Bimekizumab-Treated Patients with Active Psoriatic Arthritis Showed Sustained Improvements in Pain and Fatigue: Up to 2-Year Results from Two Phase 3 Studies

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Objective

To report the impact of longer-term bimekizumab (BKZ) treatment up to 2 years on patient-reported pain and fatigue in patients with psoriatic arthritis (PsA) who were biologic disease-modifying antirheumatic drug (bDMARD)-naïve or had inadequate response or intolerance to tumor necrosis factor inhibitors (TNFi-IR).

Background

- Sustained relief from pain and fatigue are important treatment goals for improving the quality of life of patients with PsA.[1]
- BKZ, a monoclonal IgG1 antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A, has demonstrated improvements in pain and fatigue to Week 16 that were sustained to 1 year in patients with active PsA.[2]

Methods

- The BE OPTIMAL (NCT03895203) and BE COMPLETE (NCT03896581) phase 3 studies assessed subcutaneous BKZ 160 mg every 4 weeks (Q4W) in patients with PsA who were bDMARD-naïve or TNFi-IR (**Figure 1**).[3]
- Patients who completed Week 52 of BE OPTIMAL and Week 16 of BE COMPLETE were eligible to enter the open-label extension, BE VITAL (NCT04009499), in which all patients received BKZ 160 mg Q4W.[3]
- Data for patients randomized to placebo (PBO) or BKZ in BE OPTIMAL and BE COMPLETE are reported here.
- Arthritis pain was assessed using Patient's Assessment of Arthritis Pain Visual Analog Scale (Pain VAS; 0 [no pain] to 100 [most severe pain]) to Week 104 in BE OPTIMAL and Week 100 in BE COMPLETE.
- Fatigue was assessed using the Functional Assessment of Chronic Illness Therapy–Fatigue (FACIT–Fatigue) subscale (0 [worst] to 52 [best]) to Week 104 in BE OPTIMAL and Week 88 in BE COMPLETE.
- Change from baseline (BL) and clinically important improvements (Pain VAS: ≥30/50/70% improvement from BL; FACIT-Fatigue minimal clinically important difference [MCID]: ≥4-point improvement in patients with BL score ≤48) are reported here.
- Data reported as observed and using non responder imputation (NRI; binary) or multiple imputation (MI; continuous).

Results

- 710/852 (83.3%) and 322/400 (80.5%) patients completed Week 104/100 of BE OPTIMAL and BE COMPLETE.
- Improvements in pain achieved at 1 year were sustained up to 2 years in PBO/BKZ and BKZ-randomized patients (**Figure 2A** and **Figure 3**).
- Approximately half of patients in all treatment groups achieved a substantial reduction (≥50% improvement from BL)[4] in Pain VAS at Week 104/100 (**Figure 3**).
- Similarly, improvements in fatigue outcomes achieved at 1 year were sustained up to 2 years in PBO/BKZ and BKZ-randomized patients (**Figure 2B** and **Figure 4**).

Conclusions

Treatment with bimekizumab demonstrated substantial improvements in pain and clinically meaningful improvements in fatigue that were sustained up to 2 years. Similar improvements were observed irrespective of prior bDMARD treatment.

Summary

Pain and **fatigue** are key features of psoriatic arthritis that impact patients' **quality of life**

Improvements in patient-reported **pain** and **fatigue** at 1 year in **bimekizumab-treated patients** were **sustained up to 2 years** in both **bDMARD-naïve** and **TNFi-IR** patients with active PsA:

Placebo → Bimekizumab ● Bimekizumab

≥50% improvement in Pain VAS (Pain50)

	Week 52	Week 104	Week 40	Week 100
bDMARD-naïve (BE OPTIMAL)	56.2%	54.8%	40.6%	48.9%
TNFi-IR (BE COMPLETE)	56.4%	51.5%	57.3%	56.2%

