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E071 BIMEKIZUMAB DEMONSTRATES SUSTAINED IMPROVEMENT IN QUALITY OF LIFE UP TO WEEK 52 IN PATIENTS ACROSS THE FULL SPECTRUM OF AXIAL SPONDYLOARTHRITIS: 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 demonstrated rapid and clinically meaningful improvements in disease activity in patients across the full spectrum of axial spondyloarthritis (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 report health-related quality of life (HRQoL) outcomes (ASQoL, SF-36 and EQ-5D-3L) from the two parallel phase 3 studies up to Week (Wk)52.

Methods

BE MOBILE 1 and 2 have similar study designs: 16-Wk double-blind placebo (PBO)-controlled period followed by 36-Wk maintenance period. Patients were randomised (1:1 in BE MOBILE 1; 2:1 in BE MOBILE 2) to receive BKZ 160 mg Q4W or PBO. All patients received BKZ 160 mg Q4W from Wk16 to Wk52. We report ASQoL, SF-36 - physical component summary (PCS) and SF-36 - mental component summary (MCS) scores up to Wk52 and proportion of patients with 'no problem' in each of the 5 EQ- 5D-3L domains (mobility, selfcare, usual activity, pain/discomfort, and anxiety/ depression). The results are presented as observed cases (OC), and missing data were imputed using multiple imputation (MI).

Results

254 nr-axSpA (BKZ: 128; PBO: 126) and 332 r-axSpA(BKZ: 221; PBO: 111) patients were randomised with 86.6% and 89.8% completing to Wk52, respectively. At Wk16, BKZ treated patients reported greater improvements in ASQoL and SF-36 PCS compared to PBO ($p < 0.001$, all comparisons, using Analysis of Covariance [ANCOVA]). By Wk52, these improvements across all HRQoL outcomes were sustained in BKZ treated patients and improved in patients who switched to BKZ at Wk16. (Table). The baseline SF-36 MCS levels indicated that on average patients had normal scores which remained unchanged throughout the study. The proportion of patients reporting 'no problem' across all five EQ-5D-3L domains improved over time up to Wk52. In patients with ASQoL $\geq$4 at baseline, >60% of patients had $\geq$4-point improvement in ASQoL at Wk52.

Conclusion

Across the axSpA disease spectrum, treatment with BKZ compared with PBO at Wk16 significantly improved quality of life outcomes measured by EQ-5D-3L, ASQoL and SF-36 PCS scores which were sustained to Wk52.

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

Population		Week 16												Week 52											
		BE MOBILE 1 (nr-axSpA)						BE MOBILE 2 (r-axSpA)						BE MOBILE 1 (nr-axSpA)						BE MOBILE 2 (r-axSpA)					
		PBO (N=126)			BKZ 160 mg Q4W (N=128)			PBO (N=111)			BKZ 160 mg Q4W (N=221)			PBO→BKZ (N=126)			BKZ 160 mg Q4W (N=128)			PBO→BKZ (N=111)			BKZ 160 mg Q4W (N=221)		
		n	BL	CfB	n	BL	CfB	n	BL	CfB	n	BL	CfB	n	BL	CfB	n	BL	CfB	n	BL	CfB	n	BL	CfB
ASQoL	Overall (OC); mean (SD)	118	9.4	-2.6 (4.2)	127	9.4	-5.2 (4.8)	109	8.4	-4.2 (3.8)	210	9.0	-5.0 (4.4)	108	9.2	-5.5 (4.5)	110	9.6	-6.2 (4.8)	102	8.4	-5.5 (4.3)	196	9.0	-5.8 (4.6)
	Overall (MI); mean (SE)	126	9.4	-2.5 (0.4)	128	9.5	-5.2 (0.4)	111	8.5	-4.2 (0.3)	221	9.0	-5.0 (0.3)	126	9.4	-5.3 (0.4)	128	9.5	-5.9 (0.4)	111	8.5	-5.6 (0.4)	221	9.0	-5.7 (0.3)
SF-36 PCS	Overall (OC); mean (SD)	118	33.54	5.58 (7.64)	127	33.36	9.53 (8.33)	109	34.71	5.83 (7.89)	210	34.32	9.43 (8.48)	108	33.45	11.77 (9.33)	110	33.47	12.45 (9.55)	102	34.94	12.15 (9.34)	196	34.26	12.28 (9.08)
	Overall (MI); mean (SE)	126	33.58	5.49 (0.65)	128	33.40	9.54 (0.74)	111	34.62	5.88 (0.76)	221	34.37	9.38 (0.58)	126	33.58	11.44 (0.85)	128	33.40	12.17 (0.87)	111	34.62	12.35 (0.87)	221	34.37	12.08 (0.63)
SF-36 MCS	Overall (OC); mean (SD)	118	51.86	0.51 (7.45)	127	51.48	2.50 (7.24)	109	52.05	1.81 (6.30)	210	50.92	2.45 (7.93)	108	52.67	0.88 (8.76)	110	51.51	2.78 (9.08)	102	51.65	2.87 (7.58)	196	50.98	2.16 (8.86)
	Overall (MI); mean (SE)	126	51.92	0.49 (0.69)	128	51.28	2.57 (0.64)	111	51.94	1.84 (0.60)	221	50.85	2.52 (0.54)	126	51.92	0.72 (0.88)	128	51.28	2.92 (0.81)	111	51.94	2.55 (0.75)	221	50.85	2.19 (0.62)

