Work Productivity Improved in Patients with Axial Spondyloarthritis Receiving Bimekizumab Treatment Over 52 Weeks: Results from Two Phase 3 Studies

activity time impaired

Objective

To assess the impact of bimekizumab (BKZ) on work productivity and activity impairment in patients with non-radiographic (nr-) and radiographic (r-) axial spondyloarthritis (axSpA) in the phase 3 BE MOBILE 1 and 2 studies.

Background

- Symptoms of axSpA have a direct impact on work productivity and daily activities, profoundly impacting health-related quality of life and posing an economic burden to patients and society.¹
- BKZ, a monoclonal IgG1 antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A, demonstrated rapid and sustained efficacy in improving signs and symptoms and controlling disease activity up to Week 52 in patients with nr-axSpA and r-axSpA (i.e., ankylosing spondylitis)² in the phase 3 studies BE MOBILE 1 and 2, respectively.³

Methods

- BE MOBILE 1 (NCT03928704) and 2 (NCT03928743) comprised a 16-week double-blind period followed by a 36-week maintenance period (Figure 1).³
- Mean changes from baseline are reported at Week 16 and 52 in work productivity and activity impairment (WPAI)⁴ axSpA scores, which assess:
- Disease impact on patients' productivity while at paid work (i.e., presenteeism);
- Work time missed (i.e., absenteeism [absence from paid work, including sick leave]);
- Overall work impairment (composite of presenteeism and absenteeism);
- Daily activity impairment (outside of paid work).
- The WPAI:axSpA consists of six questions, and scores are generated as percentage of time impaired, with higher scores reflecting higher impairment and less productivity.
- Observed case data are reported.

Results

• At baseline, 431/586 (73.5%) patients were employed. Patients were a young working population (nr-axSpA mean age: 39.4 years; r-axSpA mean age: 38.8 years) and had substantial overall work impairment at baseline, with presenteeism contributing most to this (**Table 1**).

Presenteeism, Overall Work Impairment, and Activity Impairment

- At Week 16, mean reductions from baseline (i.e., absolute improvements) were greater in BKZ- versus placebo (PBO)-randomized patients for overall work impairment (nr-axSpA: -26.5% vs. -14.1%; r-axSpA: -22.2% vs. -6.7%), presenteeism, and activity impairment (Figure 2).
- Mean improvements in overall work impairment were sustained or further improved to Week 52 in BKZ-randomized patients (nr-axSpA: -31.7%; r-axSpA: -27.0%).
- Patients who switched from PBO to BKZ at Week 16 reached similar levels of improvement to BKZ-randomized patients at Week 52; similar trends were seen in presenteeism and activity impairment (Figure 2).
- Similar results were seen between patients with r-axSpA and nr-axSpA (Figure 2).

Absenteeism

- Baseline absenteeism scores were low compared with other WPAI items (Table 1), leaving limited room for improvement.
- At Week 16, no clear separation between groups was seen; this response was improved or sustained in BKZ-randomized patients at Week 52 (Figure 2).

Conclusions

Bimekizumab treatment resulted in substantial improvements in presenteeism, overall work productivity, and activity impairment at Week 16 compared with PBO, with further improvements at Week 52 in patients across the full disease spectrum of axSpA.

Summary

Patients across the full disease spectrum of axSpA receiving BKZ 160 mg Q4W over 52 weeks showed improvements in:

Presenteeism Productivity loss while at paid work

and presenteeism

Activity impairment Outside of paid work

Table 1

WPAI:axSpA item s

Employment, n (%)

Time since first s (years), mean (SD) Randomized set. WPAI:axSpA ite

SPA: or assessment in Spondyloarthritis; BASDAI: analysis of covariance; **ASAS:** Assessment in Spondyloarthritis; **BASDAI:** analysis of covariance; **PBO:** placebo; **Q4W:** every 4 weeks; **r-axSpA:** non-radiographic axSpA; **OC:** observed case; **PBO:** placebo; **CI:** confidence interval; **CI:** confidence interval; **CI:** confidence interval; **CI:** confidence interval; **CRP:** C-reactive protein; **IL:** interleukin; **BASDAI:** analysis of covariance; **PBO:** placebo; **Q4W:** every 4 weeks; **r-axSpA:** non-radiographic axSpA; **OC:** observed case; **PBO:** placebo; **CI:** confidence interval; **CI:** confidence interval; **CI:** confidence interval; **CRP:** C-reactive protein; **IL:** interleukin; **CI:** confidence interval; **CRP:** C-reactive protein; **IL:** interleukin; **CI:** confidence interval; **CI:** confidence



Patients were eligible to receive non-biologic rescue therapy from Week 20 at the discretion of the investigator while continuing to receive BKZ. All patients ha active nr-axSpA or r-axSpA at baseline (BASDAI >4 and spinal pain >4). [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 r-axSpA fulfilling modified New York criteria; all patients in BE MOBILE 2 also fulfilled ASAS classification criteria.

Baseline demographics and WPAI:axSpA item scores (OC)

activity time impaired

	BE MOBILE 1 (nr-axSpA)		BE MOBILE 2 (r-axSpA)	
	PBO/BKZ 160 mg Q4W n=126	BKZ 160 mg Q4W n=128	PBO/BKZ 160 mg Q4W n=111	BKZ 160 mg Q4W n=221
NPAI:axSpA item score , mean % (SD)				
Presenteeism ^{a,b}	47.1 (20.9) (n=84)	49.2 (25.1) (n=86)	42.3 (23.4) (n=74)	46.1 (24.9) (n=149)
Absenteeism ^{a,c}	11.6 (26.7) (n=93)	12.8 (25.0) (n=95)	10.9 (26.9) (n=82)	11.5 (23.6) (n=161)
Overall work impairment ^{a,d}	49.1 (21.5) (n=84)	52.2 (26.6) (n=86)	43.9 (24.5) (n=74)	49.2 (25.6) (n=149)
Activity impairment	53.4 (21.7) (n=126)	57.3 (22.9) (n=128)	54.1 (24.2) (n=111)	53.3 (23.6) (n=221)
Employment , n (%)	93 (73.8)	95 (74.2)	82 (73.9)	161 (72.9)
Baseline demographics of employed batients				
Age , (years), mean (SD)	39.5 (10.1) (n=93)	39.3 (9.4) (n=95)	38.1 (10.5) (n=82)	39.2 (10.0) (n=161)
Male , n (%)	50 (53.8) (n=93)	53 (55.8) (n=95)	65 (79.3) (n=82)	124 (77.0) (n=161)
Time since first symptoms of axSpA , (years), mean (SD)	8.6 (7.9) (n=93)	8.3 (8.0) (n=95)	11.0 (7.6) (n=82)	12.4 (8.8) (n=161)

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A) BE MOBILE 1 (nr-axSpA)



Mean absolute score,

B) BE MOBILE 2 (r-axSpA)

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Randomized set. Error bars represent 95% CI. WPAI:axSpA item scores are expressed as a percentage, with a greater reduction indicating greater improvement. Week 16 nominal p values were calculated using ANCOVA with baseline WPAI:axSpA item score as covariate and treatment, region and either MRI/CRP classification at baseline (nr-axSpA) or prior TNF inhibitor exposure (r-axSpA) as fixed effects. [a] Absenteeism, presenteeism, and overall work due to axSpA; [c] Work time missed due to axSpA; [d] Overall work impairment is a composite of absenteeism and presenteeism

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Figure 2 Mean absolute change from baseline in WPAI:axSpA scores at Week 16 and Week 52 (OC)

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