Bimekizumab treatment resulted in sustained improvements in pain and fatigue in patients with active psoriatic arthritis and baseline psoriasis: 2-year results from two phase 3 studies

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Presentation Number: 62763

OBJECTIVE

- To report the **long-term impact of bimekizumab treatment on pain and fatigue outcomes to 2 years** in patients with active psoriatic arthritis (PsA) and baseline psoriasis (≥3% body surface area [BSA]), who were either biologic disease-modifying antirheumatic drug naïve (biologic-naïve) or had prior intolerance/inadequate response to TNF inhibitors (TNFi-IR).

Background

- Assessing the **long-term impact of bimekizumab treatment** on **pain and fatigue** among patients with PsA and psoriasis is clinically important.

Methods

- Post hoc analysis of patients with PsA and psoriasis (≥3% BSA) at baseline in BE OPTIMAL (biologic-naïve) and BE COMPLETE (TNFi-IR).[1]
- BE OPTIMAL (Week 52)/BE COMPLETE (Week 16) completers could enter the BE VITAL open-label extension (OLE).[1]
- Missing data were imputed using non-responder imputation (NRI; discrete) and multiple imputation (MI; continuous).

Pain and fatigue are included in the GRAPPA-OMERACT Core Domain Set for PsA[2]

Pain outcomes:

- Change from baseline (CfB) in pain visual analog scale (VAS) score.
- Major improvement: ≥50% improvement from baseline in Pain VAS.[3]

Core domains

- Physical function
- Pain
- HRQoL
- Patient's global assessment
- Systemic inflammation
- Musculoskeletal
- Fatigue
- Skin

Fatigue outcomes:

- FACIT-Fatigue CfB and minimal clinically important difference (MCID; score increase from baseline ≥4) to assess self-reported fatigue and its impact on daily activities and function over the past 7 days.[4,a]

[a] FACIT-Fatigue score ranges from 0 to 52, with 52 being the best possible score. **1.** Mease PJ et al. Rheumatol Ther 2024;11:1363–82; **2.** Ogdie A et al. J Rheumatol 2017;44:697–700; **3.** Dworkin RH et al. J Pain 2008;9:105–21; **4.** Cella D et al. J Patient Rep Outcomes 2019;3:30. BSA: body surface area; CfB: change from baseline; FACIT-Fatigue: Functional Assessment of Chronic Illness Therapy-Fatigue; GRAPPA-OMERACT: Group for Research and Assessment of Psoriasis and Psoriatic Arthritis – Outcome Measures in Rheumatology; HRQoL: health-related quality of life; MCID: minimal clinically important difference; MI: multiple imputation; NRI: non-responder imputation; OLE: open-label extension; PsA: psoriatic arthritis; TNFi-IR: inadequate response or intolerance to tumor necrosis factor inhibitors; VAS: visual analog scale.