Population			BL (Day 1)				Week 16				Week 52			
			BE MOBILE 1 (nr-axSpA)		BE MOBILE 2 (r-axSpA)		BE MOBILE 1 (nr-axSpA)		BE MOBILE 2 (r-axSpA)		BE MOBILE 1 (nr-axSpA)		BE MOBILE 2 (r-axSpA)	
			PBO (N=126)	BKZ 160 mg Q4W (N=128)	PBO (N=111)	BKZ 160 mg Q4W (N=221)	PBO (N=126)	BKZ 160 mg Q4W (N=128)	PBO (N=111)	BKZ 160 mg Q4W (N=221)	PBO→BKZ (N=126)	BKZ 160 mg Q4W (N=128)	PBO→BKZ (N=111)	BKZ 160 mg Q4W (N=221)
EQ-5D-3L (OC)	Mobility	n	126	128	111	220	118	127	108	210	108	110	102	196
		No problems in walking about, n (%)	38 (30.2)	36 (28.1)	38 (34.2)	86 (39.1)	57 (48.3)	91 (71.7)	58 (53.7)	153 (72.9)	74 (68.5)	85 (77.3)	81 (79.4)	148 (75.5)
	Selfcare	n	126	128	111	220	118	127	108	210	108	110	102	196
		No problems with self-care, n (%)	68 (54.0)	61 (47.7)	65 (58.6)	124 (56.4)	81 (68.6)	102 (80.3)	73 (67.6)	172 (81.9)	89 (82.4)	87 (79.1)	87 (85.3)	171 (87.2)
	Usual activity	n	126	128	111	220	118	127	108	210	108	110	102	196
		No problems with performing my usual activities, n (%)	35 (27.8)	27 (21.1)	34 (30.6)	71 (32.3)	49 (41.5)	74 (58.3)	53 (49.1)	128 (61.0)	71 (65.7)	72 (65.5)	74 (72.5)	145 (74.0)
	Pain/ discomfort	n	126	128	111	220	118	127	108	210	108	110	102	196
		No pain or discomfort, n (%)	4 (3.2)	3 (2.3)	4 (3.6)	7 (3.2)	20 (16.9)	34 (26.8)	14 (13.0)	52 (24.8)	40 (37.0)	43 (39.1)	46 (45.1)	77 (39.3)
	Anxiety/ Depression	n	126	128	111	220	118	127	108	210	108	110	102	196
		Not anxious or depressed, n (%)	90 (71.4)	103 (80.5)	88 (79.3)	167 (75.9)	91 (77.1)	112 (88.2)	89 (82.4)	175 (83.3)	92 (85.2)	95 (86.4)	91 (89.2)	164 (83.7)

ASQoL, Ankylosing Spondylitis Quality of Life Questionnaire; BL, baseline; BKZ, Bimekizumab; CfB, change from baseline; EQ-5D-3L, European Quality of Life Five Dimension - 3 levels; IR, inadequate responder; nr-axSpA, nonradiographic axSpA; OC, observed cases; MI, multiple imputation; Q4W, every 4 weeks; r-axSpA, ankylosing spondylitis/ radiographic axSpA; SD, standard deviation; SE, standard error; SF-36 PCS, Short Form 36 physical component summary; SF-36 MCS, Short Form 36 mental component summary; TNF, tumour necrosis factor.

Disclosure

N.D. McKay: Consultancies; NDM has received consultancy fees from Gilead and UCB Pharma. Other; NDM has received a registration fees for attendance at a conference from Abbvie, Novartis and UCB Pharma, NDM has received a fee for lecturing from Gilead, NDM has taken part in education meetings, programmes and examinations for a wide range of pharmaceutical companies. **A. Bennett:** Honoraria; AB received teaching honorarium from Abbvie Ltd, Pfizer, UCB Pharma, Novartis and Biogen. Grants/research support; AB received research grants from Pfizer. Other; AB received advisory board fees from Abbvie Ltd, Pfizer, UCB Pharma, MSD, Novartis and Lilly. **N. Goodson:** Honoraria; NG has received honoraria from UCB Pharma and Novartis. **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 employee of UCB Pharma. **H. Marzo-Ortega:** Grants/research support; HMO has received grants/ research support from Janssen, Novartis and UCB Pharma. Other; HMO has received honoraria and/or consultancy and/or speaker fees from Abbvie, Biogen, Celgene, Janssen, Eli-Lilly, Moonlake, Novartis, Pfizer and UCB Pharma. **K. Gaffney:** Shareholder/stock ownership; KG is a shareholder of Rheumatology Events. Grants/research support; KG has received grants/research support from NASS, Versus Arthritis, AbbVie, Pfizer, UCB Pharma, Norvartis, Eli 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.