Bimekizumab Treatment Impact on Pain and Fatigue in Patients with Active Psoriatic Arthritis who were Biologic DMARD-Naïve or had Inadequate Response or Intolerance to TNF-α Inhibitors: 1-Year Results from Two Phase 3 Studies

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Objective

To report the impact of bimekizumab (BKZ) treatment up to 1 year on patient-reported pain and fatigue in patients with active psoriatic arthritis (PsA) who were biologic DMARD (bDMARD)-naïve or had intolerance or inadequate response to TNF-α inhibitor (TNFi-IR).

Background

- Patients identified pain and fatigue as key features of PsA that drive the impact of PsA on their health-related quality of life (HRQoL).[1]
- BKZ, a monoclonal IgG1 antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A, has demonstrated meaningful improvements in pain and fatigue symptoms to 16 weeks vs placebo (PBO) in patients with active PsA.[2,3]

Methods

- BE OPTIMAL (NCT03895203) and BE COMPLETE (NCT03896581) were phase 3 trials assessing BKZ 160 mg every 4 weeks (Q4W) in patients with active PsA who were bDMARD-naïve or TNFi-IR, respectively (**Figure 1**).
- Both trials had a 16-week double-blind, placebo-controlled phase; at Week 16, PBO patients switched to receive BKZ (PBO/BKZ).
- Patients completing Week 52 of BE OPTIMAL or Week 16 of BE COMPLETE were eligible to enter the open-label extension, BE VITAL (NCT04009499). BE COMPLETE plus BE VITAL is referred to as 'BE COMPLETE' hereafter (**Figure 1**). Data reported here for up to 52 weeks of therapy from both trials.
- Here, we report individual study data up to 1 year for BKZ and PBO treatment arms for the 0–100 Patient's Assessment of Arthritis Pain Visual Analogue Scale (Pain VAS; clinically important improvements of ≥30/50/70% from baseline,[4] and change from baseline) and Functional Assessment of Chronic Illness Therapy-Fatigue subscale (FACIT-Fatigue; Minimum Clinically Important Difference [MCID] of ≥4-point improvement from baseline in patients with score ≤48 at baseline, and change from baseline).
- BE COMPLETE FACIT-Fatigue values were collected to Week 40 only.
- Missing data were imputed using non-responder imputation (NRI; binary) and multiple imputation (MI; continuous).

Results

- Overall, 770/852 (90.4%) and 347/400 (86.8%) patients completed Week 52 of BE OPTIMAL and BE COMPLETE, respectively.*
- Baseline characteristics were generally similar between treatment arms within studies (**Table 1**).
- Compared with PBO, BKZ-treated patients demonstrated numerically greater improvements from baseline in patient-reported pain, and greater proportions achieved clinically meaningful improvements of ≥30/50/70% at Week 16; improvements were sustained from Week 16 to Week 52 on BKZ treatment (**Figure 2**).
- Compared with PBO, BKZ-treated patients achieved numerically greater improvements from baseline in patient-reported fatigue, and greater proportions achieved the clinically meaningful improvement of FACIT-Fatigue MCID at Week 16; improvements were sustained from Week 16 to Week 52 on BKZ treatment (**Figure 3**).
- Patients who switched from PBO to BKZ at Week 16 also achieved improvements in patient-reported pain and fatigue following switch to 1 year (**Figure 2**, **Figure 3**).

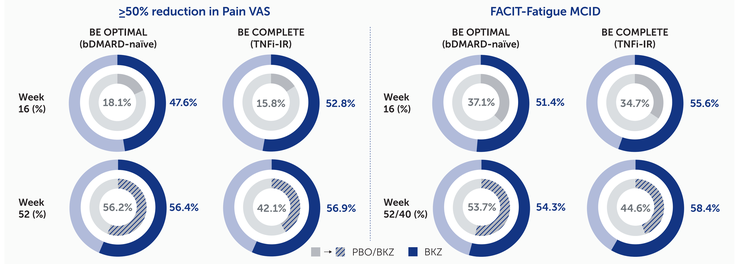
Conclusions

Treatment with bimekizumab resulted in sustained improvements in patient-reported pain and fatigue from Week 16 up to 1 year in both bDMARD-naïve and TNFi-IR patients with active PsA, with clinically meaningful improvements observed in over half of patients.

Summary

Pain and **fatigue** are key features of PsA that patients identify as impactful.

Clinically meaningful improvements achieved in patient-reported **pain** and **fatigue** at Week 16 in **bimekizumab-treated patients** are **sustained up to 1 year** in both bDMARD-naïve and TNFi-IR patients with active PsA:



Results suggest that **bimekizumab treatment** led to **improvements in pain and fatigue** irrespective of prior TNFi treatment up to 1 year.