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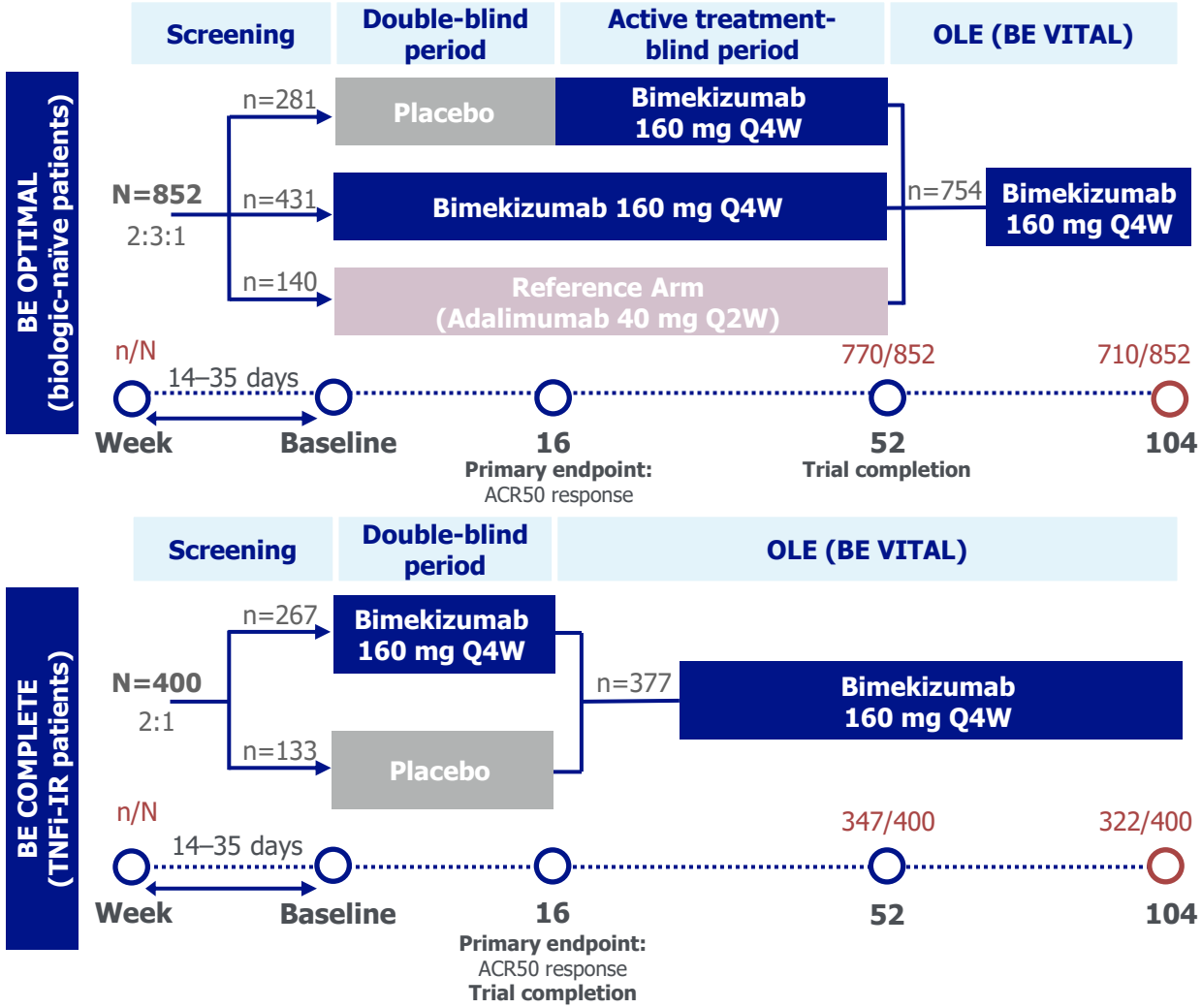
BE OPTIMAL, BE COMPLETE, and BE VITAL (OLE) Study Designs[a]



