Bimekizumab Led to Sustained Improvements in Health-Related Quality of Life and Work Productivity in Patients with Axial Spondyloarthritis: 3-Year Results from Two Phase 3 Studies

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Nikiphorou E,[1–3] Rudwaleit M,[4] Hwang M,[5] Machado PM,[6–8] Deodhar A,[9] Dubreuil M,[10] Kavanagh S,[11] Taieb V,[12] de la Loge C,[13] Mørup MF,[14] Boonen A[15,16]

[1]Centre for Rheumatic Diseases, Faculty of Life Sciences and Medicine, King's College London, London, UK; [2]Rheumatology Department, King's College Hospital NHS Foundation Trust, London, UK; [3]Centre for Education, Faculty of Life Sciences and Medicine, King's College London, London, UK; [4]Bielefeld University, Medical School and University Medical Centre OWL, Klinikum Bielefeld, Department of Rheumatology, Bielefeld, Germany; [5]Department of Internal Medicine, Division of Rheumatology, John P. and Katherine G. McGovern School of Medicine, UTHealth Houston, Houston, TX, USA; [6]Department of Rheumatology, University College London Hospitals NHS Foundation Trust, London, UK; [7]Department of Rheumatology, Northwick Park Hospital, London North West University Healthcare NHS Trust, London, UK; [8]Department of Neuromuscular Diseases, University College London, London, UK; [9]Division of Arthritis and Rheumatic Diseases, Oregon Health & Science University, Portland, OR, USA; [10]Section of Rheumatology, Boston University School of Medicine, MA, USA; [11]UCB, Morrisville, North Carolina, USA; [12]UCB, Colombes, France; [13]UCB, Brussels, Belgium; [14]UCB, Copenhagen, Denmark; [15]Department of Rheumatology, Maastricht University Medical Center; [16]Care and Public Health Research Institute (Caphri), Maastricht University, The Netherlands.

Objective

To report long-term impact of bimekizumab (BKZ) treatment on patient-reported health-related quality of life (HRQoL) and work productivity to 3 years in patients with axial spondyloarthritis (axSpA).

Background

- BKZ, a monoclonal IgG1 antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A, has demonstrated efficacy up to 3 years across the full axSpA disease spectrum.[1–3]
- The symptoms of axSpA can significantly impact patients' daily functioning, HRQoL and work productivity.[4–7]

Methods

- All patients enrolled in BE MOBILE 1 (NCT03928704; non-radiographic [nr-]axSpA) and 2 (NCT03928743; radiographic [r-]axSpA) received subcutaneous BKZ 160 mg every 4 weeks from Week 16 (**Supplementary Figure**; **see QR code**). At Week 52, eligible patients could enter the open-label extension, BE MOVING (NCT04436640; ongoing).
- To assess HRQoL, we report the following patient-reported outcomes for all randomised patients up to ~3 years:
  - Absolute scores and/or mean changes from baseline (CfB) in:
    - Ankylosing Spondylitis Quality of Life (ASQoL; multiple imputation [MI]), an axSpA-specific measure, with scores ranging from 0 to 18 (higher scores indicate poorer HRQoL).
    - EuroQoL visual analogue scale (EQ-VAS; observed case [OC]), ranging from 0 (worst health) to 100 (best health).
    - Short Form-36 (SF-36) domains (MI), covering various aspects of mental and physical health (higher scores indicate better health).
  - The proportion of patients achieving a ≥4-point reduction from baseline in ASQoL (non-responder imputation [NRI]) at Week 164, indicating meaningful improvement in HRQoL.[8]
- To assess work productivity, we report the following:
  - Mean CfB in patient-reported Work Productivity and Activity Impairment Questionnaire (WPAI:axSpA) domains (OC).
    - Domains include absenteeism, presenteeism, overall work impairment (assessed in employed patients only) and activity impairment due to axSpA (assessed in all randomised patients).
    - Each domain is expressed as a percentage of time, with higher percentages indicating greater impairment.
  - For patients employed at baseline, the proportion achieving a ≥15% decrease from baseline in overall work impairment (OC) at Week 164, indicating meaningful improvement in work productivity.[9]

Results

- In total, 86.6% (nr-axSpA; 220/254) and 89.8% (r-axSpA; 298/332) of randomised patients completed Week 52; 68.9% (175/254) and 75.3% (250/332) completed Week 164 (**Supplementary Figure**; **see QR code**).
- Baseline characteristics were generally comparable across patients with nr-axSpA and r-axSpA, except for differences in sex distribution, disease duration and symptom duration (**Supplementary Table**; **see QR code**).
  - 74.0% and 73.1% of patients with nr-axSpA and r-axSpA, respectively, were employed at baseline.

