Achieving Increasingly Stringent Clinical Response Criteria & Lower Levels of Disease Activity is Associated with Greater Improvements in Physical Function & HRQoL in Patients with Active Axial Spondyloarthritis: 16-Week Results from Two Phase 3 Randomized, Placebo-Controlled Studies

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Presented at ACR Convergence 2022 | Philadelphia, Pennsylvania, USA | November 10–14 2022

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Objective

To examine how achievement of increasingly stringent clinical response criteria and lower levels of disease activity translates into improvements in physical function and health-related quality of life (HRQoL), in patients with axial spondyloarthritis (axSpA).

Background

- Bimekizumab (BKZ) is a monoclonal IgG1 antibody that selectively inhibits both interleukin (IL)-17A and IL-17F.
- BKZ has demonstrated sustained efficacy and was well tolerated up to 24 weeks in the phase 3 studies BE MOBILE 1 (NCT03928704; non-radiographic [nr]-axSpA) and BE MOBILE 2 (NCT03928743; radiographic axSpA [r-axSpA], i.e., ankylosing spondylitis [AS]).[1–3]
- Here, we present a post hoc analysis of Week 16 results from these phase 3 studies, covering the full spectrum of axSpA independent of treatment arm.

Methods

- All patients who reached the following specified clinical response criteria at Week 16 were pooled, regardless of treatment arm (placebo/BKZ 160 mg Q4W) by study:
  - **ASAS response levels:** ASAS20 not reached (<ASAS20), ASAS20 reached but ASAS40 not reached (ASAS20–<ASAS40), ASAS40 reached (≥ASAS40)
  - **ASAS-PR:** Yes, No
  - Levels of **ASDAS disease activity:** very high disease activity (>3.5), high disease activity (≥2.1–≤3.5), low disease activity (≥1.3–<2.1), inactive disease (<1.3)
  - **ASDAS response:** ASDAS-major improvement (MI; change from baseline ≥2.0), ASDAS-clinically important improvement (CII; change ≥1.1 but <2.0) and non-response (change <1.1)
- Associations between achievement of these specified clinical response criteria/levels of disease activity and improvements in patient-reported measures of physical function (**BASFI:** 0 [best] to 10 [worst]; **SF-36 PCS:** standardized measure, higher score reflects better HRQoL) and HRQoL (**ASQoL:** scored from 0 [best] to 18 [worst]) were assessed. It should be noted that BASFI is a component of the ASAS response criteria.
- Observed case data are reported.

Results

Patients

- Of randomized patients, 244/254 (96.1%) patients with nr-axSpA and 322/332 (97.0%) patients with r-axSpA completed Week 16.
- Baseline characteristics were comparable between nr-axSpA and r-axSpA patients, with the exception of gender, symptom duration and time since diagnosis, indicating similar burden of symptom severity, reduced physical function and HRQoL (Table 1).

Association Between Clinical Response Levels and Physical Function or Quality of Life

- Patients achieving higher ASAS response levels demonstrated sequentially greater mean (95% confidence interval) improvements from baseline in BASFI (Figure 1A) and SF-36 PCS (Figure 1B) score across studies.
- Achievement of higher ASAS response levels was also associated with greater improvements in ASQoL score (Figure 2).
- Similar sequential associations were observed with ASAS-PR and ASDAS outcome measures (Figure 1–2).

Summary

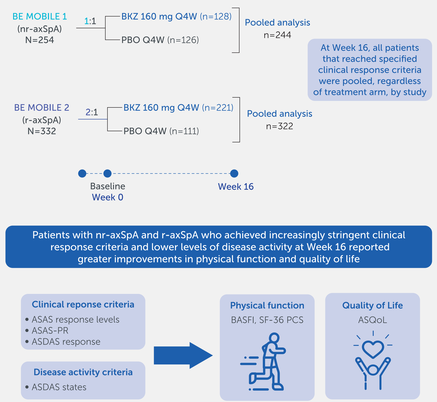


Table 1 Patient demographics and baseline characteristics

	BE MOBILE 1 (nr-axSpA) N=254	BE MOBILE 2 (r-axSpA) N=332
Age, years	39.4 (11.5)	40.4 (12.3)
Sex, male	138 (54.3)	240 (72.3)
HLA-B27 positive	197 (77.6)	284 (85.5)
Symptom duration, years	9.0 (8.8)	13.5 (10.3)
Time since first diagnosis of axSpA, years	3.6 (5.8)	6.4 (7.9)
ASDAS	3.7 (0.7)	3.7 (0.8)[a]
BASDAI	6.8 (1.3)	6.5 (1.3)
hs-CRP, mg/L	6.3 (0.1, 79.1)	7.4 (0.1, 105.4)
hs-CRP >ULN[b]	141 (55.5)	204 (61.4)
Total spinal pain score	7.2 (1.5)	7.2 (1.5)
BASFI	5.4 (2.3)	5.2 (2.1)
ASQoL	9.4 (4.5)	8.9 (4.6)
SF-36 PCS	33.4 (8.5)	34.4 (8.5)
Prior TNFi inadequate response	27 (10.6)	54 (16.3)

