Achieving Stringent Clinical Disease Control Criteria is Associated with Improved Health-Related Quality of Life in Patients with Active Psoriatic Arthritis: Results from Two Phase 3 Randomised, Placebo-Controlled Studies

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Objectives

To examine the association between achieving increasingly stringent clinical disease control and improvements in patient-centric measures of health-related quality of life (HRQoL) in patients with psoriatic arthritis (PsA).

Background

- Bimekizumab (BKZ) is a monoclonal IgG1 antibody that selectively inhibits both interleukin (IL)-17F and IL-17A.
- BKZ has demonstrated efficacy and was well tolerated up to 16 weeks in patients with PsA in the phase 3 studies BE OPTIMAL (NCT03895203; biologic disease-modifying antirheumatic drug [bDMARD]-naïve patients)[1] and BE COMPLETE (NCT03896581; inadequate response/intolerance to tumor necrosis factor [TNF] inhibitors [TNFi-IR]).[2]
- Here, we present a post hoc analysis evaluating associations between achieving increasingly stringent clinical disease control and improvements in patient-reported measures of HRQoL at Week 16 in these studies.

Methods

- Within each study, all patients achieving the following disease control criteria at Week 16 were pooled regardless of treatment arm (placebo/BKZ 160 mg Q4W/adalimumab 40 mg 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.
  - **PsARC:** non-PsARC, PsARC.
- Associations between achievement of these criteria and improvements in HRQoL measures were assessed:
  - **EQ-5D-3L VAS:** 0 [worst] to 100 [best].
  - **EQ-5D-3L utility [UK tariff]:** less than 0 [worst] to 1 [best].[3]
  - Norm based **SF-36 PCS:** higher score reflects better physical function.
- Observed case data are reported.

Results

Patients

- Of randomised patients, 821/852 (96.4%) bDMARD-naïve and 388/400 (97.0%) TNFi-IR patients with PsA completed Week 16.
- Baseline EQ-5D-3L VAS, EQ-5D-3L utility and SF-36 PCS scores were comparable between bDMARD-naïve and TNFi-IR patients, indicating consistent HRQoL burden (**Table 1**).

Association Between Disease Control and Health-Related Quality of Life Measures

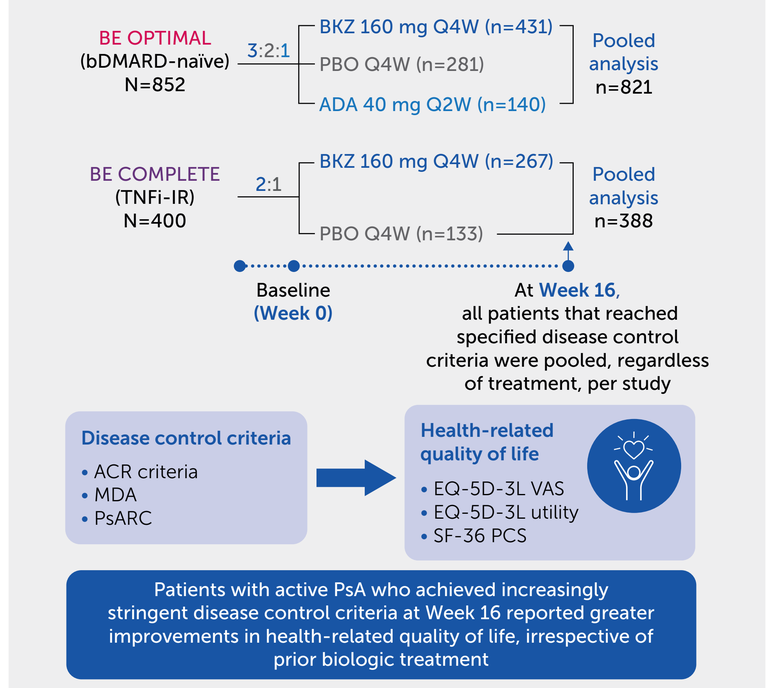
- Patients achieving higher ACR response thresholds demonstrated sequentially greater mean improvements in EQ-5D-3L VAS (**Figure 1A**) and EQ-5D-3L utility (**Figure 1B**).
- Similar associations were observed for patients that achieved MDA or PsARC response composite measures, which assess multiple domains of PsA (**Figures 1A and 1B**).
- ACR, MDA and PsARC responders showed improvements from baseline in SF-36 PCS that were superior to the between group minimally important difference (2 points), compared with non-responders (**Figure 2**).[4]
- Results were similar irrespective of prior biologic treatment (**Figures 1 and 2**).

Conclusions

Patients with active PsA who achieved increasingly stringent disease control criteria at Week 16 reported sequentially greater improvements in HRQoL and physical function, regardless of whether they were bDMARD-naïve (BE OPTIMAL) or TNFi-IR (BE COMPLETE).

