Achieving Greater Disease Control Criteria was Associated with Improved Work Productivity in Patients with Psoriatic Arthritis up to 2 Years

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Objective

To report the long-term association between achievement of stringent clinical disease control criteria and improvements in work productivity up to 2 years from two phase 3 clinical trials of bimekizumab (BKZ), in patients with active psoriatic arthritis (PsA) who were biologic disease-modifying antirheumatic drug (bDMARD)-naïve or had inadequate response or intolerance to prior tumor necrosis factor inhibitors (TNFi-IR).

Background

- PsA is a chronic, inflammatory disease that negatively impacts patients' physical health and functional ability, contributing to reduced work productivity.[1,2]
- BKZ is a monoclonal IgG1 antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A.

Methods

- This post hoc analysis used data from two phase 3 trials, BE OPTIMAL (NCT03895203; bDMARD-naïve) and BE COMPLETE (NCT03896581; TNFi-IR). Both were double-blind and placebo-controlled to Week 16. Completers of Week 52/16 (BE OPTIMAL/BE COMPLETE) could enter BE VITAL (NCT04009499; open-label extension).
- Data are reported for patients randomized to subcutaneous BKZ 160 mg every 4 weeks at baseline.
- Disease control measures: American College of Rheumatology (ACR) response criteria, Disease Activity Index for PsA (DAPSA), minimal disease activity (MDA), and the composite endpoint ACR ≥50% improvement from baseline and Psoriasis Area and Severity Index 100% improvement from baseline (ACR50+PASI100).
- Work Productivity and Activity Impairment (WPAI) domains assessed include work time missed (absenteeism), impairment while working (presenteeism), and overall work impairment (all are reported in patients employed at baseline); activity impairment is reported in all patients.
- We assessed the change from baseline in WPAI domain scores up to 2 years, and associations between achievement of disease control criteria (mutually exclusive categories) and percentage improvements from baseline in each WPAI domain score at Week 104/88 (BE OPTIMAL/BE COMPLETE; observed case).

Results

- In total, 359/431 (83.3%) and 221/267 (82.8%) BKZ-randomized patients completed Week 104/88 (BE OPTIMAL/BE COMPLETE).
  - Baseline demographics and disease characteristics were generally consistent across both trials; however, TNFi-IR patients had longer time since first PsA diagnosis and higher disease activity compared with bDMARD-naïve patients (**Table**).
  - TNFi-IR patients had numerically higher baseline mean percentage WPAI scores compared with bDMARD-naïve patients (**Table**).
- Improvements from baseline in WPAI domain scores were sustained up to Week 104/88 in BKZ-randomized patients in both the bDMARD-naïve and TNFi-IR populations (**Table**).
- At Week 104/88, patients achieving more stringent clinical disease control criteria generally demonstrated greater improvements in work productivity, particularly in the WPAI domains of presenteeism, overall work impairment, and activity impairment (**Figure 1**).
  - Similar improvements were observed in both bDMARD-naive and TNFi-IR populations across all WPAI domains, with the greatest improvements observed in the WPAI domains of presenteeism, overall work impairment, and activity impairment.
  - Improvements in work productivity in MDA responders vs non-responders were generally more pronounced in bDMARD-naïve patients compared with TNFi-IR patients.
  - Generally, the greatest improvements in WPAI domain scores continued to be seen in patients who sustained stringent disease control in both musculoskeletal and skin domains (ACR50+PASI100), in both bDMARD-naïve and TNFi-IR populations.[3]

Conclusion

At 2 years, achievement of increasingly stringent disease control criteria was associated with greater improvements in work productivity in patients with PsA who were bDMARD-naïve or had TNFi-IR. These results suggest long-term clinical disease control is critical for sustaining improvements in work productivity.

Work productivity improvements for MDA responders were more pronounced in bDMARD-naïve patients compared with TNFi-IR patients, suggesting early and sustained disease control is important for the greatest improvements in work productivity.

Summary

PsA is a chronic disease that substantially impacts patients' physical health and function, leading to **reduced work productivity**. Therefore, it is important to assess the association between **achieving long-term disease control** and patients' work productivity.