Baseline Characteristics

In patients with baseline psoriasis BSA ≥3%

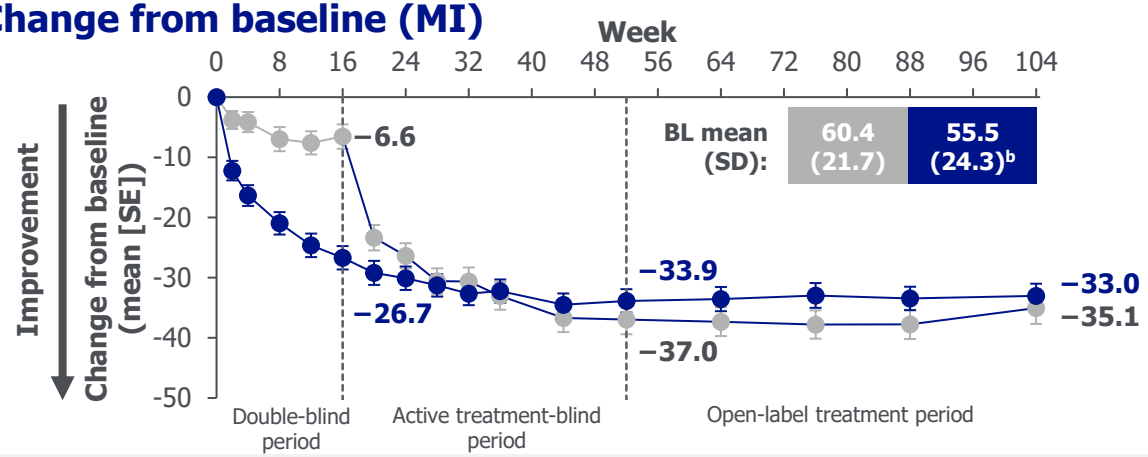
	BE OPTIMAL (biologic-naïve)		BE COMPLETE (TNFi-IR)	
	PBO n=140	BKZ 160 mg Q4W n=217	PBO n=88	BKZ 160 mg Q4W n=176
Age (years), mean (SD)	48.0 (11.4)	46.7 (12.2)	49.8 (13.1)	48.9 (12.3)
Male, n (%)	63 (45.0)	110 (50.7)	40 (45.5)	89 (50.6)
BMI (kg/m²), mean (SD)	29.4 (5.6)	30.1 (7.1)	28.7 (5.5)	29.9 (6.5)
Duration of disease, PsA (years), mean (SD)	6.6 (7.7)	7.0 (8.2)[b]	8.9 (8.1)[c]	10.3 (10.6)[d]
Duration of disease, PSO (years), mean (SD)	16.5 (12.2)	16.3 (12.5)	18.7 (11.6)	18.9 (13.6)[d]
Psoriasis BSA ≥3% to ≤10%, n (%)	92 (65.7)	144 (66.4)	63 (71.6)	109 (61.9)
Psoriasis BSA >10%, n (%)	48 (34.3)	73 (33.6)	25 (28.4)	67 (38.1)
PASI score, mean (SD)	7.9 (5.6)	8.2 (6.8)	8.5 (6.6)	10.2 (9.1)
TJC (of 68 joints), mean (SD)	17.3 (11.9)	17.4 (12.2)	19.9 (14.7)	18.1 (12.7)
SJC (of 66 joints), mean (SD)	9.9 (7.2)	9.5 (6.5)	10.8 (8.6)	10.0 (7.9)
hs-CRP ≥6 mg/dL, n (%)	67 (47.9)	98 (45.2)	46 (52.3)	83 (47.2)
Pain VAS score,[e] mean (SD)	60.4 (21.7)	55.5 (24.3)[f]	66.1 (22.0)	59.0 (24.9)
FACIT-Fatigue score,[g] mean (SD)	35.7 (10.2)	37.8 (8.9)	35.8 (9.9)	34.8 (9.9)

Study design: The ADA 40 mg Q2W treatment arm served as an active reference. The BE OPTIMAL study was not powered for statistical comparisons of ADA to BKZ or PBO. Completion rates include patients that completed to Week 52/104 in BE OPTIMAL and Week 52/100 in BE COMPLETE not on randomized treatment (BE OPTIMAL Week 52: 9 [1.1%], Week 104: 8 [0.9%]; BE COMPLETE Week 52: 4 [1.0%], Week 100: 2 [0.5%]). 2 patients in BE COMPLETE were classified as ongoing at Week 52 as they did not have a visit for Week 52 but no formal discontinuation reason was reported. **[a]** Disposition data are presented for the overall population. **Table:** Randomized set in patients with baseline psoriasis BSA ≥3%. **[b]** n=213; **[c]** n=87; **[d]** n=175; **[e]** Pain VAS measured using Patient Assessment of Arthritis Pain, which ranges from 0 to 100, with 0 representing "no pain" and 100 "most severe pain"; **[f]** n=216; **[g]** FACIT-Fatigue score ranges from 0 to 52, with 52 being the best possible score. ACR50: ≥50% improvement in American College of Rheumatology response criteria; ADA: adalimumab; BKZ: bimekizumab; BMI: body mass index; BSA: body surface area; FACIT-Fatigue: Functional Assessment of Chronic Illness Therapy – Fatigue; hs-CRP: high-sensitivity C-reactive protein; OLE: open-label extension; PASI: Psoriasis Area and Severity Index; PBO: placebo; PsA: psoriatic arthritis; PSO: psoriasis; Q2W: every 2 weeks; Q4W: every 4 weeks; SD: standard deviation; SJC: swollen joint count; TJC: tender joint count; TNFi-IR: inadequate response or intolerance to tumor necrosis factor inhibitors; VAS: visual analog scale.