Figure 1 BE OPTIMAL and BE COMPLETE/ BE VITAL study designs

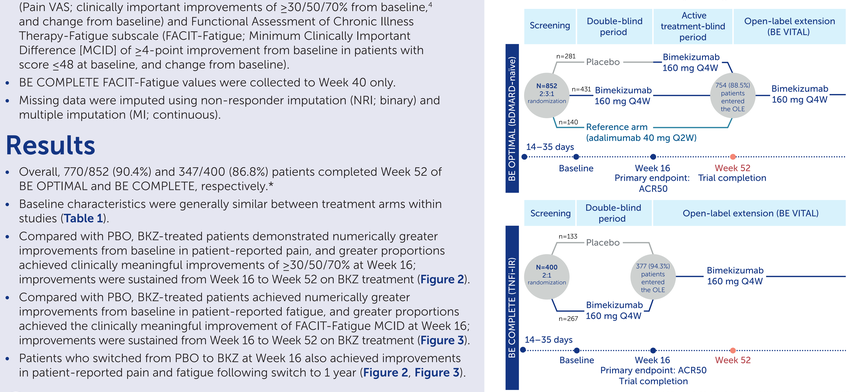


Table 1 Baseline demographics and patient characteristics

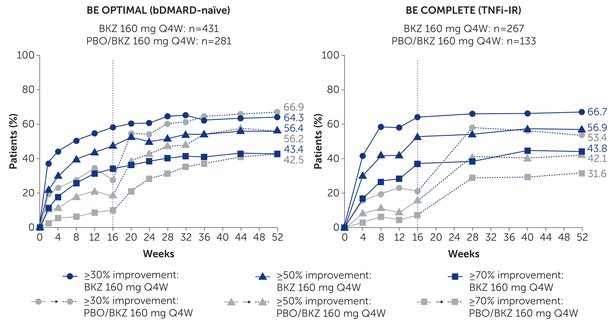
	BE OPTIMAL (bDMARD-naïve)		BE COMPLETE (TNFi-IR)	
	PBO (n=281)	BKZ 160 mg Q4W (n=431)	PBO (n=133)	BKZ 160 mg Q4W (n=267)
Age, years, mean (SD)	48.7 (11.7)	48.5 (12.6)	51.3 (12.9)	50.1 (12.4)
Male, n (%)	127 (45.2)	201 (46.6)	60 (45.1)	130 (48.7)
BMI, kg/m², mean (SD)	29.6 (6.1)	29.2 (6.8)	29.0 (5.4)	30.1 (6.5)
Time since first PsA diagnosis,[a] years, mean (SD)	5.6 (6.5)	6.0 (7.3)	9.2 (8.1)	9.6 (9.9)
BSA affected by psoriasis ≥3%, n (%)	140 (49.8)	217 (50.3)	88 (66.2)	176 (65.9)
PASI score,[b] mean (SD)	7.9 (5.6)	8.2 (6.8)	8.5 (6.6)	10.1 (9.1)
TJC (of 68 joints), mean (SD)	17.1 (12.5)	16.8 (11.8)	19.3 (14.2)	18.4 (13.6)
SJC (of 66 joints), mean (SD)	9.5 (7.3)	9.0 (6.2)	10.3 (8.2)	9.7 (7.5)
Enthesitis (LEI >0),[c] n (%)	70 (24.9)	143 (33.2)	36 (27.1)	106 (39.7)
LEI score[d]	2.9 (1.5)	2.5 (1.5)	2.9 (1.6)	2.6 (1.5)
Dactylitis (LDI >0),[e] n (%)	33 (11.7)	56 (13.0)	14 (10.5)	34 (12.7)
Dactylitic sites[f]	1.5 (0.6)	1.4 (0.8)	1.9 (2.4)	2.0 (1.8)
LDI score[f]	47.3 (41.1)	46.7 (54.3)	66.4 (127.6)	72.7 (114.4)
HAQ-DI,[g] mean (SD)	0.89 (0.61)	0.82 (0.59)	1.04 (0.69)	0.97 (0.59)
hs-CRP ≥6 mg/L, n (%)	121 (43.1)	158 (36.7)	59 (44.4)	118 (44.2)
Pain VAS,[a,h] mean (SD)	56.8 (23.2)	53.6 (24.3)	61.7 (24.6)	58.3 (24.2)
FACIT-Fatigue,[a,i] mean (SD)	36.0 (10.2)	37.8 (9.6)	36.3 (9.9)	35.3 (10.5)

Randomized set. [a] Data missing for 2 PBO and 8 BKZ patients in BE OPTIMAL, and 1 PBO and 1 BKZ patient in BE COMPLETE; [b] In patients with psoriasis involving at least 3% of BSA at baseline; [c] Data missing for 6 BKZ patients in BE OPTIMAL, and 1 PBO patient in BE COMPLETE; [d] In patients with enthesitis at baseline (LEI>0); [e] Data missing for 1 PBO and 7 BKZ patients in BE OPTIMAL, and 1 PBO patient in BE COMPLETE; [f] In patients with dactylitis at baseline (LDI>0); [g] Data missing for 1 BKZ patient in BE OPTIMAL; [h] Pain VAS score measured using PtAAP ranges from 0 (no pain) to 100 (most severe pain); [i] FACIT-Fatigue score ranges from 0 to 52, with 52 being the best possible score.

