Abstract citation ID: keae163.204

P165 SUSTAINED IMPROVEMENT IN CLINICAL OUTCOMES AND LONG-TERM SAFETY OF BIMEKIZUMAB IN PATIENTS ACROSS THE SPECTRUM OF AXIAL SPONDYLOARTHRITIS UP TO WEEK 52: RESULTS FROM TWO PHASE 3 STUDIES

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Background/Aims

Bimekizumab (BKZ), a monoclonal IgG1 antibody that selectively inhibits IL-17F in addition to IL-17A, has shown rapid and clinically meaningful improvements in disease activity across the axial spondyloarthritis spectrum (axSpA; active non-radiographic axSpA [nr-axSpA; BE MOBILE 1, NCT03928704] and ankylosing spondylitis [AS] / radiographic axSpA [r-axSpA; BE MOBILE 2, NCT03928743]). Here we present outcomes from these two phase 3 studies up to Week (Wk)52.

Methods

BE MOBILE 1 and 2 have similar study designs: 16-Wk double-blind period followed by 36-Wk maintenance period. Patients were randomised (1:1 in BE MOBILE 1; 2:1 in BE MOBILE 2) to BKZ 160 mg every 4Wks (Q4W) or placebo (PBO). All patients received BKZ 160 mg Q4W from Wk16 up to Wk52. Sustained improvements in ASAS40, BASDAI50 responses, BASDAI, BASFI and ASDAS-CRP scores were assessed up to Wk52. Missing data were imputed using non-responder or multiple imputation for binary and quantitative variables, respectively.

Results

254 nr-axSpA (BKZ: 128; PBO: 126) and 332 r-axSpA (BKZ: 221; PBO: 111) patients were randomised; 86.6% and 89.8% completed Wk52, respectively. ASAS40 responses increased from Wk16 to Wk52 with similar efficacy across TNF-naïve/IR patients (Table). Approximately 47% of patients on BKZ achieved BASDAI50 at Wk16, increasing to ~54% at Wk52 (NRI, Table). All improvements at Wk16 in BASDAI, BASFI and ASDAS were sustained up to Wk52 (Table). Efficacy was similar between treatment arms at Wk52. During the overall study period, 75% (183/244, nr-axSpA) and 75.5% (249/330, r-axSpA) patients reported ≥1 treatment-emergent adverse events (TEAEs). Most common TEAEs included nasopharyngitis, upper respiratory tract infection and oral candidiasis. Incidence of serious TEAEs were low (3.7% [nr-axSpA] and 6.1% [r-axSpA]); no incidence of systemic candidiasis, adjudicated MACE or deaths were reported. 'Any definite or probable adjudicated IBD TEAE' was reported in 0.8% (2/240, nr-axSpA) and 0.6% (2/326, r-axSpA) patients with no history of IBD and 25% (1/4, r-axSpA) patients with prior history of IBD. Incidence of uveitis (1.2% [3/244, nr-axSpA]; 2.1% [7/330, r-axSpA]) was low.

Conclusion

Across the axSpA disease spectrum, bimekizumab demonstrated sustained improvements in clinical outcomes up to Wk52 with no new safety signals.

Table. Efficacy outcomes with BKZ in patients with nr-axSpA and r-axSpA at Week 16 and Week 52