Pain VAS Improvements in Patients with PsA and Baseline Psoriasis BSA ≥3% to Week 104/100

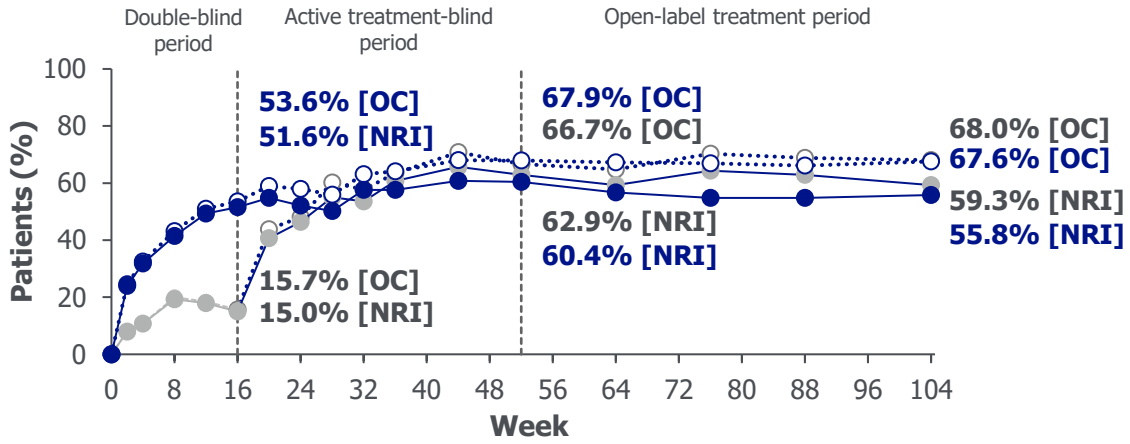
BE OPTIMAL (biologic-naïve)

Change from baseline (MI)



PBO/BKZ 160 mg Q4W; n=140 **BKZ** 160 mg Q4W; n=217

Pain VAS ≥50% improvement[c] (NRI/OC)

