Sustained reduction in pain and fatigue with bimekizumab treatment in patients with active psoriatic arthritis over 3 years: Results from two phase 3 studies

Alice B. Gottlieb,[1,a] Thierry Passeron,[2,3] Mitsumasa Kishimoto,[4] David Nicholls,[5] Fabian Proft,[6] William Tillett,[7,8] Barbara Ink,[9] Rajan Bajracharya,[9] Jason Coarse,[10] Jérémy Lambert,[11] Philip J. Mease[12]

[1]Department of Dermatology, The Icahn School of Medicine at Mount Sinai, New York, New York, USA; [2]Department of Dermatology, CHU Nice, Université Côte d'Azur, Nice, France; [3]C3M, INSERM U1065, Université Côte d'Azur, Nice, France; [4]Department of Nephrology and Rheumatology, Kyorin University School of Medicine, Tokyo, Japan; [5]Clinical Trials Unit, University of the Sunshine Coast, Queensland, Australia; [6]Department of Gastroenterology, Infectiology and Rheumatology (including Nutrition Medicine), Charité – Universitätsmedizin Berlin; corporate member of Freie Universität Berlin and Humboldt-Universität zu Berlin, Berlin, Germany; [7]Royal National Hospital of Rheumatic Diseases, Bath, UK; [8]Department of Life Sciences, Centre for Therapeutic Innovation, University of Bath, Bath, UK; [9]UCB, Slough, UK; [10]UCB, Morrisville, North Carolina, USA; [11]UCB, Colombes, France; [12]Department of Rheumatology, Providence-Swedish Medical Center and University of Washington, Seattle, Washington, USA.

Objective

To report the long-term impact of bimekizumab (BKZ) treatment on patient-reported pain and fatigue to 3 years in patients with active psoriatic arthritis (PsA) who were biologic disease-modifying antirheumatic drug (biologic)-naïve or had inadequate response/intolerance to tumour necrosis factor inhibitors (TNFi-IR).

Introduction

- Pain and fatigue, identified as key symptoms by patients with PsA, negatively impact quality of life.[1,2] Sustained improvements in these symptoms are important treatment goals.[1,2]
- BKZ is a monoclonal IgG1 antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A.

Methods

- The phase 3 BE OPTIMAL (NCT03895203; biologic-naïve) and BE COMPLETE (NCT03896581; TNFi-IR) studies assessed subcutaneous BKZ 160 mg every 4 weeks (Q4W) in patients with PsA; both were placebo (PBO)-controlled to Week 16.
- BE OPTIMAL (Week 52) and BE COMPLETE (Week 16) completers were eligible to enter BE VITAL (open-label extension; NCT04009499), in which all patients received BKZ 160 mg Q4W.
- Data for the BKZ Total group (PBO/BKZ and BKZ-randomised patients) are reported here.
- Pain was assessed using Patient's Assessment of Arthritis Pain Visual Analogue Scale (Pain VAS; 0 [no pain] to 100 [most severe pain]) up to Week 160/156 (biologic-naïve/TNFi-IR). Change from baseline (CfB) and Pain VAS ≥30/50/70% improvement from baseline (BL) are reported.
- Fatigue was assessed using the Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-Fatigue) subscale (0 [worst] to 52 [best]) up to Week 148/156 (biologic-naïve/TNFi-IR). FACIT-Fatigue CfB and minimal clinically important difference (MCID): ≥4-point improvement in patients with BL score ≤48 are reported.
- Data reported as observed case (OC) and using modified non-responder imputation (mNRI; binary) or multiple imputation (MI; continuous). mNRI considered all visits following discontinuation due to adverse events or lack of efficacy as non-response; all other missing data were imputed with MI and the response derived from the imputed values.

Results

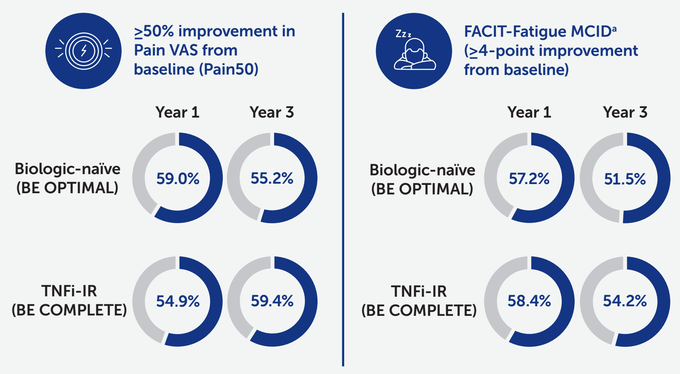
- Overall, 546/712 (76.7%) patients completed Week 160 of BE OPTIMAL; 299/400 (74.8%) completed Week 156 of BE COMPLETE.
- Baseline demographics and disease characteristics are shown in **Table 1**.
- Improvements in both pain and fatigue observed at 1 year were sustained through 3 years on BKZ treatment (**Figure 1**).
- Over half of patients treated with BKZ sustained a major improvement in Pain VAS (≥50% improvement from BL)[2] from 1 year through 3 years (**Figure 2**).
- Similarly, over half of patients treated with BKZ sustained FACIT-Fatigue MCID from 1 year through 3 years (**Figure 3**).