The association between **achieving greater disease control** and **percentage improvements from baseline in work productivity and activity impairment** was assessed up to 2 years of BKZ therapy in patients with active PsA who were bDMARD-naïve (BE OPTIMAL) or had TNFi-IR (BE COMPLETE).

Generally, the **greatest improvements** in **WPAI domains** continued to be seen in patients who sustained **stringent disease control** in both musculoskeletal and skin domains (ACR50+PASI100), in both bDMARD-naïve and TNFi-IR populations.[3]

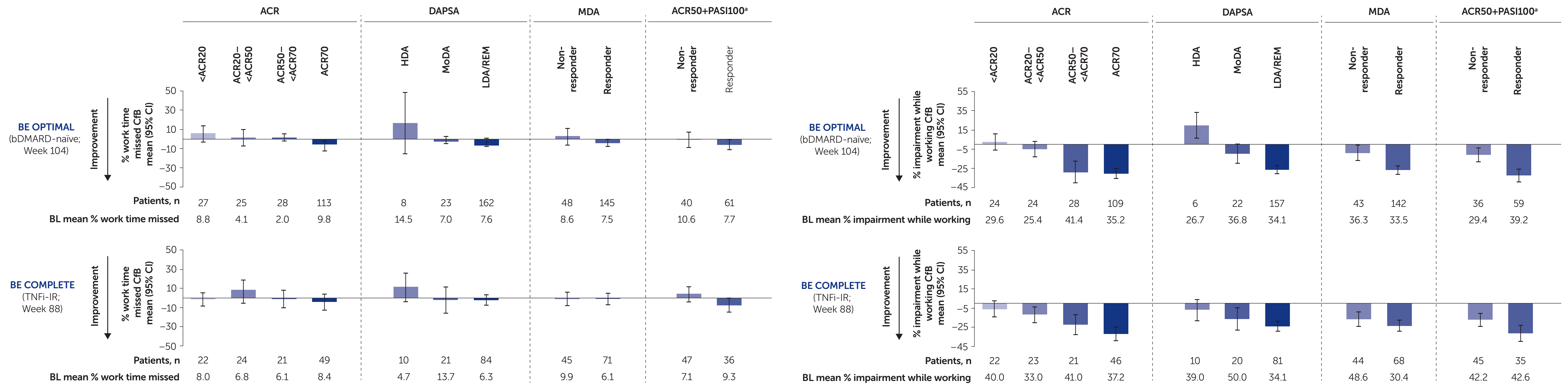
Patients who achieved **increasingly stringent disease control** criteria with **long-term BKZ therapy** demonstrated **greater improvements** in work productivity

Table Baseline characteristics and change from baseline in WPAI domain scores at Week 104/88 (OC)

	BE OPTIMAL (bDMARD-naïve) BKZ 160 mg Q4W (n=431)		BE COMPLETE (TNFi-IR) BKZ 160 mg Q4W (n=267)	
Age, years, mean (SD)	48.5 (12.6)		50.1 (12.4)	
Male, n (%)	201 (46.6)		130 (48.7)	
BMI, kg/m², mean (SD)	29.2 (6.8)		30.1 (6.5)	
Time since first PsA diagnosis (years),[a] mean (SD)	6.0 (7.3)		9.6 (9.9)	
BSA affected by psoriasis ≥3%, n (%)	217 (50.3)		176 (65.9)	
PASI score,[b] mean (SD)	8.2 (6.8)		10.2 (9.1)	
TJC (of 68 joints), mean (SD)	16.8 (11.8)		18.4 (13.6)	
SJC (of 66 joints), mean (SD)	9.0 (6.2)		9.7 (7.5)	
Enthesitis (LEI >0),[c] n (%)	143 (33.2)		106 (39.7)	
LEI score,[c,d] mean (SD)	2.5 (1.5)		2.6 (1.5)	
Dactylitis (LDI >0),[e] n (%)	56 (13.0)		34 (12.7)	
LDI score,[e,f] mean (SD)	46.7 (54.3)		72.7 (114.4)	
HAQ-DI,[g] mean (SD)	0.82 (0.59)		0.97 (0.59)	
Pain VAS,[g,h] mean (SD)	53.6 (24.3)		58.3 (24.2)	
Employed at study start,[g] n (%)	280 (65.1)		171 (64.0)	
	Baseline	**Week 104**	**Baseline**	**Week 88**
	WPAI score,[i, j, k] mean (SD)	**WPAI CfB**,[i, j, k] mean (95% CI) [OC]	**WPAI score**,[i, j, k] mean (SD)	**WPAI CfB**,[i, j, k] mean (95% CI) [OC]
Absenteeism	7.7 (21.4)[l]	−2.3 (−5.8, 1.3)[n]	9.7 (20.4)[l]	−0.9 (−5.5, 3.7)[n]
Presenteeism	34.8 (25.7)[m]	−22.3 (−26.3,−18.4)[o]	38.0 (26.3)[m]	−20.1 (−24.6, −15.6)[o]
Overall work impairment	37.0 (27.2)[m]	−21.7 (−26.0, −17.4)[o]	40.7 (27.9)[m]	−18.8 (−23.9, −13.7)[o]
Activity impairment	43.2 (24.4)[g]	−24.4 (−27.1, −21.7)[p]	46.5 (25.6)[g]	−25.4 (−28.9, −21.9)[p]

