Achieving Stringent Disease Control Criteria was Associated with Greater Work Productivity Improvements in Patients with Active Psoriatic Arthritis: Results from Two Phase 3 Studies of Bimekizumab

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Objective

To report the association between achieving stringent disease control criteria and improvements in work productivity up to 1 year in patients with psoriatic arthritis (PsA) who were biologic DMARD (bDMARD)-naïve or had inadequate response or intolerance to TNF inhibitors (TNFi-IR).

Background

- PsA negatively impacts patients' physical health and functional ability, contributing to reduced work productivity.[1,2]

Methods

- This post hoc analysis used data from two phase 3 studies of subcutaneous bimekizumab (BKZ) 160 mg every 4 weeks: BE OPTIMAL (NCT03895203; bDMARD-naïve) and BE COMPLETE (NCT03896581; TNFi-IR). Both studies were double-blind and placebo-controlled to Week 16. Patients who completed Week 52 of BE OPTIMAL or Week 16 of BE COMPLETE could enter the BE VITAL open-label extension (NCT04009499).
- Data are reported for patients randomized to BKZ at baseline.
- Disease control measures: ACR response criteria, Disease Activity Index for PsA (DAPSA), minimal disease activity (MDA), and the composite endpoint of ACR50 and Psoriasis Area and Severity Index 100% improvement from baseline (ACR50+PASI100).
- Work Productivity and Activity Impairment (WPAI) domains reported include work time missed (absenteeism), impairment while working (presenteeism), overall work impairment, and activity impairment.
  - Absenteeism, presenteeism and overall work impairment are reported in patients employed at baseline, while activity impairment is reported in all patients.
- We examined associations between achievement of disease control criteria (mutually exclusive categories) and percentage improvements from baseline in each WPAI domain score at Week 52 of BE OPTIMAL and Week 40 of BE COMPLETE (observed case).

Results

- 388/431 (90.0%) and 246/267 (92.1%) BKZ-randomized patients completed Week 52 of BE OPTIMAL and Week 40 of BE COMPLETE, respectively.
  - Baseline mean percentage WPAI scores were numerically higher in TNFi-IR patients compared with bDMARD-naïve patients (**Table**).
- At Week 52/40, patients achieving more stringent disease control criteria generally demonstrated greater improvements in work productivity, particularly in the WPAI domains of presenteeism, overall work impairment, and activity impairment (**Figure 1A–D**).
  - Similar improvements were observed in bDMARD-naïve and TNFi-IR patients; however, improvements in work productivity among MDA responders versus non-responders were more pronounced in bDMARD-naïve patients compared with TNFi-IR patients.
  - When compared with other disease control criteria, DAPSA disease states appeared to correlate least well with work productivity measures.
- Improvements in absenteeism were smaller than other WPAI domains; thus, trends were less pronounced when assessing the association of absenteeism by disease control criteria response groups (**Figure 1A**).

Conclusions

Achievement of increasingly stringent disease control criteria was associated with greater improvements in work productivity up to 1 year in patients with PsA. Similar improvements were observed in bDMARD-naïve and TNFi-IR patients.

Summary

Psoriatic arthritis imparts a substantial burden on patients' physical health and function, which can lead to **reduced work productivity**.

The association between **achievement of increasingly greater disease control** and **percentage improvements from baseline in work productivity and activity impairment** was assessed in both bDMARD-naïve (BE OPTIMAL) and TNFi-IR (BE COMPLETE) patients.

The **greatest reductions** in **presenteeism, overall work impairment, and activity impairment** were observed in patients who achieved **stringent disease control**.

Across all WPAI domains, the **greatest improvements** were seen in patients who achieved **disease control in both musculoskeletal and skin domains** (ACR50+PASI100 responders), regardless of prior TNF treatment.

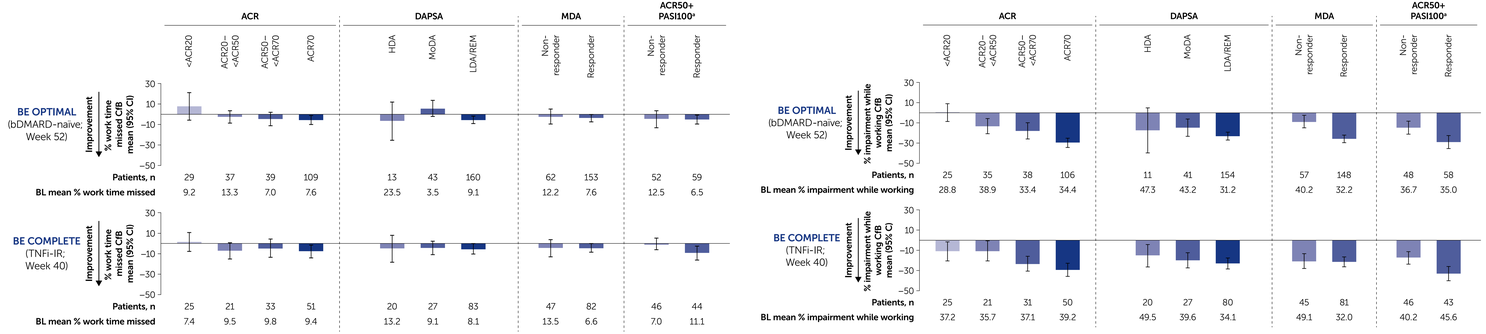
Meeting the most **stringent** thresholds of **disease control** resulted in the **greatest reduction** of **disease burden** on patients' work productivity.