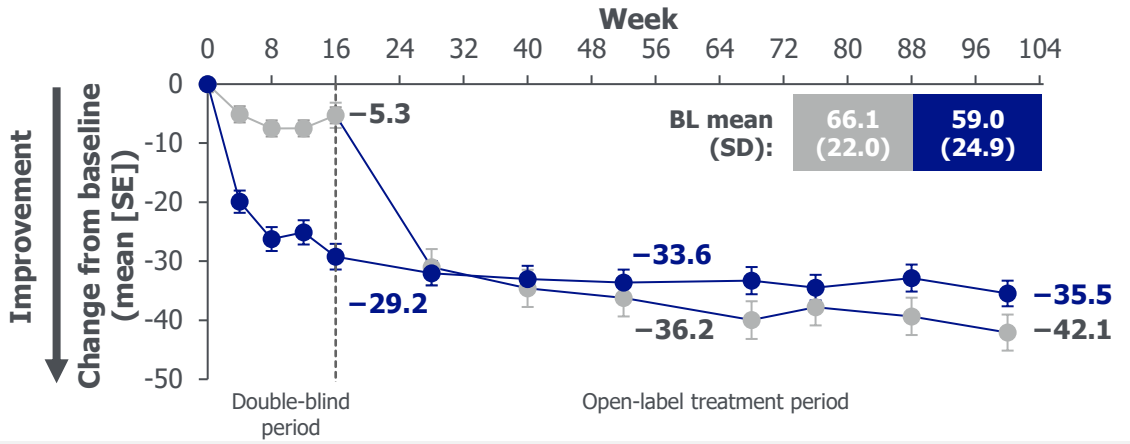


n (OC)				
PBO/BKZ	140	134	132	122
BKZ	217	209	193	179

PBO/BKZ 160 mg Q4W; n=140 **BKZ** 160 mg Q4W; n=217 **NRI** **OC**

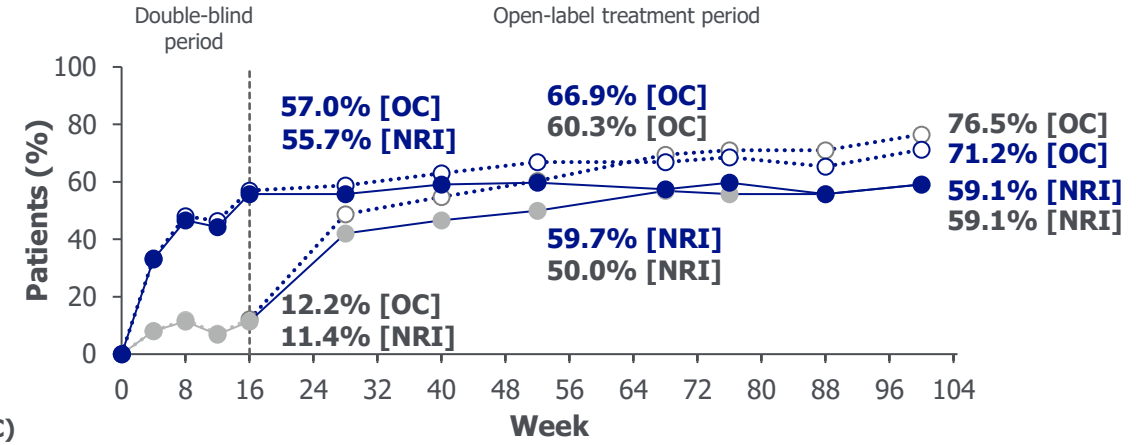
BE COMPLETE (TNFi-IR)[a]

Change from baseline (MI)



PBO/BKZ 160 mg Q4W; n=88 **BKZ** 160 mg Q4W; n=176

Pain VAS ≥50% improvement[c] (NRI/OC)



n (OC)				
PBO/BKZ	88	82	73	68
BKZ	176	172	157	146

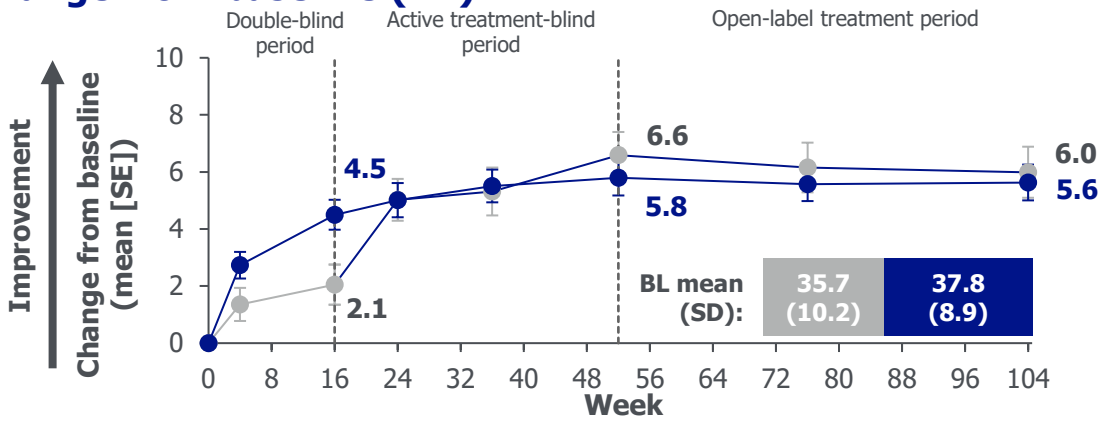
PBO/BKZ 160 mg Q4W; n=88 **BKZ** 160 mg Q4W; n=176

