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Bimekizumab impact on joint and pain outcomes in patients with active psoriatic arthritis and psoriasis: Pooled 16-week results from the BE OPTIMAL and BE COMPLETE phase 3 randomised, placebo-controlled studies

Akimichi Morita,[1] Joseph F. Merola,[2,3] Laura C. Coates,[4] Iain B. McInnes,[5] Philip J. Mease,[6] Yoshiya Tanaka,[7] Paolo Gisondi,[8] Alice B. Gottlieb,[9] Barbara Ink,[10] Rajan Bajracharya,[10] Jason Coarse,[11] Jason Eells,[10] Akihiko Asahina[12]

Objective

To assess the impact of bimekizumab vs placebo on joint and pain-specific outcomes in patients with psoriatic arthritis and psoriasis affecting ≥3% body surface area, using pooled data from the phase 3 BE OPTIMAL and BE COMPLETE trials.

Background

- Psoriatic arthritis (PsA) is a complex inflammatory disease that manifests across multiple domains, including skin and joints, occurring in up to 30% of patients with psoriasis.[1,2]
- The joint inflammation and pain experienced by patients with PsA significantly contributes to their disease burden.[3]
- Bimekizumab (BKZ), a monoclonal IgG1 antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A, has demonstrated efficacy and tolerability to 16 weeks in patients with PsA.[4,5]

Methods

- BE OPTIMAL (NCT03895203) and BE COMPLETE (NCT03896581) assessed the efficacy and safety of treatment with subcutaneous BKZ 160 mg every 4 weeks in patients with PsA who were biologic disease-modifying antirheumatic drug (bDMARD)-naïve or who had inadequate response or intolerance to TNF-α inhibitors (TNFi-IR), respectively.[4,5]
- Each study included a 16-week double-blind, placebo (PBO)-controlled phase (**Figure 1**). BE OPTIMAL included an adalimumab reference arm; data are not shown here.
- Here, data from BE OPTIMAL and BE COMPLETE were pooled for patients receiving BKZ or PBO who had psoriasis affecting ≥3% body surface area (BSA) at baseline.
- Joint outcomes were assessed by ≥20/50/70% improvements in American College of Rheumatology response criteria (ACR20/50/70) and change from baseline (CfB) in tender/swollen joint counts (TJC/SJC) to Week 16.
- Pain outcomes were assessed to Week 16 using CfB and clinically relevant improvements of ≥30% (much improved), ≥50% (very much improved) and ≥70% from baseline in Patient's Assessment of Arthritis Pain (PtAAP30/50/70) visual analogue scale (VAS).[6,7]
- Missing data were imputed using non-responder imputation (NRI) for dichotomous outcomes or multiple imputation (MI) for continuous outcomes.

Results

- 621/1,112 (55.8%) patients had baseline psoriasis ≥3% BSA (357 bDMARD-naïve [217 BKZ; 140 PBO]; 264 TNFi-IR [176 BKZ; 88 PBO]). Baseline characteristics for this subgroup are reported in **Table 1**.
- At Week 16, greater proportions of BKZ-treated patients vs PBO achieved ACR20 (69.7% vs 18.4%), ACR50 (47.6% vs 6.1%) and ACR70 (30.8% vs 2.2%; **Figure 2**).
- A greater mean (standard error [SE]) CfB at Week 16 was observed for patients receiving BKZ vs patients receiving PBO in TJC (–11.3 [0.6] vs –2.2 [0.7]), SJC (–7.5 [0.4] vs –2.1 [0.5]) and PtAAP (–27.8 [1.5] vs –6.1 [1.5]) (**Figure 3**).
- A higher proportion of BKZ vs PBO-treated patients were PtAAP30 (64.1% vs 21.9%), PtAAP50 (53.7% vs 13.6%) and PtAAP70 (38.7% vs 7.0%) responders at Week 16 (**Figure 4**).
- Results were similar across trials.