Summary

BE OPTIMAL and **BE COMPLETE** both included a **16-week placebo-controlled phase** and **primary endpoint** in both studies was the proportion of patients with **ACR50 response** at **Week 16**



Patients with active PsA who achieved increasingly stringent disease control criteria at Week 16 reported greater improvements in health-related quality of life, irrespective of prior biologic treatment

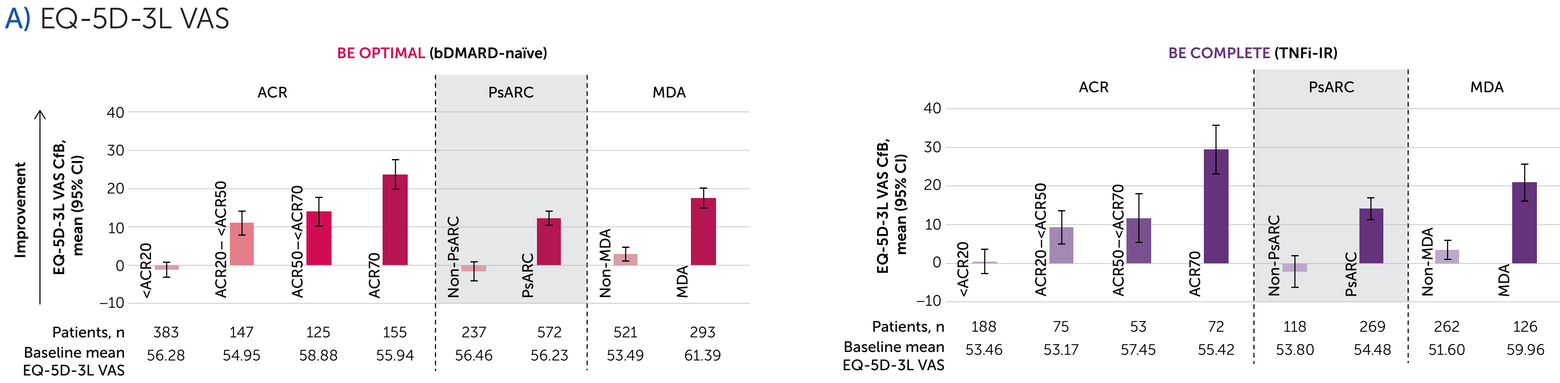
Table 1 Baseline characteristics

	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/m², 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)	0.8 (0.6)	1.0 (0.6)
PtAAP,[c,d] mean (SD)	55.2 (23.9)	59.5 (24.3)
Enthesitis,[e] n (%)	249 (29.2)	142 (35.5)
Score, mean (SD)	2.6 (1.5)	2.7 (1.5)
Dactylitis,[f] n (%)	100 (11.7)	48 (12.0)
Score, mean (SD)	47.3 (47.8)	70.9 (117.0)
EQ-5D-3L VAS,[c] mean (SD)	56.3 (20.0)	54.4 (20.4)
EQ-5D-3L utility,[c] mean (SD)	0.63 (0.23)	0.56 (0.27)
SF-36 PCS,[c] mean (SD)	37.6 (9.4)	36.3 (9.4)

Randomised set. [a]Listed as time since diagnosis of PsA; BE OPTIMAL: n=841; BE COMPLETE: n=398; [b]In patients with ≥3% BSA with PSO at baseline; [c]BE OPTIMAL: data missing for 1 patient; [d]PtAAP VAS 0 (no symptoms) – 100 (severe symptoms); [e]Leeds Enthesitis Index >0; [f]Leeds Dactylitis Index >0.

Figure 1 Achieving greater disease control is associated with greater improvements in patient-reported health-related quality of life at Week 16

A) EQ-5D-3L VAS



B) EQ-5D-3L utility [UK tariff]