1. Dworkin RH et al. J Pain 2008;9:105–21. Randomized set. Data are reported as observed case, and missing data imputed using non-responder imputation (discrete) or multiple responder imputation (continuous). **[a]** For BE COMPLETE, Pain VAS was assessed to Week 100; **[b]** n=216; **[c]** ≥50% improvement in pain represents clinically important improvement from baseline in patient-reported pain;[1] measured by ≥50% improvement in Patient Assessment of Arthritis Pain (pain VAS), with 0 representing "no pain" and 100 "most severe pain". BKZ: bimekizumab; BL: baseline; BSA: body surface area; MI: multiple imputation; NRI: non-responder imputation; OC: observed case; PBO: placebo; Q4W: every 4 weeks; SD: standard deviation; SE: standard error; TNFi-IR: inadequate response or intolerance to tumor necrosis factor inhibitors; VAS: visual analog scale.

FACIT-Fatigue Improvements in Patients with PsA and Baseline Psoriasis BSA ≥3% to Week 104/88

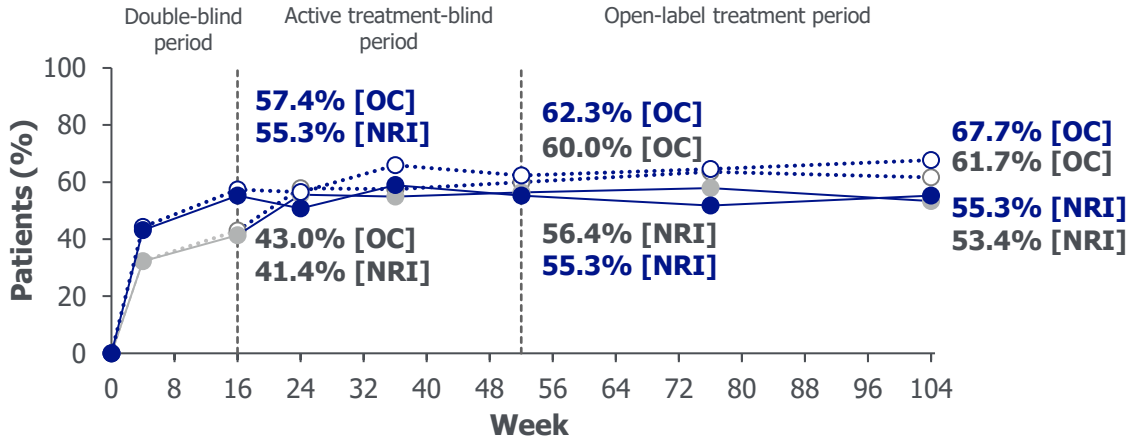
BE OPTIMAL (biologic-naïve)

Change from baseline (MI)



PBO/BKZ 160 mg Q4W; n=140 BKZ 160 mg Q4W; n=217

MCID (score increase from baseline ≥4)[b] (NRI/OC)