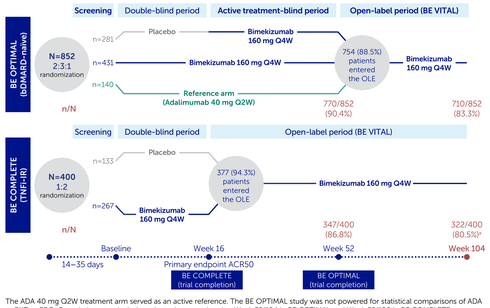
FACIT-Fatigue MCID (≥4-point improvement from baseline)

	Week 52	Week 104	Week 40	Week 88
bDMARD-naïve (BE OPTIMAL)	53.7%	49.0%	44.6%	45.5%
TNFi-IR (BE COMPLETE)	53.9%	50.0%	58.4%	52.4%

Bimekizumab treatment led to **sustained improvements in pain and fatigue** irrespective of prior bDMARD treatment up to 2 years

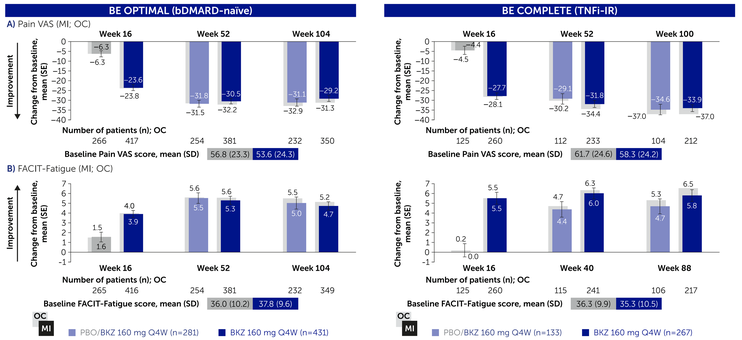
NRI data reported.

Figure 1 Study designs



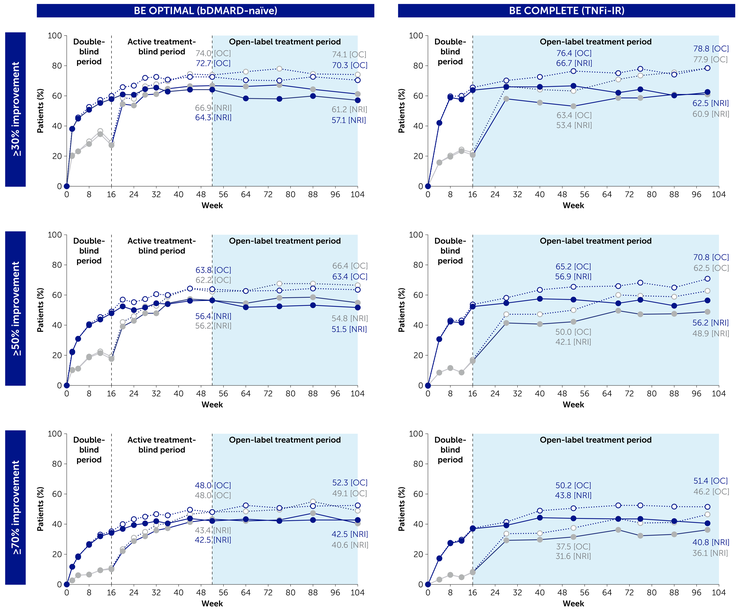
The ADA 40 mg Q2W treatment arm served as an active reference. The BE OPTIMAL study was not powered for statistical comparisons of ADA to BKZ or PBO. Completion rates include patients that completed to Week 52/104 in BE OPTIMAL and Week 52/100 in BE COMPLETE not on randomized treatment. [a] Patients who completed to Week 100 of BE COMPLETE (not including 2 ongoing patients). There were no ongoing patients in BE OPTIMAL at Week 104.