Randomized set. All data are mean (SD), with the exception of hs-CRP which is median (min, max), or n (%).
[a]n=331; [b]ULN value for hs-CRP is 5 mg/L.

Figure 1 Association between ASAS response, ASAS partial remission, and ASDAS disease activity and response at Week 16 and improvements in patient-reported measures of physical function (BASFI and SF-36 PCS)

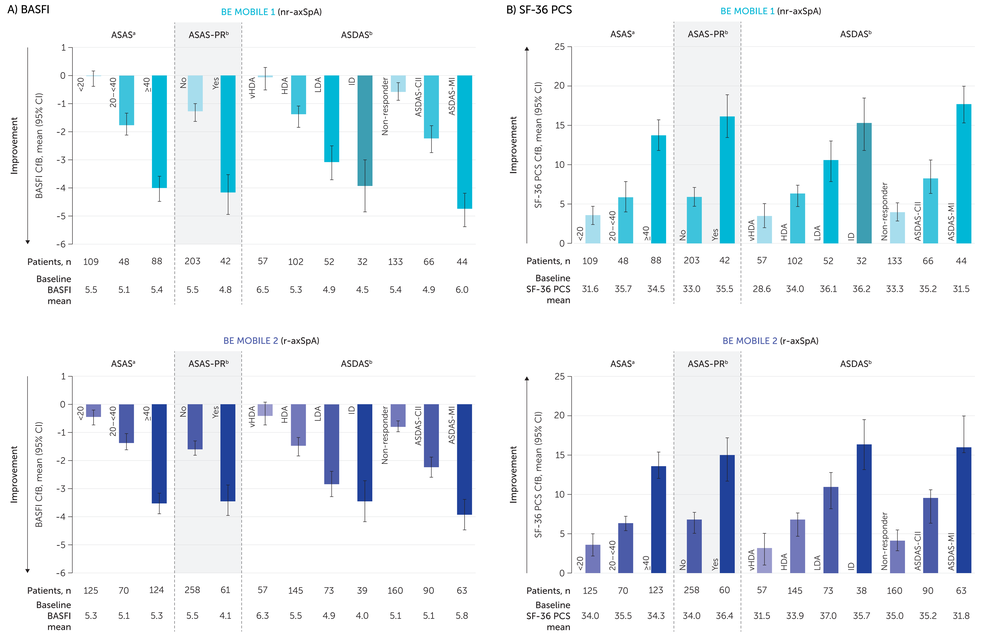
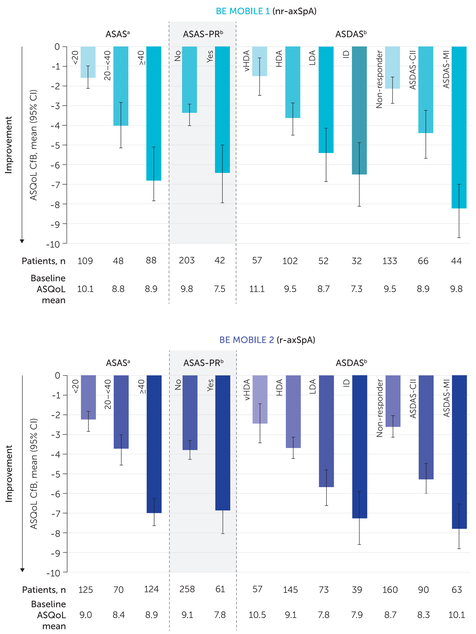


Figure 2 Association between ASAS response, ASAS partial remission, and ASDAS disease activity and response at Week 16 and improvements in patient-reported measures of HRQoL (ASQoL)



Data reported as observed case. Categories are mutually exclusive. BASFI is a component of ASAS response criteria. [a]Patients were stratified into three mutually exclusive groups based on ASAS clinical response criteria: those who did not achieve ASAS20 (<ASAS20), those who achieved ASAS20 but did not achieve ASAS40 (ASAS20–<ASAS40), and those who achieved ASAS40 (≥ASAS40). [b]ASAS-PR defined as a score ≤2 units (on a scale of 0 to 10) across all four ASAS domains.

