Achieving Increasingly Stringent Clinical Disease Control Criteria is Associated with Greater Improvements in Patient-Centric Measures of Physical Function and Pain in Patients with Active PsA: 16-Week Results from Two Phase 3 Randomized, Placebo-Controlled Studies

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Objective

To examine the association between achieving increasingly stringent clinical disease control criteria and improvements in patient-centric measures of physical function and pain in patients with psoriatic arthritis (PsA).

Background

- Bimekizumab (BKZ) is a monoclonal IgG1 antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A.
- BKZ has demonstrated superior efficacy compared with placebo and was well tolerated up to 16 weeks in patients with active PsA in the phase 3 studies BE OPTIMAL (NCT03895203; biologic disease-modifying antirheumatic drug [bDMARD]-naïve patients) and BE COMPLETE (NCT03896581; prior inadequate response or intolerance to tumor necrosis factor inhibitor [TNFi-IR]).[1,2]
- Here, we present a post hoc analysis of the association between achievement of increasingly stringent clinical disease control at Week 16 and improvements in patient-reported measures of physical function and pain in these studies.

Methods

- Within each study, all patients who reached the following disease control criteria at Week 16 were pooled regardless of treatment arm (placebo/BKZ 160 mg every four weeks [Q4W]/adalimumab 40 mg every two weeks [Q2W; additional reference arm in BE OPTIMAL]):
  - **ACR:** ACR20 not reached (<ACR20), ACR20 reached but ACR50 not reached (ACR20–<ACR50), ACR50 reached but ACR70 not reached (ACR50–<ACR70), ACR70 reached (≥ACR70)
  - **MDA:** non-MDA, MDA
  - **DAPSA:** high disease activity (HDA), moderate disease activity (MoDA), low disease activity/remission (LDA/REM)
  - **PASI:** 50% improvement from baseline not reached (<PASI50), ≥50% reached but 75% not reached (PASI50–<PASI75), ≥75% reached but 90% not reached (PASI75–<PASI90), ≥90% reached (PASI90)
- Associations between achievement of these criteria and improvements in patient-reported measures of physical function (**HAQ-DI:** 0 [best] to 3 [worst]) and pain (**PtAAP:** 0 [best] to 100 [worst]) were assessed; it should be noted that PtAAP is a component of ACR, DAPSA and MDA and HAQ-DI is a component of ACR and MDA.
- Observed case data are reported.

Results

Patients

- Of randomized patients, 821/852 (96.4%) bDMARD-naïve patients and 388/400 (97.0%) TNFi-IR patients completed Week 16.
- Baseline HAQ-DI and PtAAP scores were similar between bDMARD-naïve and TNFi-IR patients, indicating consistent physical function and pain burden (Table 1).

Association Between Disease Control and Patient-Reported Physical Function and Pain

- Patients achieving higher ACR response thresholds demonstrated sequentially greater mean improvements from baseline in HAQ-DI scores, irrespective of prior biologic treatment (Figure 1).
- Patients achieving MDA demonstrated greater improvements from baseline in HAQ-DI scores than those who did not achieve MDA. For DAPSA, sequentially greater improvements were observed in patients with HDA, MoDA and LDA/REM, respectively (Figure 1).
- Patients achieving greater improvements from baseline in PASI score generally reported greater improvements from baseline in HAQ-DI scores (Figure 1).
- Similar results were seen for pain, with patients achieving increasingly stringent disease control criteria also demonstrating sequentially greater improvements from baseline in PtAAP scores, irrespective of prior biologic treatment (Figure 2).

Summary

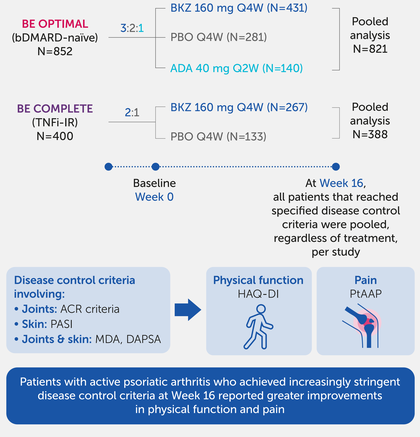


Table 1 Patient demographics and baseline characteristics

	BE OPTIMAL (bDMARD-naïve) N=852	BE COMPLETE (TNFi-IR) N=400
Age, years, mean (SD)	48.7 (12.3)	50.5 (12.5)
Sex, male, n (%)	399 (46.8)	190 (47.5)
BMI, kg/m^2, mean (SD)	29.2 (6.4)	29.8 (6.2)
PsA duration,[a] years, mean (SD)	5.9 (7.0)	9.5 (9.3)
Concomitant methotrexate, n (%)	496 (58.2)	170 (42.5)
TJC (of 68 joints), mean (SD)	17.0 (12.2)	18.7 (13.8)
SJC (of 66 joints), mean (SD)	9.2 (6.7)	9.9 (7.7)
hs-CRP ≥6 mg/L, n (%)	323 (37.9)	177 (44.3)
Psoriasis BSA ≥3%, n (%)	425 (49.9)	264 (66.0)
PASI score,[b] mean (SD)	8.1 (6.6)	9.6 (8.4)
HAQ-DI,[c] mean (SD)	0.85 (0.59)	0.99 (0.62)
PtAAP;[c,d] mean (SD)	55.2 (23.9)	59.5 (24.3)
Enthesitis,[e] n (%)	249 (29.2)[f]	142 (35.5)[g]
Score,[h] mean (SD)	2.6 (1.5)	2.7 (1.5)
Dactylitis,[i] n (%)	100 (11.7)[j]	48 (12.0)[g]
Score,[k] mean (SD)	47.3 (47.8)	70.9 (117.0)