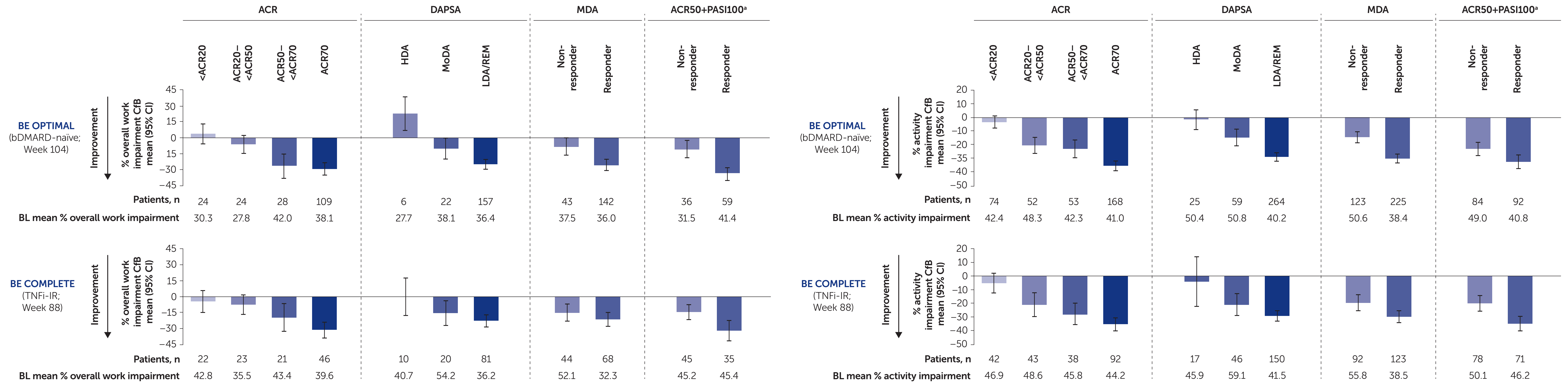
Randomized set. [a] Data missing for 8 patients in BE OPTIMAL and 1 patient in BE COMPLETE; [b] In patients with psoriasis affecting body surface area ≥3% at baseline; [c] Data missing for 6 patients in BE OPTIMAL; [d] In patients with enthesitis at baseline; [e] Data missing for 7 patients in BE OPTIMAL; [f] In patients with dactylitis at baseline; [g] BE OPTIMAL n=430, BE COMPLETE n=267; [h] Pain VAS assessed using the Patient's Assessment of Arthritis Pain 100 mm visual analog scale which ranges from 0 to 100, 0 representing 'no pain' and 100 'most severe pain'; [i] Measured using WPAI:SHP, adapted for PsA; [j] Scores presented as percent impairment, with the exception of absenteeism which is presented as percent work time missed; [k] Absenteeism, presenteeism, and overall work impairment are reported in patients employed at baseline, while activity impairment is reported in all patients; [l] BE OPTIMAL n=270, BE COMPLETE n=162; [m] BE OPTIMAL n=262, BE COMPLETE n=158; [n] BE OPTIMAL n=193, BE COMPLETE n=117; [o] BE OPTIMAL n=185, BE COMPLETE n=113; [p] BE OPTIMAL n=349, BE COMPLETE n=217.