HRQoL

- Improvements in ASQoL with BKZ treatment, from baseline to Week 52, were sustained to Week 164 in patients with nr-axSpA and r-axSpA (**Figure 1**).
  - At Week 164, 51.8% of patients with nr-axSpA (115/222) and 58.5% of patients with r-axSpA (165/282) had a ≥4-point ASQoL reduction from baseline.
- EQ-VAS improvements from baseline at Week 52 were sustained to Week 164 across patients with nr-axSpA and r-axSpA (**Figure 2**).
- Higher scores across all SF-36 domains (indicating improvement) were seen at Week 52 compared with baseline and remained similar to Week 164 (**Figure 3**).
  - For both patients with nr-axSpA and r-axSpA, the greatest mean (95% confidence interval) improvement to Week 164 was seen in Bodily Pain (CfB: +12.5 [11.1, 13.9] and +13.4 [12.3, 14.5]), while the smallest was seen in Role Emotional (CfB: +2.0 [0.9, 3.1] and +3.0 [2.1, 3.9]), which was within the normal range at baseline (**Figure 3**).

Work Productivity

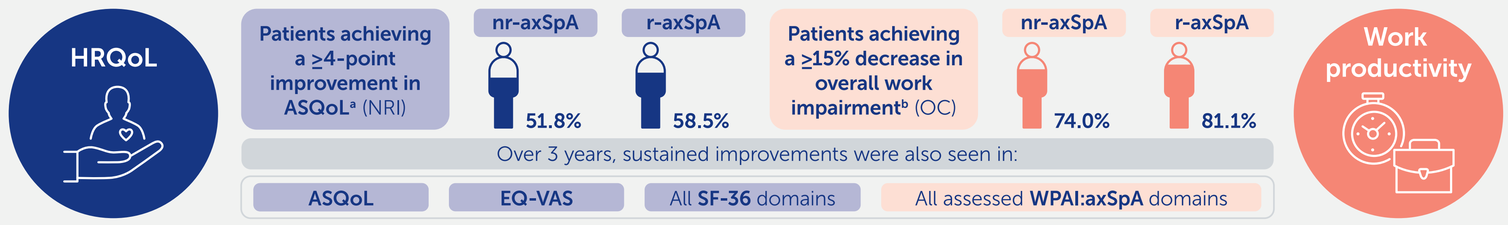
- Among employed patients, improvements from baseline to Week 52 in WPAI:axSpA absenteeism, presenteeism and overall work impairment domains were sustained to Week 164 across the full disease spectrum of axSpA (**Figure 4**).
  - At Week 164, 74.0% (nr-axSpA; 71/96) and 81.1% (r-axSpA; 99/122) of employed patients achieved a ≥15% decrease from baseline in overall work impairment.
- Improvements from baseline to Week 52 in WPAI:axSpA activity impairment were sustained to Week 164 across patients with nr-axSpA and r-axSpA (**Figure 4**).

Conclusions

Bimekizumab resulted in sustained improvements in patient-reported measures of HRQoL and work productivity up to 3 years, across the full disease spectrum of axSpA.