Conclusions

- **Bimekizumab treatment resulted in sustained improvements through 3 years in patient-reported pain and fatigue, symptoms that greatly impact the quality of life of patients with PsA.[1,2]**
- **Consistent results were observed in biologic-naïve and TNFi-IR patients.**
- **These results complement the clinical improvements with bimekizumab treatment reported previously.[3,4]**

Summary

Pain and **fatigue** are features of psoriatic arthritis with a profound impact on patients' **quality of life**



Bimekizumab treatment demonstrated **sustained, clinically meaningful improvements** through **3 years** in **patient-reported pain and fatigue** in patients with PsA who were biologic-naïve or had TNFi-IR

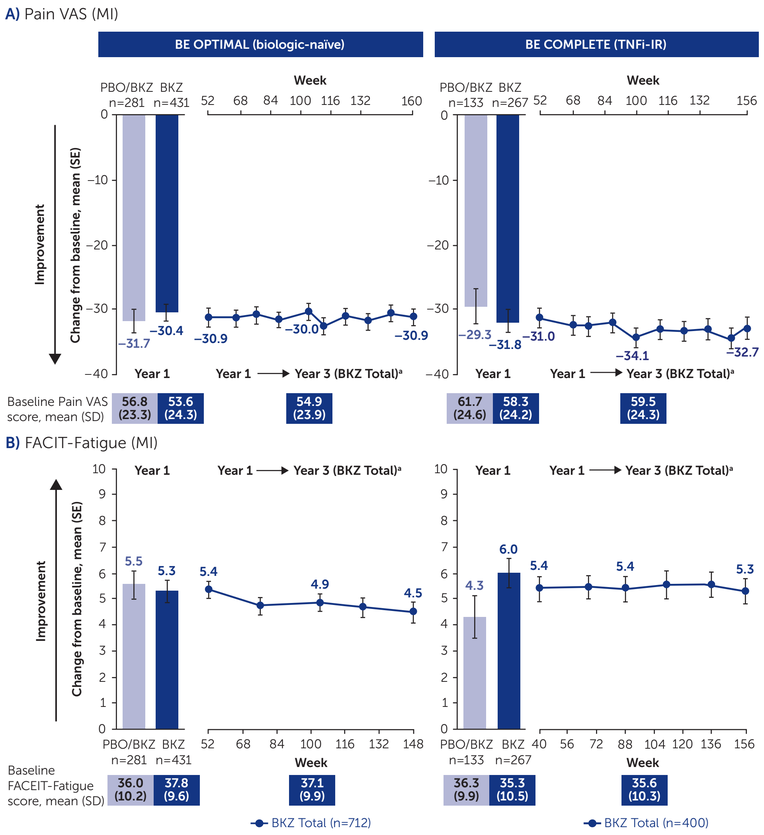
mNRI data reported. The Bimekizumab Total group included bimekizumab-randomised patients and placebo patients that switched to bimekizumab at Week 16. Pain VAS reported from Year 1 (Week 52 in biologic-naïve and TNFi-IR patients) through Year 3 (Week 160 in biologic-naïve patients and Week 156 in TNFi-IR patients). FACIT-Fatigue reported from Year 1 (Week 52 in biologic-naïve patients and Week 40 in TNFi-IR patients), through Year 3 (Week 148 in biologic-naïve patients and Week 156 in TNFi-IR patients). **[a]** In patients with FACIT-Fatigue score ≤48 at baseline.