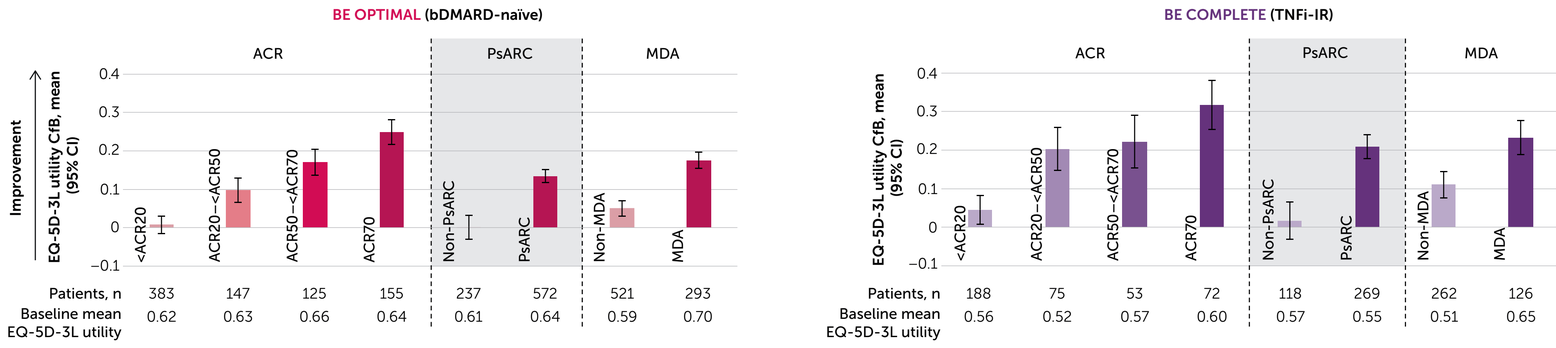
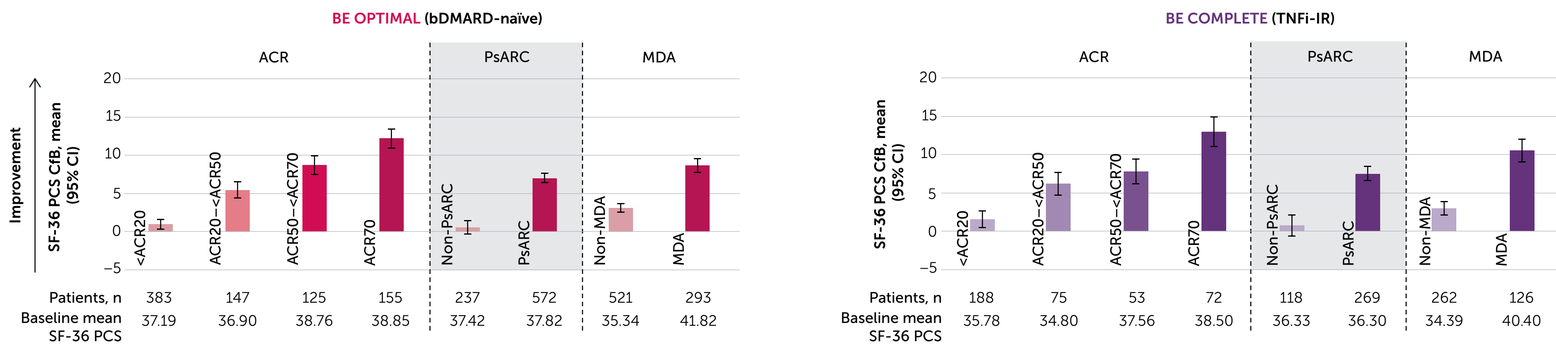


Figure 2 Achieving greater disease control is associated with greater improvements in patient-reported physical functioning at Week 16



Data reported as observed case. Categories are mutually exclusive. 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.

ACR: American College of Rheumatology; **ADA:** adalimumab; **bDMARD:** biologic disease-modifying antirheumatic drug; **BKZ:** bimekizumab; **BMI:** body mass index; **BSA:** body surface area; **CfB:** change from baseline; **CI:** confidence interval; **EQ-5D-3L:** EuroQol-5 Dimensions-3 Level; **HAQ-DI:** Health Assessment Questionnaire-Disability Index; **HRQoL:** health-related quality of life; **hs-CRP:** high sensitivity C-reactive protein; **IL:** interleukin; **MDA:** minimal disease activity; **PASI:** Psoriasis Area and Severity Index; **PBO:** placebo; **PCS:** Physical Component Summary; **PsA:** psoriatic arthritis; **PsARC:** Psoriatic Arthritis Response Criteria; **PSO:** psoriasis; **PtAAP:** Patient's Assessment of Arthritis Pain; **Q2W:** every 2 weeks; **Q4W:** every 4 weeks; **SD:** standard deviation; **SF-36:** Short-Form 36-item Health Survey; **SJC:** swollen joint count; **TJC:** tender joint count; **TNFi-IR:** inadequate response/intolerance to tumour necrosis factor inhibitors; **VAS:** visual analogue scale.

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References: [1]McInnes IB. Ann Rheum Dis 2022;81:206–7; [2]Merola JF. Ann Rheum Dis 2022;81:167–9; [3]Dolan P. Med Care 2002;40:442–6; [4]Maruish ME, editor. 3rd ed. Lincoln, RI: QualityMetric Incorporated; 2011. **Author Disclosures: LEK:** Grant/research support from AbbVie, Eli Lilly, Novartis, Novo Nordisk, and UCB Pharma; speaking fees from/consultant for AbbVie, Amgen, Biogen, BMS, Eli Lilly, Gilead, Janssen, MSD, Novartis, Pfizer, and UCB Pharma. **LCC:** Grant/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. **PN:** Funding for research, clinical trials, and honoraria for advice and lectures on behalf of AbbVie, Boehringer Ingelheim, BMS, Eli Lilly, Galapagos/Gilead, GSK, Janssen, Novartis, Pfizer, Samsung, Sanofi, and UCB Pharma. **ARO:** Grant/research support from AbbVie, Amgen, Novartis, and Pfizer; 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. **ARP** is an employee and stockholder of UCB Pharma, and stockholder of GSK. **DA, RB** and **JL** are employees and stockholders of UCB Pharma. **VT** and **DW** are employees of UCB Pharma. **JAW:** Consultant for/grant/research support from AbbVie, Amgen, Eli Lilly, Janssen, Novartis, Pfizer, and UCB Pharma. **Acknowledgements:** 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, Jessica A. Buttress, BSc, 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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