Table Baseline characteristics and change from baseline in WPAI domain scores at Week 52/40 (OC)

	BE OPTIMAL (bDMARD-naïve)	BE COMPLETE (TNFi-IR)
	BKZ 160 mg Q4W (n=431)	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/m^2, 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)	10.1 (9.1)
TJC (of 68 joints), mean (SD)	16.8 (11.8)	18.4 (13.5)
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)
WPAI score,[i] mean (SD)		
Absenteeism[a]	7.7 (21.4)	9.7 (20.4)
Presenteeism[i]	34.8 (25.7)	38.0 (26.3)
Overall work impairment[a,i]	37.0 (27.2)	40.7 (27.9)
Activity impairment[a,i]	43.2 (24.4)	46.5 (25.6)
	Week 52	**Week 40**
WPAI CfB,[j] mean (95% CI)		
Absenteeism[a]	−11.1 (−23.9, 1.7)	−24.8 (−34.7, −14.8)
Presenteeism[a]	−45.4 (−54.9, −35.9)	−49.4 (−58.1, −40.8)
Overall work impairment[a]	−40.7 (−51.7, −29.6)	−45.1 (−55.3, −34.8)
Activity impairment[a]	−46.3 (−53.4, −39.2)	−44.8 (−52.6, −37.0)

Randomized set. **[a]** Data missing for 8 patients in BE OPTIMAL and 1 patient in BE COMPLETE; **[b]** In patients with psoriasis involving at least 3% of BSA at baseline; **[c]** Data missing for 6 patients in BE OPTIMAL; **[d]** In patients with enthesitis at baseline (LEI >0); **[e]** Data missing for 7 patients in BE OPTIMAL; **[f]** In patients with dactylitis at baseline (LDI >0); **[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]** Scores presented as percent impairment, with the exception of absenteeism which is presented as percent work time missed; **[j]** Absenteeism, presenteeism and overall work impairment are reported in patients employed at baseline; while activity impairment is reported in all patients; **[k]** BE OPTIMAL n=270, BE COMPLETE n=162; **[l]** BE OPTIMAL n=262, BE COMPLETE n=158; **[m]** BE OPTIMAL n=262, BE COMPLETE n=158; **[n]** BE OPTIMAL n=430, BE COMPLETE n=267; **[o]** BE OPTIMAL n=216, BE COMPLETE n=131; **[p]** BE OPTIMAL n=206, BE COMPLETE n=128; **[q]** BE OPTIMAL n=206, BE COMPLETE n=128; **[r]** BE OPTIMAL n=382, BE COMPLETE n=241.

Figure 1 Association between disease control and improvements in WPAI domain scores at Week 52 of BE OPTIMAL (bDMARD-naïve) and Week 40 of BE COMPLETE (TNFi-IR), (OC)



Randomized set. 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; **LDA:** low disease activity; **LDI:** Leeds Dactylitis Index; **LEI:** Leeds Enthesitis Index; **MDA:** minimal disease activity; **MoDA:** moderate disease activity; **OC:** observed case; **PsA:** psoriatic arthritis; **Q4W:** every 4 weeks; **REM:** remission; **SD:** standard deviation; **SJC:** swollen joint count; **TJC:** tender joint count; **TNF:** tumor necrosis factor; **TNFi-IR:** prior inadequate response or intolerance to tumor necrosis factor inhibitors; **VAS:** visual analog scale; **WPAI:** Work Productivity and Activity Impairment.

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References: [1]Gudu T. Expert Rev Clin Immunol. 2018;14:405–17; [2]Husni ME. Semin Arthritis Rheum 2017;47:351–60. **Author Contributions:** Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: **WT, DDG, LG, JE, PH, BI, NL, JAW**; Drafting of the publication, or reviewing it critically for important intellectual content: **WT, DDG, LG, JE, PH, BI, NL, JAW**; Final approval of the publication: **WT, DDG, LG, JE, PH, BI, NL, JAW**. **Author Disclosures: WT:** Research grants, consulting fees, speaking fees, and/or honoraria from AbbVie, Amgen Inc., BMS, Celgene, Eli Lilly and Company, GSK, Janssen, MSD, Novartis, Ono Pharma, Pfizer, and UCB. **DDG:** Consultant and/or received grant support from AbbVie, Amgen, BMS, Eli Lilly and Company, Gilead, Galapagos, Janssen, Novartis, Pfizer, and UCB. **LG:** Received grants or contracts from AbbVie, Biogen, Eli Lilly and Company, Novartis, and UCB; consulting fees from AbbVie, BMS, Celltrion, Janssen, Novartis, Pfizer, and UCB; honoraria for lectures from AbbVie, Amgen, BMS, Celltrion, Janssen, Eli Lilly and Company, MSD, Novartis, Pfizer, Stada, and 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. **JE, PH, NK:** Employee and shareholder of UCB. **BI:** Employee of UCB; shareholder of AbbVie, GSK, and UCB. **JAW:** Consultant for/grant support from AbbVie, Amgen, Eli Lilly and Company, Janssen, Merck, Novartis, Pfizer, and UCB.
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