Table 1 Baseline characteristics

	BE OPTIMAL (Biologic-naïve)	BE COMPLETE (TNFi-IR)
	BKZ Total[a] (n=712)	BKZ Total[a] (n=400)
Age, **years**, mean (SD)	48.6 (12.2)	50.5 (12.5)
Sex, **male**, n (%)	328 (46.1)	190 (47.5)
BMI, kg/m², mean (SD)	29.4 (6.5)	29.8 (6.2)
Time since first PsA diagnosis (years),[b] mean (SD)	5.8 (7.0)	9.5 (9.3)
BSA affected by psoriasis ≥3%, n (%)	357 (50.1)	264 (66.0)
PASI score,[c] mean (SD)	8.1 (6.4)	9.6 (8.4)
TJC (of 68 joints), mean (SD)	16.9 (12.1)	18.7 (13.8)
SJC (of 66 joints), mean (SD)	9.2 (6.6)	9.9 (7.7)
HAQ-DI,[d] mean (SD)	0.85 (0.59)	0.99 (0.62)
Enthesitis (LEI >0),[e] n (%)	213 (29.9)	142 (35.5)
LEI score,[e,f] mean (SD)	2.6 (1.5)	2.7 (1.5)
Dactylitis (LDI >0),[g] n (%)	89 (12.5)	48 (12.0)
LDI score,[g,h] mean (SD)	47.0 (49.6)	70.9 (117.0)
Pain VAS,[i] mean (SD)	54.9 (23.9)	59.5 (24.3)
FACIT-Fatigue,[i] mean (SD)	37.1 (9.9)	35.6 (10.3)

Randomised set. **[a]** BKZ Total group included BKZ-randomised patients and PBO patients that switched to BKZ at Week 16; **[b]** Data missing for 9 biologic-naïve patients and 2 TNFi-IR patients; **[c]** In patients with psoriasis affecting body surface area ≥3% at baseline; **[d]** Data missing for 1 biologic-naïve patient; **[e]** Data missing for 6 biologic-naïve patients and 1 TNFi-IR patient; **[f]** In patients with enthesitis at baseline (LEI >0); **[g]** Data missing for 7 biologic-naïve patients and 1 TNFi-IR patient; **[h]** In patients with dactylitis at baseline (LDI >0); **[i]** Data missing for 1 biologic-naïve patient.

Figure 1 Change from baseline in Pain VAS and FACIT-Fatigue scores to Week 160/156 (MI)



Randomised set. Pain VAS reported from Year 1 (Week 52 in biologic-naïve and TNFi-IR patients), through Year 2 (Week 104 in biologic-naïve patients and Week 100 in TNFi-IR patients), and Year 3 (Week 160 in biologic-naïve patients and Week 156 in TNFi-IR patients). FACIT-Fatigue reported from Year 1 (Week 52 in biologic-naïve patients and Week 40 in TNFi-IR patients), through Year 2 (Week 104 in biologic-naïve patients and Week 88 in TNFi-IR patients) and Year 3 (Week 148 in biologic-naïve patients and Week 156 in TNFi-IR patients). **[a]** BKZ Total group included BKZ-randomised patients and PBO patients that switched to BKZ at Week 16.

Figure 2 Pain VAS clinically important improvements (≥30/50/70% from baseline) to Week 160/156 (mNRI, OC)