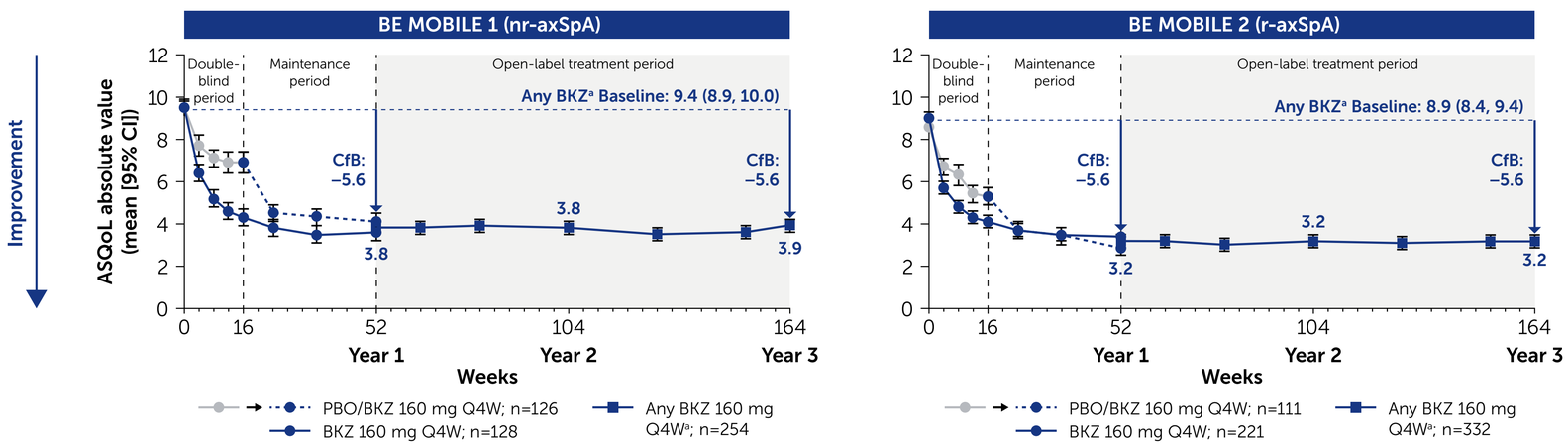
Summary

Meaningful improvements in **HRQoL and work productivity** were **sustained for up to 3 years** with bimekizumab treatment, across the **full disease spectrum of axSpA**



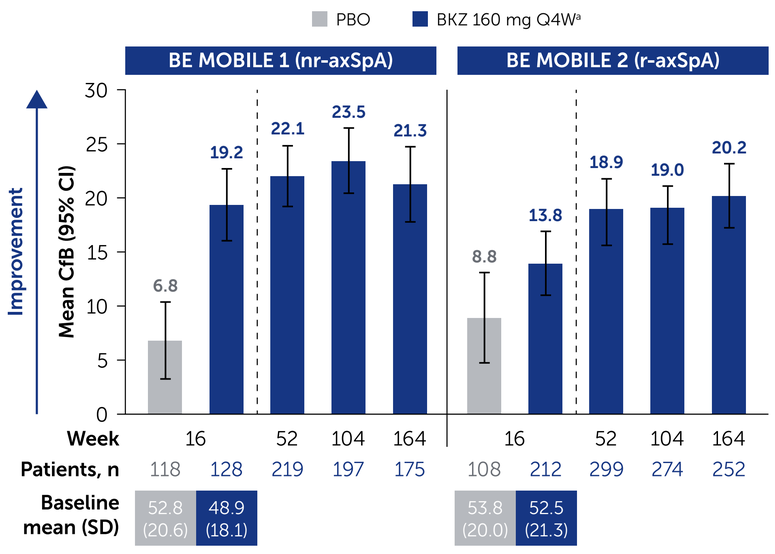
All values are reported for Week 164. **[a]** Corresponding to a meaningful improvement in HRQoL; **[b]** Corresponding to a meaningful improvement in work productivity.

Figure 1 Absolute ASQoL score and change from baseline to 3 years (Week 164) (MI)



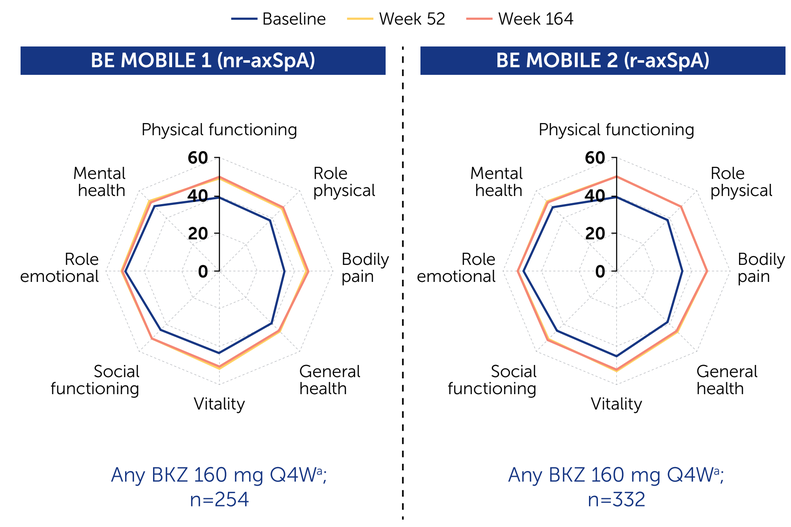
Randomised set. **[a]** From Week 52, this includes patients randomised to BKZ and patients originally randomised to PBO who switched to BKZ at Week 16.

Figure 2 Change from baseline in EQ-VAS to 3 years (Week 164) (OC)