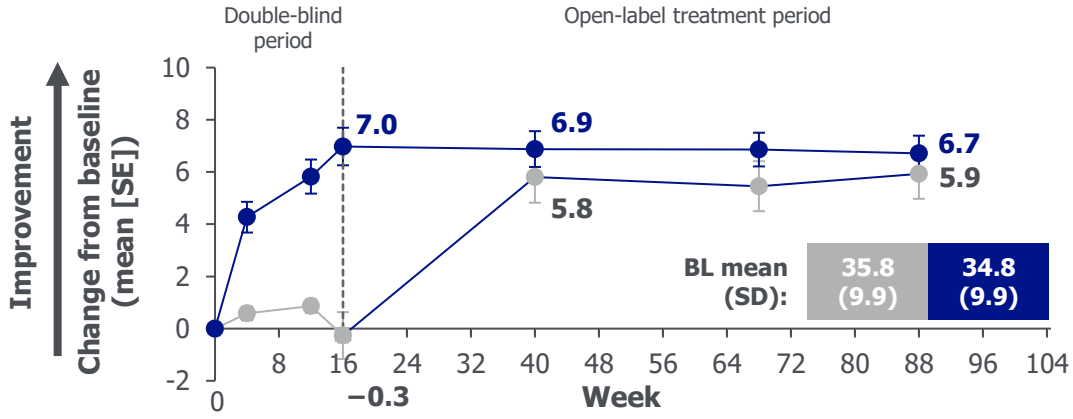


n (OC)			
PBO/BKZ	128	125	115
BKZ	190	175	161

PBO/BKZ 160 mg Q4W; n=133 BKZ 160 mg Q4W; n=197 NRI OC

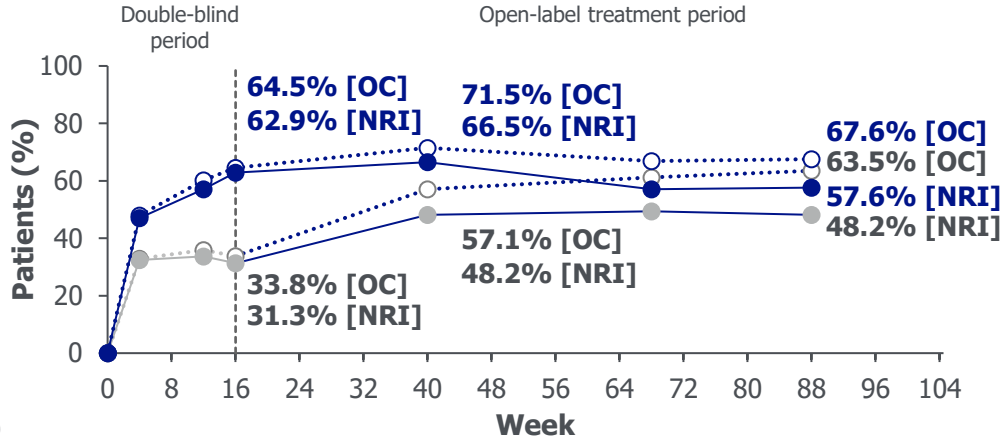
BE COMPLETE (TNFi-IR)[a]

Change from baseline (MI)



PBO/BKZ 160 mg Q4W; n=88 BKZ 160 mg Q4W; n=176

MCID (score increase from baseline ≥4)[b] (NRI/OC)



n (OC)			
PBO/BKZ	77	70	63
BKZ	166	158	145

PBO/BKZ 160 mg Q4W; n=83 BKZ 160 mg Q4W; n=170

Randomized set. Data are reported as observed case, and missing data imputed using non-responder imputation (discrete) or multiple responder imputation (continuous). **[a]** For BE COMPLETE, FACIT-Fatigue values were collected at Week 40 and Week 88; **[b]** FACIT-Fatigue MCID defined as score increase from BL ≥4 in patients with FACIT-Fatigue ≤48 at BL (to ensure a possible increase of 4 points; score ranges from 0 to 52, with 52 being the best possible score). BKZ: bimekizumab; BL: baseline; FACIT-Fatigue: Functional Assessment of Chronic Illness Therapy – Fatigue; MCID: minimal clinically important difference; MI: multiple imputation; NRI: non-responder imputation; OC: observed case; PBO: placebo; Q4W: every 4 weeks; SD: standard deviation; SE: standard error; TNFi-IR inadequate response or intolerance to tumor necrosis factor inhibitors.