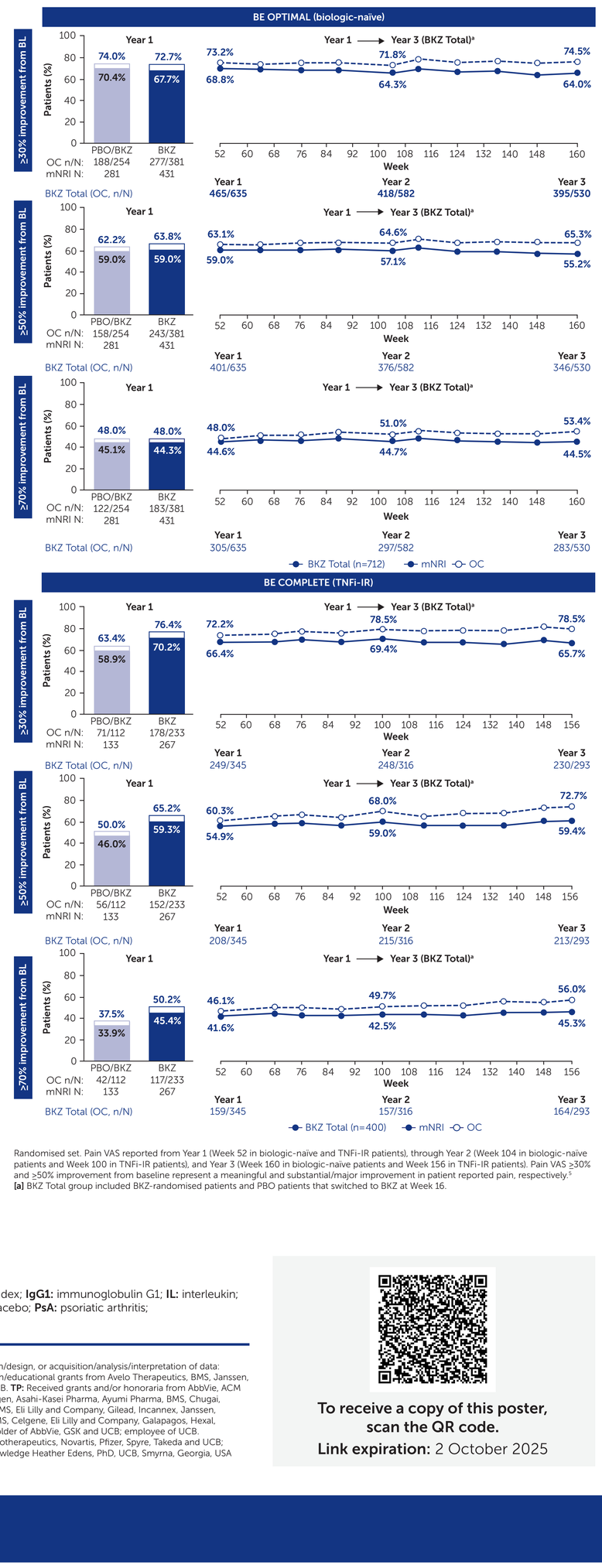
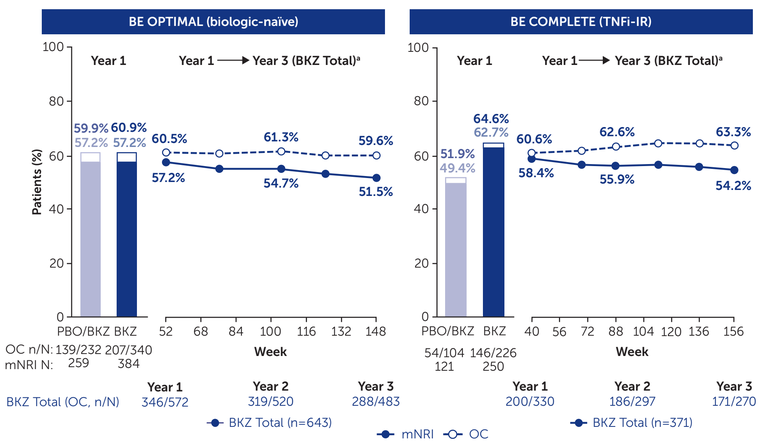


Figure 3 FACIT-Fatigue minimal clinically important difference (MCID) to Week 148/156 (mNRI, OC)



Randomised set, in patients with FACIT-Fatigue score ≤48 at baseline. FACIT-Fatigue reported from Year 1 (Week 52 in biologic-naïve patients and Week 40 in TNFi-IR patients), through Year 2 (Week 104 in biologic-naïve patients and Week 88 in TNFi-IR patients) and Year 3 (Week 148 in biologic-naïve patients and Week 156 in TNFi-IR patients). **[a]** BKZ Total group included BKZ-randomised patients and PBO patients that switched to BKZ at Week 16.

Randomised set. Pain VAS reported from Year 1 (Week 52 in biologic-naïve and TNFi-IR patients), through Year 2 (Week 104 in biologic-naïve patients and Week 100 in TNFi-IR patients), and Year 3 (Week 160 in biologic-naïve patients and Week 156 in TNFi-IR patients). Pain VAS ≥30% and ≥50% improvement from baseline represent a meaningful and substantial/major improvement in patient reported pain, respectively.[5] **[a]** BKZ Total group included BKZ-randomised patients and PBO patients that switched to BKZ at Week 16.

[a] Affiliation at time of studies. Current affiliation: Department of Dermatology, UT Southwestern Medical Center, Dallas, Texas, USA.

BKZ: bimekizumab; **BL:** baseline; **BSA:** body surface area; **BMI:** body mass index; **CfB:** change from baseline; **FACIT-Fatigue:** Functional Assessment of Chronic Illness Therapy-Fatigue; **HAQ-DI:** Health Assessment Questionnaire-Disability Index; **IgG1:** immunoglobulin G1; **IL:** interleukin; **LEI:** Leeds Enthesitis Index; **LDI:** Leeds Dactylitis Index; **MCID:** minimal clinically important difference; **MI:** multiple imputation; **mNRI:** modified non-responder imputation; **OC:** observed case; **PASI:** Psoriasis Area and Severity Index; **PBO:** placebo; **PsA:** psoriatic arthritis; **Q4W:** every 4 weeks; **SD:** standard deviation; **SE:** standard error; **SJC:** swollen joint count; **TJC:** tender joint count; **TNFi-IR:** tumour necrosis factor inhibitor inadequate response/intolerance; **VAS:** visual analogue scale.