Conclusions

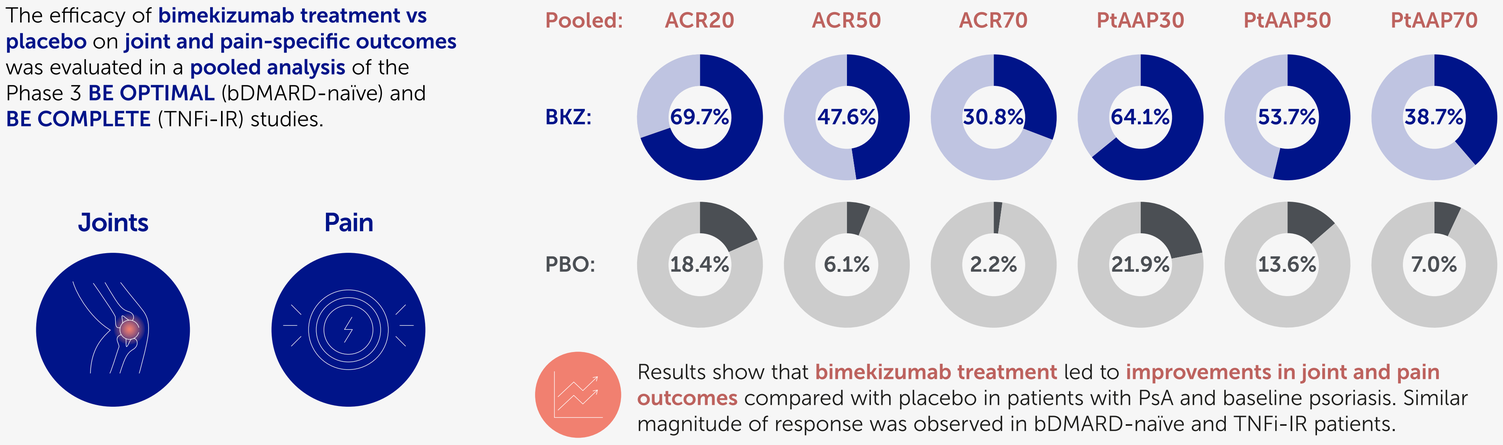
Bimekizumab treatment demonstrated improvement across joint and pain outcomes in patients with PsA and baseline psoriasis, as compared with PBO at Week 16. Results were consistent in patients who were bDMARD-naïve or TNFi-IR, suggesting that bimekizumab treatment improved joint and pain outcomes irrespective of prior bDMARD use.

Summary

55.8% (621/1,112) of patients had **baseline psoriasis** affecting ≥3% body surface area.

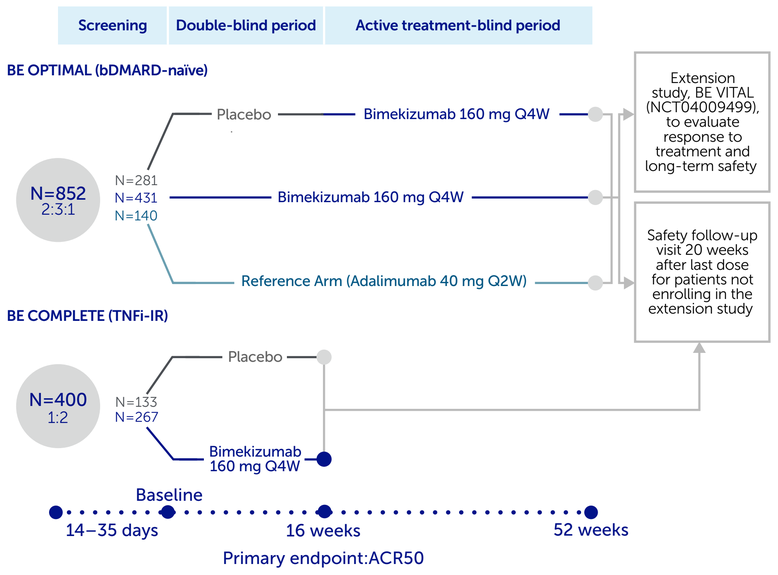
The efficacy of **bimekizumab treatment vs placebo** on **joint and pain-specific outcomes** was evaluated in a **pooled analysis** of the Phase 3 **BE OPTIMAL** (bDMARD-naïve) and **BE COMPLETE** (TNFi-IR) studies.

Numerically higher proportions of **bimekizumab-treated patients** achieved **clinically relevant joint and pain outcomes** at Week 16, irrespective of prior bDMARD use.