CONCLUSIONS

Bimekizumab treatment demonstrated sustained and clinically meaningful improvements in patient-reported pain and fatigue up to 2 years.

Consistent efficacy was observed across both studied populations of patients with psoriatic arthritis and baseline psoriasis: those who were biologic-naïve and those who had inadequate response or intolerance to tumor necrosis factor inhibitors (TNFi-IR).

Author Contributions: Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: **ABG, AA, DT, RBW, BI, RB, JL, JC, JFM;** Drafting of the publication, or reviewing it critically for important intellectual content: **ABG, AA, DT, RBW, BI, RB, JL, JC, JFM**; Final approval of the publication: **ABG, AA, DT, RBW, BI, RB, JL, JC, JFM**.

Disclosures: ABG: Receives research/educational grants from BMS, Janssen, MoonLake Immuotherapeutics, and UCB (all paid to Mount Sinai School of Medicine); received honoraria as an advisory board member and consultant for Amgen, Eli Lilly and Company, Highlights Therapeutics, Janssen, Novartis, Sanofi, SunPharma, Takeda, Teva Pharmaceuticals, UCB, and Xbiotech (stock options for RA). **AA**: Honoraria and/or research grants from AbbVie, Amgen, BMS, Boehringer Ingelheim, Eisai, Eli Lilly and Company, Janssen, Kyowa Kirin, LEO Pharma, Maruho, Mitsubishi Tanabe Pharma, Novartis, Pfizer, Sun Pharma, Taiho Pharma, Torii Pharmaceutical Co., and UCB. **DT**: Investigator and/or consultant/advisor for AbbVie, Almirall, Amgen, Boehringer Ingelheim, BMS, Celltrion, Eli Lilly and Company, Galderma, Johnsson and Johnsson, Kyowa Kirin, LEO Pharma, L'Oreal, New Bridge, Novartis, Pfizer, Regeneron, Samsung, Sanofi, Takeda, Target-RWE, UCB, and Vichy; received grants from AbbVie, LEO Pharma, and Novartis. **RBW**: Consulting fees from AbbVie, Almirall, Amgen, Arena, Astellas, Avillion, Biogen, Boehringer Ingelheim, BMS, Celgene, DICE Therapeutics, Eli Lilly and Company, GSK, Janssen, LEO Pharma, Meiji Pharma, Novartis, Pfizer, RAPT Therapeutics, Sanofi, Sun Pharma, UCB, and Union; research grants to his institution from AbbVie, Almirall, Amgen, Celgene, Eli Lilly and Company, Janssen, LEO Pharma, Novartis, Pfizer, and UCB; honoraria from AbbVie, Almirall, BMS, Eli Lilly and Company, Galderma, Janssen, and Novartis. **BI**: Employee of UCB; shareholder of AbbVie, GSK and UCB. **RB, JL, JC**: Employee and shareholder of UCB. **JFM**: Consultant and/or investigator for AbbVie, Amgen, AstraZeneca, Biogen, Boehringer Ingelheim, BMS, Dermavant, Eli Lilly and Company, Incyte, Janssen, LEO Pharma, MoonLake Immunotherapeutics, Novartis, Pfizer, Sanofi, Sun Pharma, and UCB.

Acknowledgments: This study was funded by UCB. We would like to thank the patients and their caregivers in addition to all the investigators and their teams who contributed to this study. The authors acknowledge Heather Edens, PhD, UCB, Smyrna, GA, USA for publication coordination, and Lilit Ghazaryan, MBiol, Costello Medical, London, UK for medical writing support and editorial assistance. All costs associated with development of this presentation were funded by UCB.