Figure 2 Pain VAS and FACIT-Fatigue change from baseline at Week 16, Week 52/40 and Week 104/100/88 (MI, OC)



Randomized set. MI (colored bars) and OC (light grey bars) data reported. MI SE bars presented here; OC SD data not shown. Pain VAS assessed to Week 100 in BE COMPLETE. FACIT-Fatigue data collected at Week 40 and Week 88 in BE COMPLETE.

Figure 3 Pain VAS clinically important improvements (≥30/50/70% from baseline) to Week 104/100 (NRI, OC)



Number of patients (n); OC

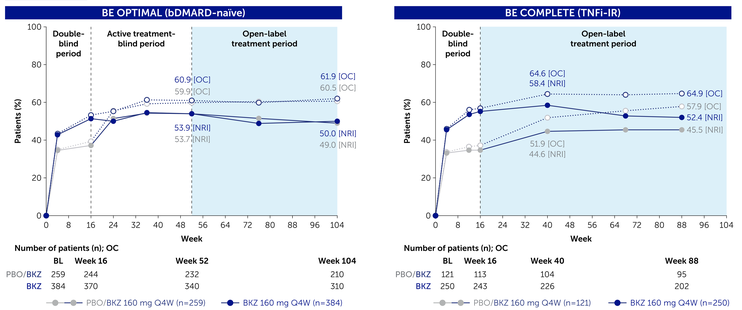
	BL	Week 16	Week 52	Week 104
PBO/BKZ	281	266	254	232
BKZ	430	416	381	350

	BL	Week 16	Week 52	Week 100
PBO/BKZ	133	125	112	104
BKZ	267	260	233	212

PBO/BKZ 160 mg Q4W (BE OPTIMAL: n=281; BE COMPLETE: n=133)
BKZ 160 mg Q4W (BE OPTIMAL: n=431; BE COMPLETE: n=267)
NRI ··○·· OC

Randomized set. Pain VAS assessed to Week 104 in BE OPTIMAL and Week 100 in BE COMPLETE. Pain VAS ≥30% and ≥50% improvement from baseline represent a meaningful and substantial improvement in patient reported pain, respectively.[4]

Figure 4 FACIT-Fatigue minimal clinically important difference (MCID) to Week 104/88 (NRI, OC)



Number of patients (n); OC

	BL	Week 16	Week 52	Week 104
PBO/BKZ	259	244	232	210
BKZ	384	370	340	310

	BL	Week 16	Week 40	Week 88
PBO/BKZ	121	113	104	95
BKZ	250	243	226	202

PBO/BKZ 160 mg Q4W (n=259)
BKZ 160 mg Q4W (n=384)
PBO/BKZ 160 mg Q4W (n=121)
BKZ 160 mg Q4W (n=250)
NRI ··○·· OC

Randomized set. Data collected at Week 40 and Week 88 in BE COMPLETE. FACIT–Fatigue MCID defined as score increase from baseline ≥4 in patients with FACIT-Fatigue score ≤48 at baseline.

ACR50: ≥50% improvement from baseline in American College of Rheumatology response criteria; **ADA:** adalimumab; **bDMARD:** biologic disease-modifying antirheumatic drug; **BKZ:** bimekizumab; **BL:** baseline; **FACIT-Fatigue:** Functional Assessment of Chronic Illness Therapy–Fatigue; **IL:** interleukin; **MCID:** minimal clinically important difference; **MI:** multiple imputation; **NRI:** non-responder imputation; **OC:** observed case; **OLE:** open-label extension; **PBO:** placebo; **PsA:** psoriatic arthritis; **Q2W:** every 2 weeks; **Q4W:** every 4 weeks; **SD:** standard deviation; **SE:** standard error; **TNFi-IR:** prior inadequate response or intolerance to tumor necrosis factor inhibitors; **VAS:** visual analog scale.