Results show that **bimekizumab treatment** led to **improvements in joint and pain outcomes** compared with placebo in patients with PsA and baseline psoriasis. Similar magnitude of response was observed in bDMARD-naïve and TNFi-IR patients.

Figure 1 BE OPTIMAL and BE COMPLETE study designs



Study designs that made up the pooled population, BE OPTIMAL (NCT03895203) and BE COMPLETE (NCT03896581). Adalimumab 40 mg Q2W served as an active reference arm. BE OPTIMAL was not powered for comparisons of adalimumab to bimekizumab or adalimumab to placebo. Adalimumab 40 mg Q2W data are not shown in this poster.

Table 1 Baseline characteristics in patients with baseline psoriasis (≥3% BSA)

	Pooled Analysis (bDMARD-naïve + TNFi-IR)		BE OPTIMAL (bDMARD-naïve)		BE COMPLETE (TNFi-IR)	
	PBO n=228	BKZ 160 mg Q4W n=393	PBO n=140	BKZ 160 mg Q4W n=217	PBO n=88	BKZ 160 mg Q4W n=176
Age, years, mean (SD)	48.7 (12.1)	47.7 (12.3)	48.0 (11.4)	46.7 (12.2)	49.8 (13.1)	48.9 (12.3)
Male, n (%)	103 (45.2)	199 (50.6)	63 (45.0)	110 (50.7)	40 (45.5)	89 (50.6)
BMI, kg/m², mean (SD)	29.1 (5.5)	30.0 (6.8)	29.4 (5.6)	30.1 (7.1)	28.7 (5.5)	29.9 (6.5)
BSA affected by PSO ≥3–≤10%, n (%)	155 (68.0)	253 (64.4)	92 (65.7)	144 (66.4)	63 (71.6)	109 (61.9)
BSA affected by PSO >10%, n (%)	73 (32.0)	140 (35.6)	48 (34.3)	73 (33.6)	25 (28.4)	67 (38.1)
Time since PsA diagnosis, years, mean (SD)	7.5 (7.9)[a]	8.5 (9.5)[b]	6.6 (7.7)	7.0 (8.2)[c]	8.9 (8.1)[a]	10.3 (10.6)[a]
MTX at baseline, n (%)	118 (51.8)	206 (52.4)	83 (59.3)	126 (58.1)	35 (39.8)	80 (45.5)
PASI, mean (SD)	8.1 (6.0)	9.1 (8.0)	7.9 (5.6)	8.2 (6.8)	8.5 (6.6)	10.2 (9.1)
HAQ-DI, mean (SD)	1.02 (0.65)	0.93 (0.58)[a]	0.93 (0.63)	0.87 (0.59)[a]	1.15 (0.67)	1.01 (0.55)
hs-CRP ≥6 mg/L, n (%)	113 (49.6)	181 (46.1)	67 (47.9)	98 (45.2)	46 (52.3)	83 (47.2)
PtAAP, mean (SD)	62.6 (22.0)	57.0 (24.6)[a]	60.4 (21.7)	55.5 (24.3)[a]	66.1 (22.0)	59.0 (24.9)
TJC (of 68 joints), mean (SD)	18.3 (13.1)	17.7 (12.4)	17.3 (11.9)	17.4 (12.2)	19.9 (14.7)	18.1 (12.7)
SJC (of 66 joints), mean (SD)	10.2 (7.8)	9.8 (7.1)	9.9 (7.2)	9.5 (6.5)	10.8 (8.6)	10.0 (7.9)

[a]Data unavailable for 1 patient; [b]n=388; [c]n=213.

