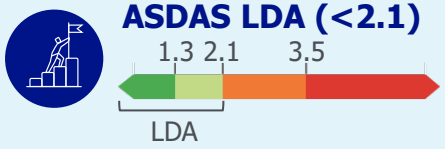
ASAS40

Relative improvement of ≥40% and absolute improvement of ≥2 units in at least 3 of the following 4 domains and no worsening in the remaining domain: Patient's Global Assessment of Disease Activity, total spinal pain, physical function, and morning stiffness

Maintenance of ASDAS LDA to Week 104 among patients who achieved ASDAS LDA at Week 16 (OC, MI, WCI)



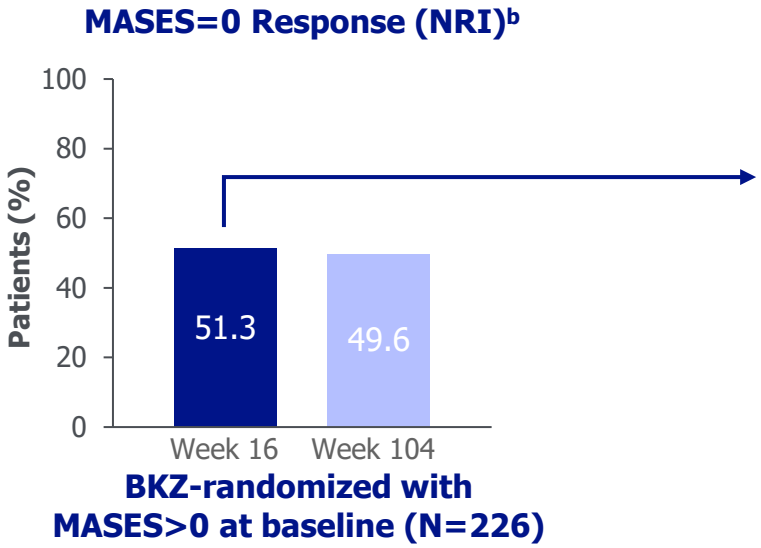


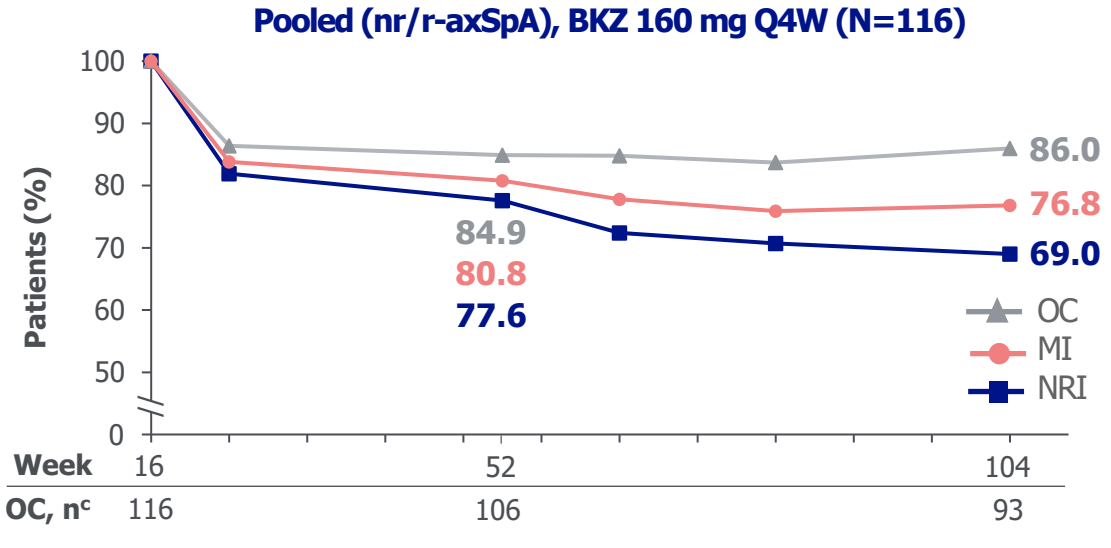


ASDAS is a composite outcome comprised of total back pain, morning stiffness, Patient's Global Assessment of Disease Activity, peripheral pain/swelling, and hs-CRP. An ASDAS score <2.1 is considered ASDAS low disease activity

[a] Response at Week 16 and Week 104 in patients randomized to BKZ 160 mg Q4W at baseline; **[b]** n represents the total number of patients with a non-missing assessment for ASAS40 or ASDAS LDA, respectively, at the given week; **[c]** For WCI, missing data were assigned to the worst ASDAS state possible (i.e., very high disease activity; ASDAS >3.5). ASAS40: Assessment of SpondyloArthritis international Society 40% response; ASDAS: Axial Spondyloarthritis Disease Activity; axSpA: axial spondyloarthritis; BKZ: bimekizumab; hs-CRP: high-sensitivity C-reactive protein; LDA: low disease activity; MI: multiple imputation; nr-axSpA: non-radiographic axSpA; NRI: non-responder imputation; OC: observed case; Q4W: every four weeks; r-axSpA: radiographic axSpA; WCI: worst category imputation.

Maintenance of MASES=0 to Week 104 among patients who achieved MASES=0 at Week 16[a] (OC, MI, NRI)





Resolution of enthesitis

Measured using MASES, where 13 sites are scored dichotomously for presence or absence of enthesitis. MASES=0 indicates complete resolution of enthesitis

Summary of TEAEs reported to Week 104[d]

n (%) [EAIR/100 PY]	Any BKZ 160 mg Q4W (N=574; 1,430 PY)
Any TEAE	514 (89.5) [141.9]
Severe TEAEs	46 (8.0) [3.4]
TEAEs leading to study discontinuation	34 (5.9) [2.4]
TEAEs leading to BKZ discontinuation	39 (6.8) [2.8]
Drug-related TEAEs	283 (49.3) [30.7]
Serious TEAEs	72 (12.5) [5.4]
Deaths	0

[a] Evaluated in patients with MASES >0 at baseline, N=226; **[b]** Response at Week 16 and Week 104 in patients randomized to BKZ 160 mg Q4W at baseline who also had MASES>0; **[c]** n represents the total number of patients with a non-missing assessment for MASES at the given week; **[d]** Data to the most recent data-cut (July 2023) shown, including all patients who received ≥1 dose of BKZ 160 mg Q4W in the phase 3 studies and their ongoing OLE.
axSpA: axial spondyloarthritis; BKZ: bimekizumab; EAIR: exposure-adjusted incidence rate; MASES: Maastricht Ankylosing Spondylitis Enthesitis Score; MI: multiple imputation; nr-axSpA: non-radiographic axSpA; NRI: non-responder imputation; OC: observed case; OLE: open-label extension; PY: patient-years; Q4W: every four weeks; r-axSpA: radiographic axSpA; TEAE: treatment-emergent adverse event.

CONCLUSIONS

Bimekizumab maintained stringent clinical responses from Week 16 to Week 104 across the full disease spectrum of axSpA.

No new safety signals were observed.

These findings suggest bimekizumab may provide a valuable long-term treatment option for achieving and maintaining treatment targets in axSpA.

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