Conclusions

Patients with nr-axSpA and r-axSpA who achieved increasingly stringent clinical response criteria and lower levels of disease activity at Week 16 reported sequentially greater improvements in physical function and HRQoL. Similar amplitudes of improvement for each response level were observed across the axSpA disease spectrum.

AS: ankylosing spondylitis; **ASAS:** Assessment of SpondyloArthritis international Society; **ASAS20/40**: ≥20/40% reduction from baseline in ASAS; **ASAS-PR:** ASAS partial remission; **ASDAS:** Ankylosing Spondylitis Disease Activity Score; **ASDAS-CII:** ASDAS clinically important improvement; **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; **BKZ:** bimekizumab; **CfB:** change from baseline; **CI:** confidence interval; **CRP:** C-reactive protein; **HDA:** high disease activity; **HLA-B27:** human leukocyte antigen B27; **HRQoL:** health-related quality of life; **hs:** high sensitivity; **ID:** inactive disease; **IL:** interleukin; **LDA:** low disease activity; **MRI:** magnetic resonance imaging; **nr-axSpA:** non-radiographic axial spondyloarthritis; **r-axSpA:** radiographic axial spondyloarthritis; **Q4W:** every 4 weeks; **SD:** standard deviation; **SF-36 PCS:** Short-Form 36-Item Health Survey Physical Component Summary; **TNFi:** tumor necrosis factor inhibitor; **ULN:** upper limit of normal; **vHDA:** very high disease activity.

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References: 1. Deodhar A. Ann Rheum Dis 2022;81:772–3. 2. van der Heijde D. Ann Rheum Dis 2022;81:12–3. 3. Boel A. Ann Rheum Dis 2019;78:1545–9. **Author Disclosures: MM:** Consultant for AbbVie, Eli Lilly, Novartis, Pfizer, and UCB Pharma; research grants from AbbVie and UCB Pharma. **AD**: Speakers bureau from Janssen, Novartis and Pfizer; consulting fees from AbbVie, Amgen, Aurinia, BMS, Celgene, Eli Lilly, GSK, Janssen, MoonLake, Novartis, Pfizer, and UCB Pharma; research grants from AbbVie, BMS, Eli Lilly, GSK, Novartis, Pfizer, and UCB Pharma. **PJM:** Speakers bureau from AbbVie, Amgen, Eli Lilly, Janssen, Novartis, Pfizer, and UCB Pharma; consultant for AbbVie, Amgen, BMS, Boehringer Ingelheim, Eli Lilly, Galapagos, Gilead, GSK, Janssen, Novartis, Pfizer, Sun Pharma, and UCB Pharma; research grants from AbbVie, Amgen, BMS, Eli Lilly, Gilead, Janssen, Novartis, Pfizer, Sun Pharma, and UCB Pharma. **VNC:** Speakers bureau from AbbVie, Eli Lilly, Janssen, MSD, Novartis, Pfizer, and UCB Pharma; consultant for AbbVie, Eli Lilly, MSD, Novartis, Pfizer, and UCB Pharma; research grants from AbbVie and Novartis. **SR:** Grants from AbbVie, Galapagos, MSD, Novartis, Pfizer, UCB Pharma; consultant for AbbVie, Eli Lilly, Novartis, Pfizer, Sanofi, and UCB Pharma. **MR:** Speakers bureau from AbbVie, BMS, Boehringer Ingelheim, Chugai, Eli Lilly, Janssen, Novartis, Pfizer, and UCB Pharma; paid instructor for Janssen, Novartis, and UCB Pharma; consultant for AbbVie, Novartis, and UCB Pharma. **CdlL:** Consultant for UCB Pharma, Brussels, Belgium. **CF, VT, MFM:** Employees of UCB Pharma. **MO:** Employee and stockholder of UCB Pharma. **JK:** Consulting fees from Alvotech Swiss AG, Boehringer Ingelheim GmbH, Organon, Ridgeline Discovery, Samsung Bioepis, Sandoz Inc., Scipher Medicine and UCB Pharma; grant/research support paid to institution from Gilead and Novartis. **Acknowledgments:** We would like to thank the patients and their caregivers in addition to all the investigators and their teams who contributed to this study. The authors acknowledge Celia Menckeberg, PhD, UCB Pharma, Breda, The Netherlands, for publication coordination, Evelyn Turner, BSc, Costello Medical, Cambridge, UK for medical writing and editorial assistance, and the Costello Medical Design Team for design support. This study was funded by UCB Pharma. All costs associated with development of this presentation were funded by UCB Pharma.