Bimekizumab treatment resulted in sustained improvements in pain and fatigue in patients with active psoriatic arthritis and baseline psoriasis: 1-year results from two phase 3 studies

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OBJECTIVES:

- To assess the impact of bimekizumab (BKZ) on patient-reported pain and fatigue outcomes in patients with active psoriatic arthritis (PsA) and baseline psoriasis (body surface area [BSA] ≥3%), using 1-year data from two phase 3 trials of patients who were bDMARD-naïve or TNFi-IR.

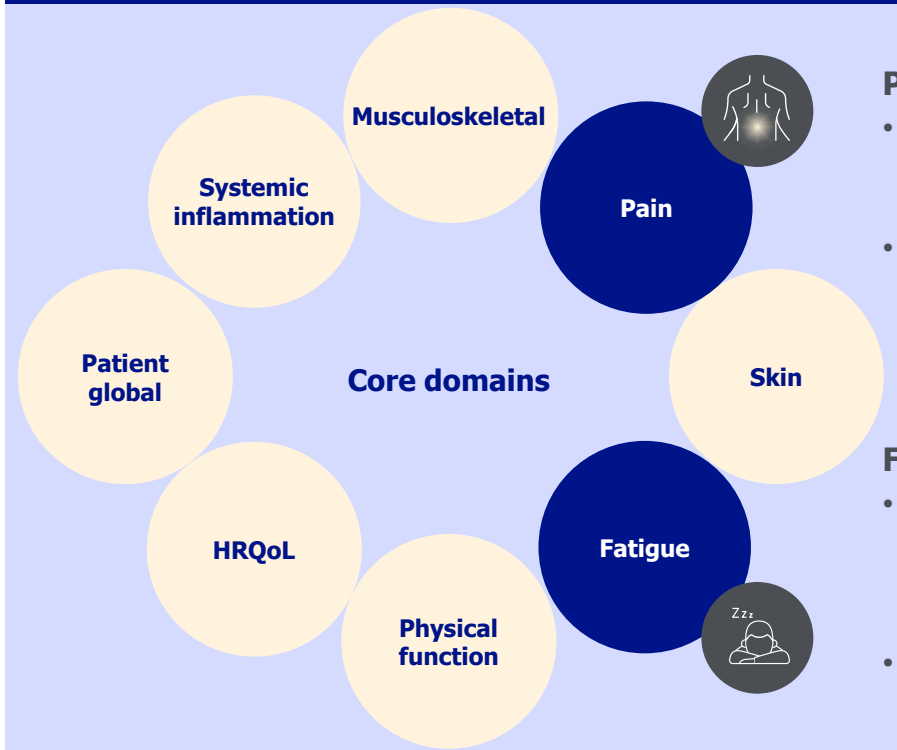
Background:

- Patients with PsA identified pain and fatigue as salient symptoms of disease burden.[1]
- Evaluating long-term BKZ impact on these symptoms among patients with PsA and skin involvement is of clinical interest.

Methods:

- Data are reported from BE OPTIMAL (NCT03895203)[2] and BE COMPLETE (NCT03896581)[3]/BE VITAL (NCT04009499).[4]
- Missing data imputed using non-responder imputation (NRI; discrete) and multiple imputation (MI; continuous).

Pain and fatigue are included in the GRAPPA-OMERACT Core Outcome Set for PsA[5]



Pain outcomes:

- Substantial improvement: ≥50% improvement from baseline in Pain VAS[6]
- Change from baseline (CfB) in Pain VAS score

Fatigue outcomes:

- FACIT-Fatigue minimal important clinical difference (MCID; score increase from baseline ≥4)
- CfB in FACIT-Fatigue score

1. Ogdie A. RMD Open 2020;6:e001321; **2.** McInnes IB. Lancet 2023;401:25–37; NCT03895203; **3.** Merola JF. Lancet 2023;401:38–48; NCT03896581; **4.** BE VITAL: https://clinicaltrials.gov/ct2/show/NCT04009499; **5.** Ogdie A. J Rheumatol 2017;44:697–700 **6.** Dworkin RH. J Pain 2008;9:105–21. bDMARD-naïve: biologic disease-modifying antirheumatic drug; BKZ: bimekziumab; BSA: body surface area; CfB: change from baseline; FACIT-Fatigue: Functional Assessment of Chronic Illness Therapy – Fatigue; GRAPPA-OMERACT: Group for Research and Assessment of Psoriasis and Psoriatic Arthritis – Outcome Measures in Rheumatology; HRQoL: health-related quality of life; MCID: minimum clinically important difference; MI: multiple imputation; NRI: non-responder imputation; PsA: psoriatic arthritis; TNFi-IR: inadequate response or intolerance to tumor necrosis factor inhibitors.