References: [1]Coates LC et al. Nat Rev Rheumatol 2022;18:465–79; [2]Ogdie A et al. RMD Open 2020;6:e001321; [3]Gossec L et al. EULAR 2025 (Abstract); [4]McInnes IB et al. EULAR 2025 (Abstract); [5]Dworkin RH et al. J Pain 2008;9:105–21. **Author Contributions:** Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: **ABG**, **TP**, **MK**, **DN**, **FP**, **WT**, **BI**, **RB**, **JC**, **JL**, **PJM**; Drafting of the publication, or reviewing it critically for important intellectual content: **ABG**, **TP**, **MK**, **DN**, **FP**, **WT**, **BI**, **RB**, **JC**, **JL**, **PJM**; Final approval of the publication: **ABG**, **TP**, **MK**, **DN**, **FP**, **WT**, **BI**, **RB**, **JC**, **JL**, **PJM**. **Author Disclosures: ABG:** Received research/educational grants from Avelo Therapeutics, BMS, Janssen, MoonLake Immunotherapeutics and UCB (all paid to Mount Sinai School of Medicine until 2 May 2025); received honoraria/speaker fees as an advisory board member and consultant for Amgen, Eli Lilly and Company, Highlights Therapeutics, Janssen, Novartis, Sanofi, Sun Pharma, Takeda, Teva and UCB. **TP:** Received grants and/or honoraria from AbbVie, ACM Pharma, Almirall, Amgen, Astellas, BMS, Calypso, Celgene, Eli Lilly and Company, Galderma, Genzyme/Sanofi, GSK, Incyte, Janssen, LEO Pharma, Novartis, Pfizer, Sun Pharmaceuticals, Takeda, UCB and Vyne Therapeutics; is the cofounder of NIKAIA Pharmaceuticals. **MK:** Speakers' bureau: AbbVie, Amgen, Asahi-Kasei Pharma, Ayumi Pharma, BMS, Chugai, Daiichi Sankyo, Eisai, Gilead, Janssen, Eli Lilly and Company, Novartis, Tanabe-Mitsubishi and UCB. Consultant: AbbVie, Amgen, Asahi-Kasei Pharma, Ayumi Pharma, BMS, Chugai, Gilead, Janssen, Eli Lilly and Company, Novartis, Takeda, Tanabe-Mitsubishi and UCB. **DN:** Research support from Abbvie, BMS, Eli Lilly and Company, Gilead, Incannex, Janssen, Novartis, Pfizer, Servatus, Sun Pharma and UCB. Advisory board or speaker fees: Abbvie, AstraZeneca, Janssen, Novartis, Pfizer, Sandoz and UCB. **FP:** Received grant/research support from Eli Lilly and Company, Novartis and UCB; received consultancy fees and speakers bureau from AbbVie, Amgen, BMS, Celgene, Eli Lilly and Company, Galapagos, Hexal, Janssen, Medscape, MoonLake Immunotherapeutics, MSD, Novartis, Pfizer, Roche and UCB. **WT:** Research grants, consulting fees, speaking fees and/or honoraria from AbbVie, Amgen, BMS, Celgene, Eli Lilly and Company, GSK, Janssen, MSD, Novartis, Ono Pharma, Pfizer, Takeda and UCB. **BI:** Shareholder of AbbVie, GSK and UCB; employee of UCB. **RB**, **JC**, **JL:** Employee and shareholder of UCB. **PJM:** Research grants from AbbVie, Acelyrin, Amgen, BMS, Eli Lilly and Company, Janssen, Novartis, Pfizer, Sana, and UCB; consulting fees from AbbVie, Acelyrin, Amgen, BMS, Century, Cullinan, Eli Lilly and Company, Inmagene, Janssen, Moonlake Immunotherapeutics, Novartis, Pfizer, Spyre, Takeda and UCB; speakers bureau fees from AbbVie, Amgen, Eli Lilly and Company, Janssen, Novartis, Pfizer and UCB. **Acknowledgements:** These studies were funded by UCB. We thank the patients and their caregivers in addition to the investigators and their teams who contributed to these studies. The authors acknowledge Heather Edens, PhD, UCB, Smyrna, Georgia, USA for publication coordination, Lilit Ghazaryan, MBiol, Costello Medical, London, UK for medical writing and editorial assistance and the Costello Medical Creative Team for design support. All costs associated with development of this poster were funded by UCB.

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Presented at the International Conference of the Skin Inflammation & Psoriasis International Network | 2–4 July 2025 | Paris, France