Figure 2 Proportion of patients with baseline psoriasis (≥3% BSA) achieving ACR20/50/70 to Week 16 (NRI)

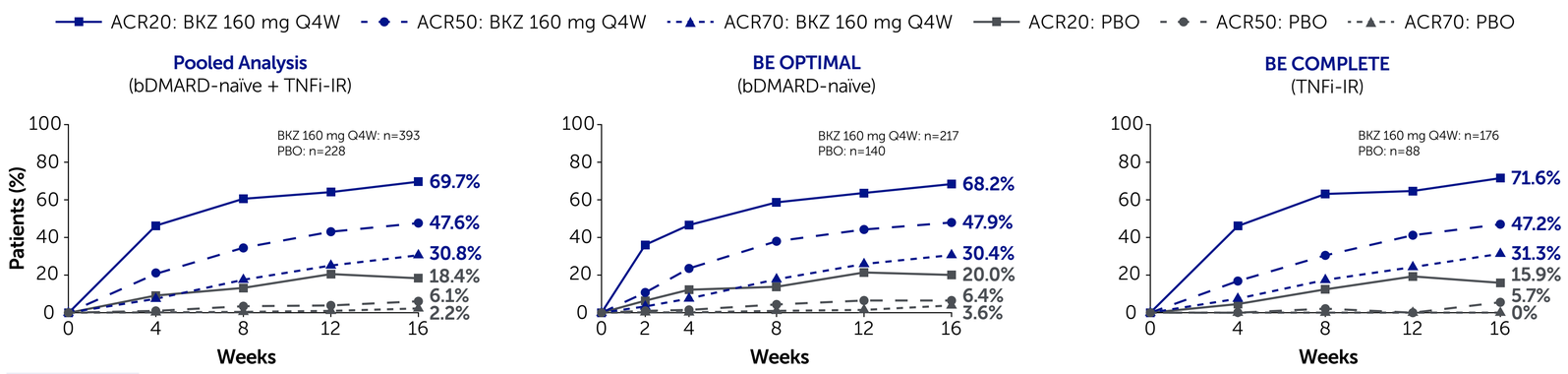


Figure 3 Change from baseline in TJC, SJC and PtAAP in patients with baseline psoriasis (≥3% BSA) at Week 16 (MI)

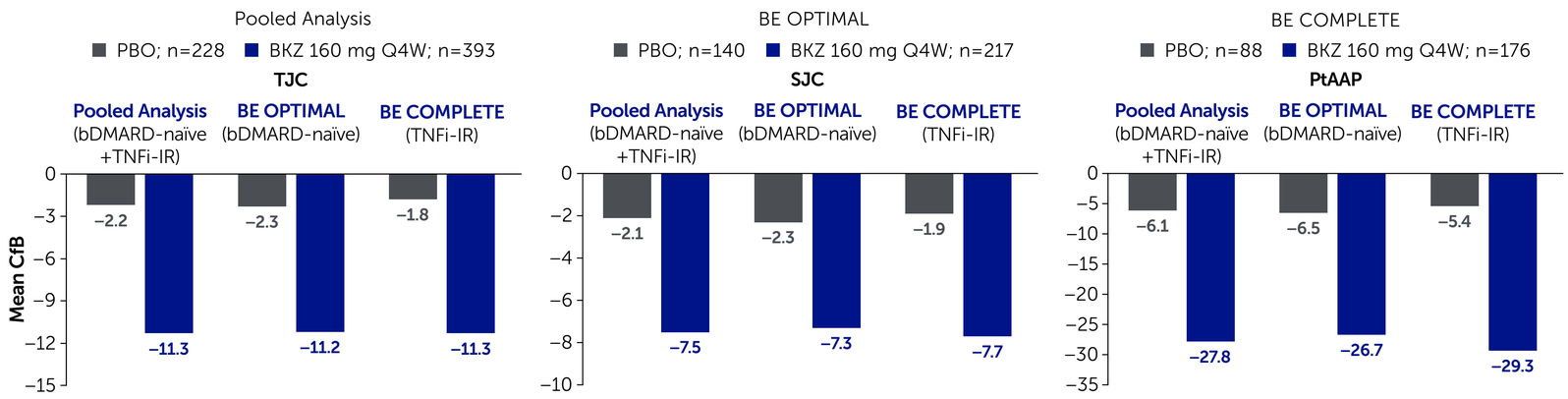
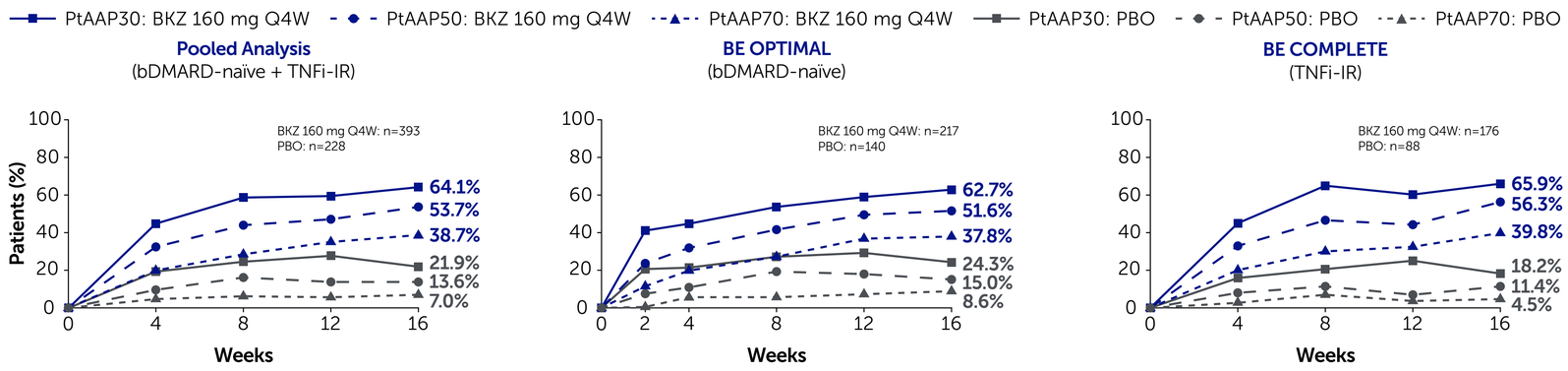