Randomized set. [a]Listed as time since diagnosis of PsA; BE OPTIMAL: placebo n=279, BKZ n=423, ADA n=139; BE COMPLETE: data missing for one patient receiving placebo and one patient receiving BKZ; [b]In patients with ≥3% BSA with PSO at baseline; [c]BE OPTIMAL: data missing for 1 BKZ patient; [d]PtAAP VAS 0–100; [e]Leeds Enthesitis Index >0; [f]Data missing for 7 patients; [g]Data missing for 1 patient; [h]In patients with enthesitis; [i]Leeds Dactylitis Index >0; [j]Data missing for 9 patients; [k]In patients with dactylitis.

Figure 1 Achieving greater disease control is associated with greater improvements in patient-reported physical function (HAQ-DI)

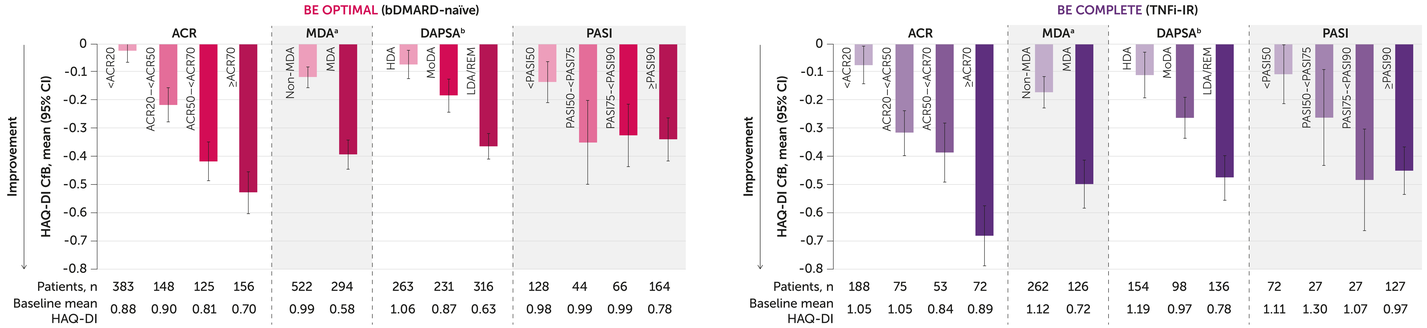
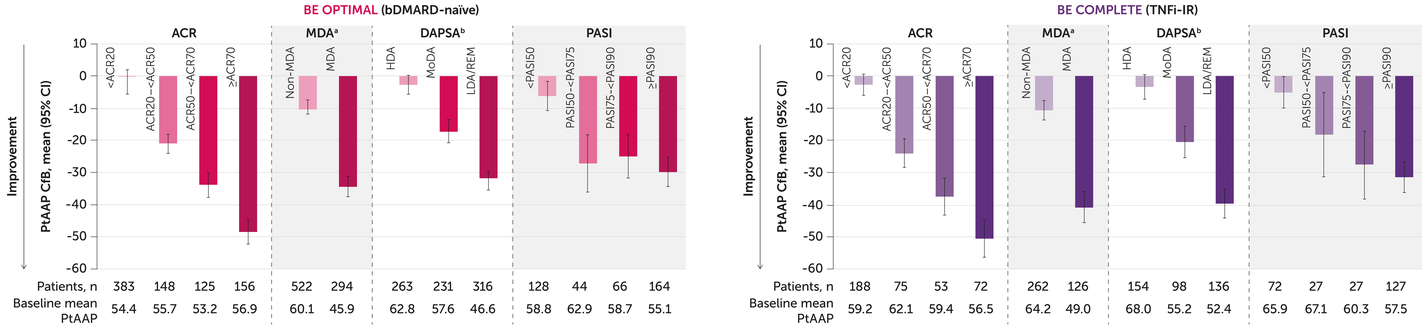


Figure 2 Achieving greater disease control is associated with greater improvements in patient-reported pain (PtAAP)



Data reported as observed case. Categories are mutually exclusive. [a]MDA response defined as achievement of at least 5 of the 7 following criteria: TJC ≤1; SJC ≤1; PASI ≤1 or BSA ≤3%; PtAAP ≤15 mm; Patient's Global Assessment-PsA ≤20 mm; HAQ-DI ≤0.5; Leeds Enthesitis Index ≤1; [b]HDA: >28; MoDA: >14 to ≤28; LDA/REM: ≤14.