	Population, n (%)	BE MOBILE 1 (nr-axSpA)					BE MOBILE 2 (r-axSpA)				
		Week 16		Week 52			Week 16		Week 52		
		PBO (N=126)	BKZ 160 mg Q4W (N=128)	PBO→BKZ 160 mg Q4W (N=126)	BKZ 160 mg Q4W (N=128)		PBO (N=111)	BKZ 160 mg Q4W (N=221)	PBO→BKZ 160 mg Q4W (N=111)	BKZ 160 mg Q4W (N=221)	
ASAS40 response	Overall, NRI	27 (21.4)	61 (47.7)	64 (50.8)	78 (60.9)		25 (22.5)	99 (44.8)	76 (68.5)	129 (58.4)	
	TNFi-naïve, NRI	25 (22.9)	55 (48.0)	58 (53.2)	73 (61.9)		22 (25.4)	84 (45.7)	67 (71.3)	108 (58.7)	
	TNFi-IR, NRI	2 (11.8)	6 (60.0)	6 (35.3)	5 (50.0)		3 (17.6)	15 (40.5)	9 (52.9)	21 (56.8)	
BASDAI50	Overall, NRI	27 (21.4)	60 (46.9)	62 (49.2)	69 (53.9)		29 (26.1)	103 (46.6)	69 (62.2)	119 (53.8)	
	Population, mean (SE)	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)		
		BL	Week 16	Week 52	BL	Week 16	Week 52	BL	Week 16	Week 52	BL	Week 16	Week 52
BASDAI	Overall, MI	6.67 (0.12)	5.16 (0.21)	5.22 (0.19)	6.93 (0.11)	3.85 (0.21)	3.68 (0.19)	6.51 (0.12)	4.62 (0.20)	2.55 (0.18)	6.45 (0.09)	3.55 (0.14)	2.87 (0.13)
BASFI	Overall, MI	5.33 (0.21)	4.35 (0.24)	4.72 (0.21)	5.54 (0.19)	3.01 (0.21)	2.51 (0.20)	5.18 (0.19)	4.08 (0.23)	2.38 (0.20)	5.27 (0.15)	3.10 (0.16)	2.49 (0.14)
ASDAS-CRP	Overall, MI	3.68 (0.06)	3.04 (0.10)	3.03 (0.08)	3.75 (0.07)	2.26 (0.09)	1.94 (0.08)	3.71 (0.07)	3.00 (0.09)	1.79 (0.08)	3.73 (0.06)	2.28 (0.06)	1.98 (0.06)

ASAS40: Assessment in Spondyloarthritis international Society 40; ASDAS-CRP: ankylosing spondylitis disease activity score c-reactive protein; BASDAI: Bath Ankylosing Spondylitis Disease Activity Index; BASFI: Bath Ankylosing Spondylitis Functional Index; BKZ: Bimekizumab; BL: baseline; CI: confidence interval; IR: inadequate responder; MI: multiple imputation; nr-axSpA: nonradiographic axSpA; NRI: non-responder imputation; OC: observed cases; PBO: placebo; r-axSpA: radiographic axSpA/ ankylosing spondylitis; SE: standard error; TNFi: tumour necrosis factor inhibitor.

Disclosure

K. Gaffney: Shareholder/stock ownership; KG is a shareholder of Rheumatology events. Grants/research support; KG received grant/ research support from NASS, Versus Arthritis, AbbVie, Pfizer, UCB Pharma, Novartis, Lilly, Cellgene, Celltrion, Janssen, Gilead and Biogen. Other; KG has received honoraria/ consultation fees from Novartis, AbbVie, UCB Pharma, Lilly and Pfizer, KG has received speaker's bureau from Novartis, UCB Pharma, AbbVie and Lilly; meeting expenses from AbbVie, Lilly, Roche, Novartis, Pfizer and UCB Pharma. **N.D. McKay:** Other; NDM received travel fees from UCB Pharma and Gilead, and Speaker's bureau from Gilead. **R. Sengupta:** Grants/research support; RS received grants/ research support from AbbVie, Celgene, Novartis and UCB Pharma. Other; RS recevied honoraria or consultancy fees from Abbvie, Biogen, Novartis, Celgene, Lilly, Chugai, MSD and UCB Pharma, RS is on the advisory boards for AbbVie, Biogen, Chugai, Lilly, Novartis and UCB Pharma. **C. Fleurinck:** Other; CF is an employee of UCB Pharma. **C. de la Loge:** Consultancies; CdlL is a consultant to UCB Pharma, Brussels, Belgium. **U. Massow:** Other; UM is an employee of UCB Pharma. **V. Taieb:** Other; VT is an employee of UCB Pharma. **S. Zhao:** Honoraria; SSZ received honoraria from UCB Pharma. **H. Marzo-Ortega:** Grants/research support; HMO received grants/research support from Janssen, Novartis and UCB Pharma. Other; HMO received honoraria and/or consultancy and/or speaker fees from Abbvie, Biogen, Celgene, Janssen, Eli-Lilly, Moonlake, Novartis, Pfizer and UCB Pharma.

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