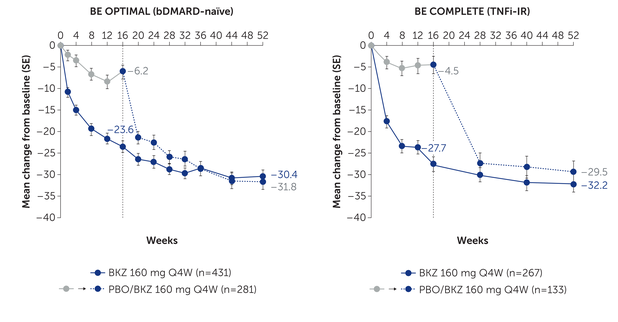
*Including patients not on randomized treatment (BE OPTIMAL: 9; BE COMPLETE: 4). **bDMARD:** biologic DMARD; **BKZ:** bimekizumab; **CfB:** change from baseline; **FACIT-Fatigue:** Functional Assessment of Chronic Illness Therapy—Fatigue; **HAQ-DI:** Health Assessment Questionnaire-Disability Index; **HRQoL:** health-related quality of life; **hs-CRP:** high-sensitivity C-reactive protein; **IL:** interleukin; **LDI:** Leeds Dactylitis Index; **LEI:** Leeds Enthesitis Index; **MCID:** minimum clinically important difference; **MI:** multiple imputation; **NRI:** non-responder imputation; **OC:** observed case; **OLE:** open-label extension; **Pain VAS:** Patient's Assessment of Arthritis Pain Visual Analogue Scale; **PASI:** Psoriasis Area Severity Index; **PBO:** placebo; **PsA:** psoriatic arthritis; **PtAAP:** Patient's Assessment of Arthritis Pain; **Q2W:** every 2 weeks; **Q4W:** every 4 weeks; **SD:** standard deviation; **SE:** standard error; **SJC:** swollen joint count; **TJC:** tender joint count; **TNFi-IR:** inadequate response or intolerance to TNF-α inhibitor.

Figure 2 Improvements in patient-reported pain up to 1 year

A) Improvements of ≥30/50/70% in Pain VAS (NRI)



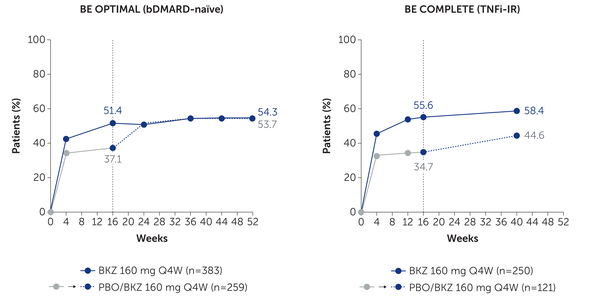
B) Pain VAS change from baseline (MI)



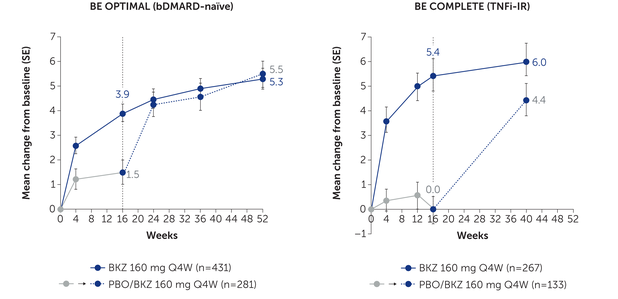
Randomized set. Pain VAS ranges from 0 to 100, with 0 representing "no pain" and 100 "most severe pain".

Figure 3 Improvements in patient-reported fatigue up to 1 year

A) FACIT-Fatigue MCID[a] (NRI)



B) FACIT-Fatigue change from baseline (MI)



Randomized set. FACIT-Fatigue score ranges from 0 to 52, with 52 being the best possible score. [a] For BE COMPLETE, FACIT-Fatigue values were not collected at Week 52; only collected to Week 40. FACIT-Fatigue MCID defined as score increase from baseline ≥4 in patients with FACIT-Fatigue ≤48 at baseline.

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