Conclusions

Patients with active PsA who achieved increasingly stringent disease control criteria at Week 16 reported sequentially greater improvements in physical function and reductions in pain, which would be expected to lead to improved quality of life, regardless of whether they were bDMARD-naïve (BE OPTIMAL) or TNFi-IR (BE COMPLETE).

ADA: adalimumab; **ACR:** American College of Rheumatology; **bDMARD:** biologic disease-modifying antirheumatic drug; **BKZ:** bimekizumab; **BMI:** body mass index; **BSA:** body surface area; **CfB:** change from baseline; **CI:** confidence interval; **DAPSA:** Disease Activity in Psoriatic Arthritis; **HAQ-DI:** Health Assessment Questionnaire-Disability Index; **HDA:** high disease activity; **hs-CRP:** high-sensitivity C-reactive protein; **IL:** interleukin; **LDA:** low disease activity; **MDA:** minimal disease activity; **MoDA:** moderate disease activity; **PASI:** Psoriasis Area and Severity Index; **PsA:** psoriatic arthritis; **PSO:** psoriasis; **PtAAP:** Patient's Assessment of Arthritis Pain; **Q2W:** every 2 weeks; **Q4W:** every 4 weeks; **REM:** remission; **SD:** standard deviation; **SJC:** swollen joint count; **TJC:** tender joint count; **TNFi-IR:** inadequate response or intolerance to tumor necrosis factor inhibitor; **VAS:** visual analogue scale.

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References: [1]McInnes I. Ann Rheum Dis 2022;81:206–7; [2]Merola JF. Ann Rheum Dis 2022;81:167–9. **Author Disclosures: JAW:** Consultant for/grant support from AbbVie, Amgen, Eli Lilly, Janssen, Novartis, Pfizer, and UCB Pharma; **LCC:** Grants/research support from AbbVie, Amgen, Celgene, Eli Lilly, Gilead, Janssen, Novartis, Pfizer, and UCB Pharma; consultant for AbbVie, Amgen, BMS, Boehringer Ingelheim, Celgene, Domain, Eli Lilly, Galapagos, Gilead, Janssen, Moonlake, Novartis, Pfizer, and UCB Pharma; speaking fees from AbbVie, Amgen, Biogen, Celgene, Eli Lilly, Galapagos, Gilead, GSK, Janssen, Medac, Novartis, Pfizer, and UCB Pharma; **PJM:** Research grants from AbbVie, Amgen, BMS, Eli Lilly, Gilead, Janssen, Novartis, Pfizer, Sun Pharma, and UCB Pharma; consultancy fees from AbbVie, Acelyrin, Aclaris, Amgen, BMS, Boehringer Ingelheim, Eli Lilly, Galapagos, Gilead, GSK, Janssen, Moonlake Pharma, Novartis, Pfizer, Sun Pharma and UCB Pharma; speakers' bureau from AbbVie, Amgen, Eli Lilly, Janssen, Novartis, Pfizer and UCB Pharma; **JFM:** Consultant and/or investigator for AbbVie, Amgen, Biogen, BMS, Dermavant, Eli Lilly, Janssen, LEO Pharma, Novartis, Pfizer, Regeneron, Sanofi, Sun Pharma, and UCB Pharma; **PN:** Funding for research, clinical trials, and honoraria for advice and lectures on behalf of AbbVie, BMS, Boehringer Ingelheim, Celgene, Eli Lilly, Galapagos/Gilead, GSK, Janssen, Novartis, Pfizer, Samsung, Sanofi, and UCB Pharma; **ARO:** Grant/research support from AbbVie, Amgen, Novartis, and Pfizer and consultant for AbbVie, Amgen, BMS, Celgene, CorEvitas, Eli Lilly, Gilead, GSK, Janssen, Novartis, Pfizer, and UCB Pharma; **WT:** Grant/research support, consulting fees, speaking fees, and/or honoraria from AbbVie, Amgen, Celgene, Eli Lilly, GSK, Janssen, MSD, Novartis, Pfizer, and UCB Pharma; **PG:** Consultant for AbbVie, Abiogen, Almirall, Celgene, Eli Lilly, Janssen, LEO Pharma, Merck, MSD, Novartis, Otsuka, Pfizer, Pierre Fabre, Sanofi, and UCB Pharma; **BI:** Employee and stockholder of UCB Pharma, and stockholder of AbbVie and GSK; **DA, RB, JL** are all employees and stockholders of UCB Pharma; **VT** and **DW** are employees of UCB Pharma; **LEK:** Grant/research support from AbbVie, Eli Lilly, Novartis, Novo Nordisk, and UCB Pharma, and speaking fees from/consultant for AbbVie, Amgen, Biogen, BMS, Eli Lilly, Gilead, Janssen, MSD, Novartis, and Pfizer, **Acknowledgments:** 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 Pharma, Smyrna, Georgia, USA for publication coordination, Joseph Smith, PhD, Costello Medical, Cambridge, UK for medical writing and editorial assistance, and the Costello Medical Design Team for design support. This study was funded by UCB Pharma. All costs associated with development of this presentation were funded by UCB Pharma.

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