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References: [1]Coates LC. Nat Rev Rheumatol 2022;18:465–79; [2]Husni ME. ACR 2023 (Poster 0527); [3]Mease PJ. Rheumatol Ther 2024;11:1363–82; [4]Dworkin RH. J Pain 2008;9:105–21. **Author Contributions:** Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: **PJM, WT, MdW, LG, MEH, FP, BI, RB, JC, JL, LCC, ABG.** Drafting of the publication, or reviewing it critically for important intellectual content: **PJM, WT, MdW, LG, MEH, FP, BI, RB, JC, JL, LCC, ABG.** Final approval of the publication: **PJM, WT, MdW, LG, MEH, FP, BI, RB, JC, JL, LCC, ABG.** **Author Disclosures: PJM:** Research grants from AbbVie, Acelyrin, Amgen, Bristol-Myers Squibb, Eli Lilly and Company, Janssen, Novartis, Pfizer, Sana, and UCB; consulting fees from AbbVie, Acelyrin, Amgen, Bristol-Myers Squibb, Cullinan, Eli Lilly and Company, GSK, Inmagene, Janssen, Moonlake Pharma, Novartis, Pfizer, Takeda, UCB, and Ventyx; speakers bureau fees from AbbVie, Amgen, Eli Lilly and Company, Janssen, Novartis, Pfizer, and UCB. **WT:** Received 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, and UCB. **MdW:** Received fees for speaking and consultancy from Celgene, Eli Lilly, Janssen-Cilag, Pfizer, and UCB (all paid to Stichting Tools). **LG:** Received grants or contracts from AbbVie, Biogen, Eli Lilly, Novartis, and UCB; consulting fees from AbbVie, BMS, Celltrion, Janssen, Novartis, Pfizer, UCB; honoraria for lectures from AbbVie, Amgen, BMS, Celltrion, Janssen, Lilly, MSD, Novartis, Pfizer, Stada, UCB; support for attending meetings and/or travel from MSD, Novartis, and Pfizer; medical writing support from AbbVie, Amgen, Galapagos, Janssen, Pfizer, and UCB; membership on an entity's Board of Directors or advisory committees: EULAR Treasurer. **MEH:** Advisory board member and consultant for AbbVie, Amgen, BMS, Eli Lilly, Janssen, Novartis, Pfizer, and UCB. **FP:** Received grant/research support from Eli Lilly and Company, Novartis and UCB; consultancy fees and speakers bureau from AbbVie, Amgen, BMS, Celgene, Eli Lilly and Company, Galapagos, Hexal, Janssen, Medscape, Moonlake Pharma, MSD, Novartis, Pfizer, Roche and UCB. **BI:** Employee of UCB; shareholder of AbbVie, GSK, and UCB. **RB, JC, JL:** Employees and shareholders of UCB. **LCC:** Received grants/research support from AbbVie, Amgen, Celgene, Eli Lilly, Gilead, Janssen, Novartis, Pfizer, and UCB; consultant for AbbVie, Amgen, BMS, Boehringer Ingelheim, Celgene, Domain, Eli Lilly, Galapagos, Gilead, Janssen, MoonLake Immunotherapeutics, Novartis, Pfizer, and UCB; received speaking fees from AbbVie, Amgen, Biogen, Celgene, Eli Lilly, Galapagos, Gilead, GSK, Janssen, medac, Novartis, Pfizer, and UCB. **ABG:** Received honoraria as an advisory board member and consultant for Amgen, Eli Lilly and Company, Highlights Therapeutics, Janssen, Novartis, Sanofi, SunPharma, Takeda, Teva, UCB, and XBiotech (stock options for RA; research/educational grants from Bristol Myers Squibb, Janssen, MoonLake Immunotherapeutics and UCB (all paid to Mount Sinai School of Medicine). **Acknowledgments:** We would like to thank the patients and their caregivers in addition to all the investigators and their teams who contributed to these studies. The authors acknowledge Heather Edens, PhD, UCB, Smyrna, GA, USA, for publication coordination, Orla Woodward, PhD, Costello Medical, London, UK, for medical writing and editorial assistance, and the Costello Medical Creative team for graphic design assistance. These studies were funded by UCB. All costs associated with development of this presentation were funded by UCB.

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