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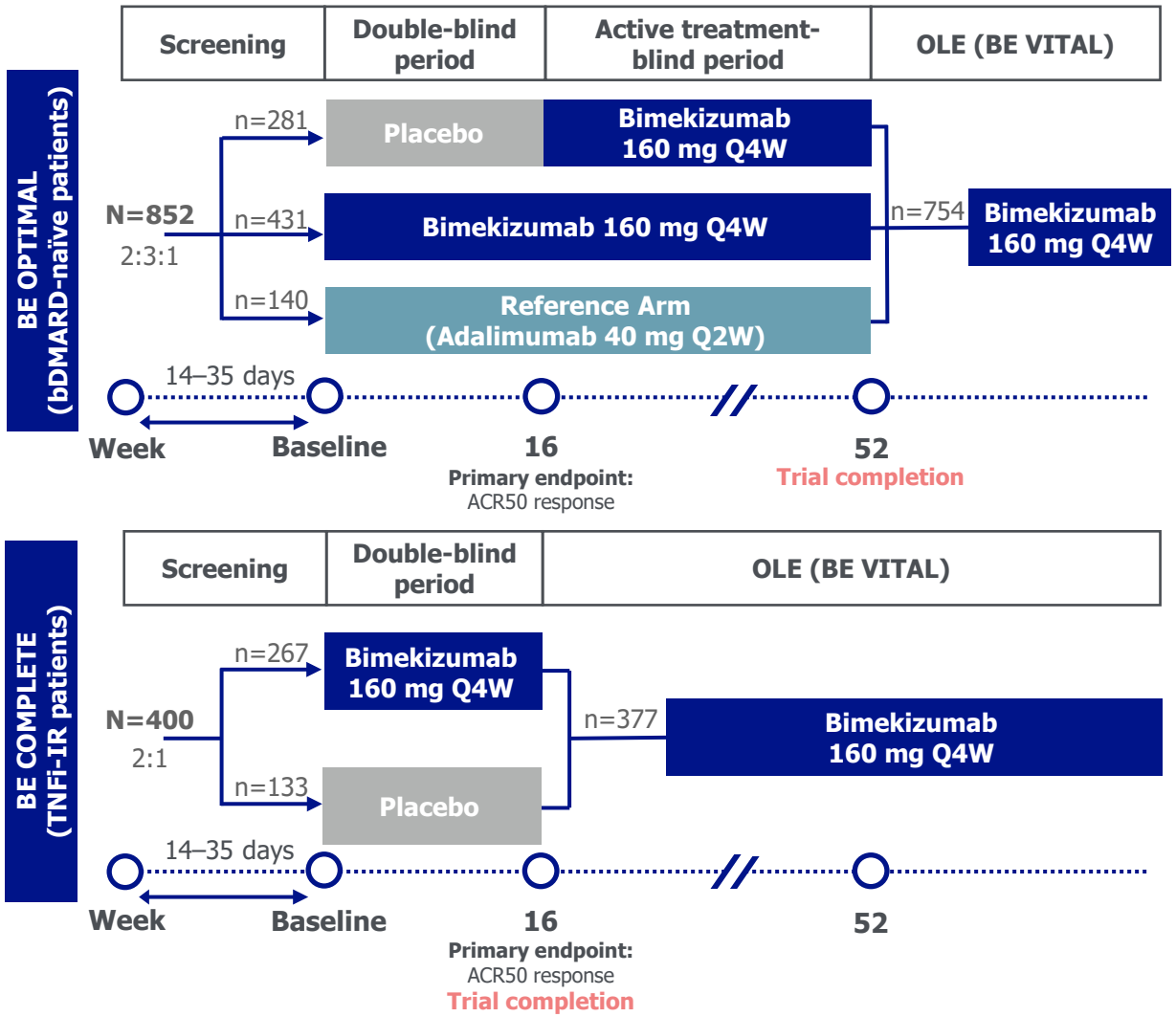
BE OPTIMAL, BE COMPLETE, and BE VITAL (OLE) Study Designs



Baseline Characteristics

(In patients with baseline psoriasis BSA ≥3%)