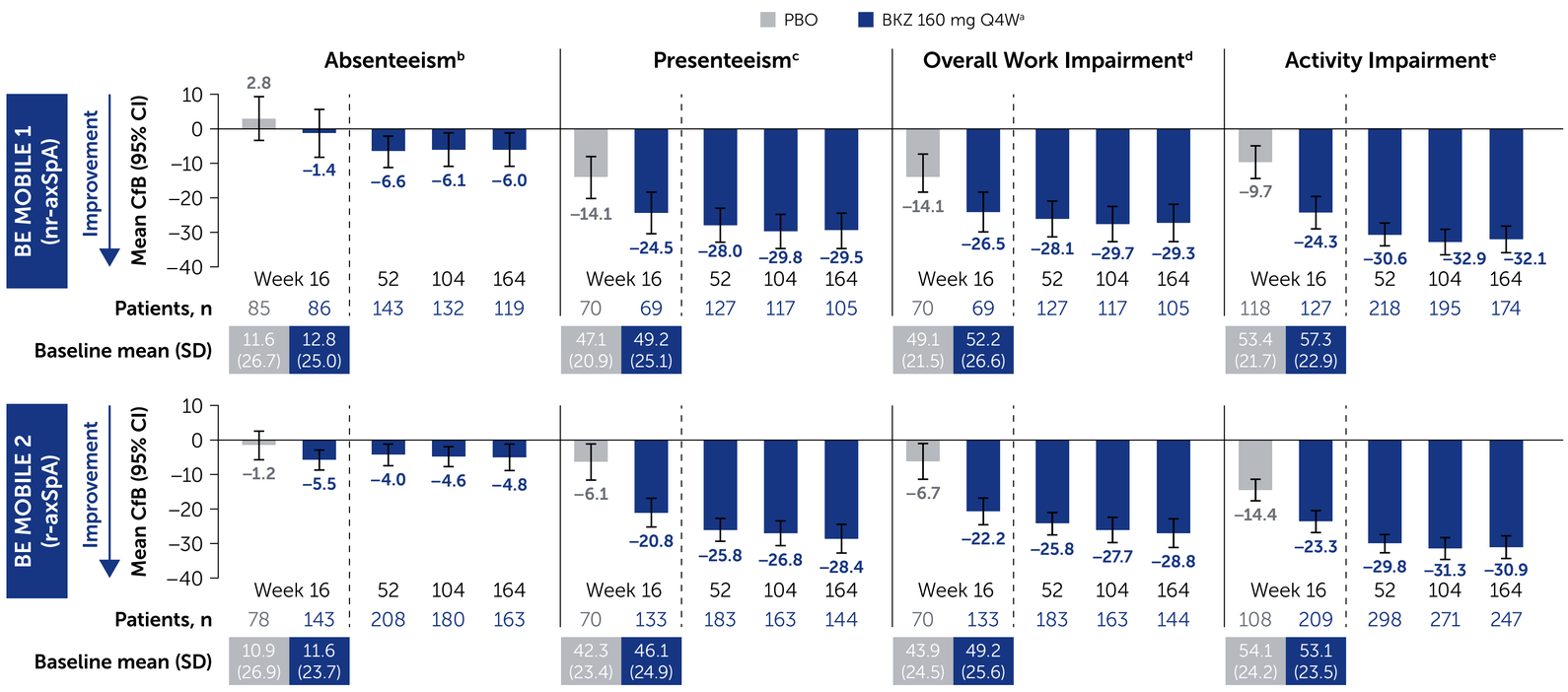
Randomised set. **[a]** From Week 52, this includes patients randomised to BKZ and patients originally randomised to PBO who switched to BKZ at Week 16.

Figure 3 Mean SF-36 domain scores at Weeks 0, 52 and 164 (MI)



Randomised set. **[a]** Includes patients originally randomised to PBO who switched to BKZ at Week 16. For SF-36, group-level mean scores between 47 and 53 can be considered within the 'average' or 'normal' range for the US general population.[10]

Figure 4 Change from baseline in work productivity to 3 years (Week 164) (OC)



Randomised set. Measured using WPAI:axSpA. Absenteeism, presenteeism and overall work impairment are reported for patients employed at baseline. Activity impairment is reported for all randomised patients. **[a]** From Week 52, this includes patients randomised to BKZ and patients originally randomised to PBO who switched to BKZ at Week 16; **[b]** Percentage of work time missed due to axSpA; **[c]** Impairment while working due to axSpA; **[d]** Absenteeism and presenteeism combined; **[e]** Impairment in ability to undertake regular, non-work-related activities (e.g. childcare) due to axSpA.

ASQoL: Ankylosing Spondylitis Quality of Life; **axSpA:** axial spondyloarthritis; **BKZ:** bimekizumab; **CfB:** change from baseline; **CI:** confidence interval; **EQ-VAS:** EuroQoL visual analogue scale; **HRQoL:** health-related quality of life; **IgG1:** immunoglobulin G1; **IL:** interleukin; **MI:** multiple imputation; **nr-axSpA:** non-radiographic axial spondyloarthritis; **NRI:** non-responder imputation; **OC:** observed case; **PBO:** placebo; **Q4W:** every 4 weeks; **r-axSpA:** radiographic axial spondyloarthritis; **SD:** standard deviation; **SF-36:** 36-Item Short-Form Health Survey; **WPAI:axSpA:** Work Productivity and Activity Impairment Questionnaire.

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