Figure 1 Association between disease control and improvements in WPAI domain scores at Week 104 of BE OPTIMAL (bDMARD-naïve) and Week 88 of BE COMPLETE (TNFi-IR) (OC)



A) Absenteeism: % work time missed

B) Presenteeism: % impairment while working



C) % Overall work impairment

D) % Activity impairment

Randomized set. Measured using WPAI:SHP, adapted for PsA. Categories are mutually exclusive. DAPSA HDA: >28; MoDA: >14 to ≤28; LDA/REM: ≤14. [a] In patients with psoriasis affecting body surface area ≥3% at baseline.

ACR: American College of Rheumatology; **ACR20/50/70:** ≥20%/50%/70% improvement from baseline in ACR response criteria; **ACR50+PASI100:** ≥50% improvement from baseline in ACR response criteria and 100% improvement from baseline in Psoriasis Area and Severity Index; **bDMARD:** biologic disease-modifying antirheumatic drug; **BKZ:** bimekizumab; **BL:** baseline; **BMI:** body mass index; **BSA:** body surface area; **CfB:** change from baseline; **CI:** confidence interval; **DAPSA:** Disease Activity Index for Psoriatic Arthritis; **HAQ-DI:** Health Assessment Questionnaire-Disability Index; **HDA:** high disease activity; **IL:** interleukin; **LDA:** low disease activity; **LDI:** Leeds Dactylitis Index; **LEI:** Leeds Enthesitis Index; **MDA:** minimal disease activity; **MoDA:** moderate disease activity; **OC:** observed case; **PASI:** Psoriasis Area and Severity Index; **PsA:** psoriatic arthritis; **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 analog scale; **WPAI:** Work Productivity and Activity Impairment Questionnaire; **WPAI:SHP:** Work Productivity and Activity Impairment Questionnaire: Specific Health Problem v2.0.

References: [1]Gudu T. Expert Rev Clin Immunol 2018;14:405–17; [2]Husni ME. Semin Arthritis Rheum 2017;47:351–60; [3]Tillett W. Arthritis Rheumatol 2024;76(suppl 9). **Author Contributions:** Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: **JAW**, **DDG**, **LG**, **AJB**, **GA**, **PH**, **BI**, **WT**; Drafting of the publication, or reviewing it critically for important intellectual content: **JAW**, **DDG**, **LG**, **AJB**, **GA**, **PH**, **BI**, **WT**; Final approval of the publication: **JAW**, **DDG**, **LG**, **AJB**, **GA**, **PH**, **BI**, **WT**. **Author Disclosures: JAW:** Consultant for/grant support from AbbVie, Amgen, Eli Lilly, Janssen, Merck, Novartis, Pfizer, and UCB; **DDG:** Consultant for AbbVie, Amgen, AstraZeneca, BMS, Eli Lilly, Gilead, Galapagos, Janssen, Johnson & Johnson, Novartis, Pfizer, Roche, and UCB; received grant/research support from AbbVie, Amgen, BMS, Eli Lilly, Janssen, Novartis, Pfizer, and UCB. **LG:** Received grants or contracts from AbbVie, Biogen, Lilly, Novartis and UCB; consulting fees from AbbVie, Amgen, BMS, Celltrion, Janssen, Lilly, MSD, Novartis, Pfizer, and UCB. **AJB:** Employee of UCB. **GA:** Employee of UCB; shareholder of Vertex Pharmaceuticals. **PH:** Employee and shareholder of UCB. **BI:** Employee of UCB; shareholder of AbbVie, GSK, and UCB; **WT:** Research grants, consulting fees, speaking fees and/or honoraria from AbbVie, Amgen, BMS, Celgene, Eli Lilly, GSK, Janssen, MSD, Novartis, Ono Pharma, Pfizer, Takeda, and UCB. **Acknowledgements:** 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, 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. These studies were funded by UCB. All costs associated with development of this presentation were funded by UCB.

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Presented at CCR East 2025 | May 1–4 | Destin, FL