Figure 4 Proportion of patients with baseline psoriasis (≥3% BSA) achieving PtAAP30/50/70 to Week 16 (NRI)



ACR: American College of Rheumatology; **ACR20/50/70:** ≥20/50/70% improvement in ACR criteria; **bDMARD:** biologic disease modifying antirheumatic drug; **BKZ:** bimekizumab; **BMI:** body mass index; **BSA:** body surface area; **CfB:** change from baseline; **HAQ-DI:** Health Assessment Questionnaire-Disability Index; **hs-CRP:** high-sensitivity C-reactive protein; **IL:** interleukin; **MI:** multiple imputation; **MTX:** methotrexate; **NRI:** non-responder imputation; **PASI:** Psoriasis Area and Severity Index; **PBO:** placebo; **PsA:** psoriatic arthritis; **PSO:** psoriasis; **PtAAP:** Patient's Assessment of Arthritis Pain; **PtAAP30/50/70:** 30/50/70% improvement in PtAAP score from baseline; **Q2W:** every 2 weeks; **Q4W:** every 4 weeks; **SD:** standard deviation; **SE:** standard error; **SJC:** swollen joint count; **TJC:** tender joint count; **TNFi-IR:** tumour necrosis factor-α inhibitor inadequate response or intolerance; **VAS:** Visual Analogue Scale.

Institutions: [1]Department of Geriatric and Environmental Dermatology, Nagoya City University Graduate School of Medical Sciences, Nagoya, Japan; [2]Department of Dermatology, Harvard Medical School, Brigham and Women's Hospital, Boston, Massachusetts, USA; [3]Division of Rheumatology, Department of Medicine, Harvard Medical School, Brigham and Women's Hospital, Boston, Massachusetts, USA; [4]Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Diseases, University of Oxford and Oxford Biomedical Research Centre, Oxford University Hospitals NHS Trust, Oxford, UK; [5]College of Medical Veterinary and Life Sciences, University of Glasgow, Glasgow, UK; [6]Swedish Medical Center and Providence St. Joseph Health and University of Washington, Seattle, Washington, USA; [7]The First Department of Internal Medicine, University of Occupational and Environmental Health, Japan, Kitakyushu, Fukuoka, Japan; [8]Dermatology and Venereology, Department of Medicine, Universita di Verona, Verona, Italy; [9]Department of Dermatology; The Icahn School of Medicine at Mount Sinai, New York, New York, USA; [10]UCB Pharma, Slough, UK; [11]UCB Pharma, Morrisville, North Carolina, USA; [12]Department of Dermatology, The Jikei University School of Medicine, Tokyo, Japan.

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