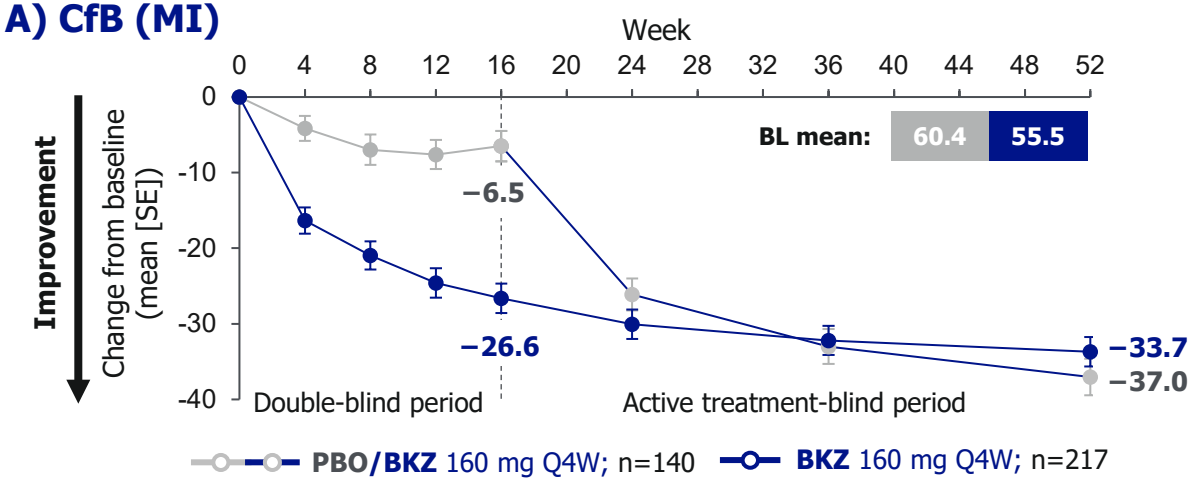
	BE OPTIMAL (bDMARD-naïve)		BE COMPLETE (TNFi-IR)	
	PBO (n=140)	BKZ 160 mg Q4W (n=217)	PBO (n=88)	BKZ 160 mg Q4W (n=176)
Age (years), mean ± SD	48.0 ± 11.4	46.7 ± 12.2	49.8 ± 13.1	48.9 ± 12.3
Male, n (%)	63 (45.0)	110 (50.7)	40 (45.5)	89 (50.6)
BMI (kg/m^2), mean ± SD	29.4 ± 5.6	30.1 ± 7.1	28.7 ± 5.5	29.9 ± 6.5
Time since first PsA diagnosis, (year), mean ± SD	6.6 ± 7.7	7.0 ± 8.2[a]	8.9 ± 8.1[b]	10.3 ± 10.6[c]
Psoriasis BSA ≥3% to ≤10%, n (%)	92 (65.7)	144 (66.4)	63 (71.6)	109 (61.9)
Psoriasis BSA >10%, n (%)	48 (34.3)	73 (33.6)	25 (28.4)	67 (38.1)
PASI score, mean ± SD	7.9 ± 5.6	8.2 ± 6.8	8.5 ± 6.6	10.2 ± 9.1
TJC (of 68 joints), mean ± SD	17.3 ± 11.9	17.4 ± 12.2	19.9 ± 14.7	18.1 ± 12.7
SJC (of 66 joints), mean ± SD	9.9 ± 7.2	9.5 ± 6.5	10.8 ± 8.6	10.0 ± 7.9
hs-CRP ≥6 mg, n (%)	67 (47.9)	98 (45.2)	46 (52.3)	83 (47.2)
Pain VAS,[e] mean ± SD	60.4 ± 21.7	55.5 ± 24.3[d]	66.1 ± 22.0	59.0 ± 24.9
FACIT-Fatigue,[f] mean ± SD	35.7 ± 10.2	37.8 ± 8.9[d]	35.8 ± 9.9	34.8 ± 9.9

Study design: The adalimumab arm was included in BE OPTIMAL for reference versus standard of care for safety to Week 52; data not reported here. **Table:** Randomized set. [a] n=213; [b] n=87; [c] n=175; [d] n=216; [e] Pain VAS measured using Patient Assessment of Arthritis Pain, which ranges from 0 to 100, with 0 representing "no pain" and 100 "most severe pain"; [f] FACIT-Fatigue score ranges from 0 to 52, with 52 being the best possible score.
ACR50: ≥50% improvement in American College of Rheumatology response criteria; bDMARD-naïve: biologic disease-modifying antirheumatic drug naïve; BKZ: bimekizumab; BMI: body mass index; BSA: body surface area; FACIT-Fatigue: Functional Assessment of Chronic Illness Therapy – Fatigue; hs-CRP: high-sensitivity C-reactive protein; OLE: open-label extension; PASI: Psoriasis Area and Severity Index; PBO: placebo; PsA: psoriatic arthritis; Q2W: every 2 weeks; Q4W: every 4 weeks; SD: standard deviation; SJC: swollen joint count; TJC: tender joint count; TNFi-IR: inadequate response or intolerance to tumor necrosis factor inhibitors; VAS: visual analogue scale.

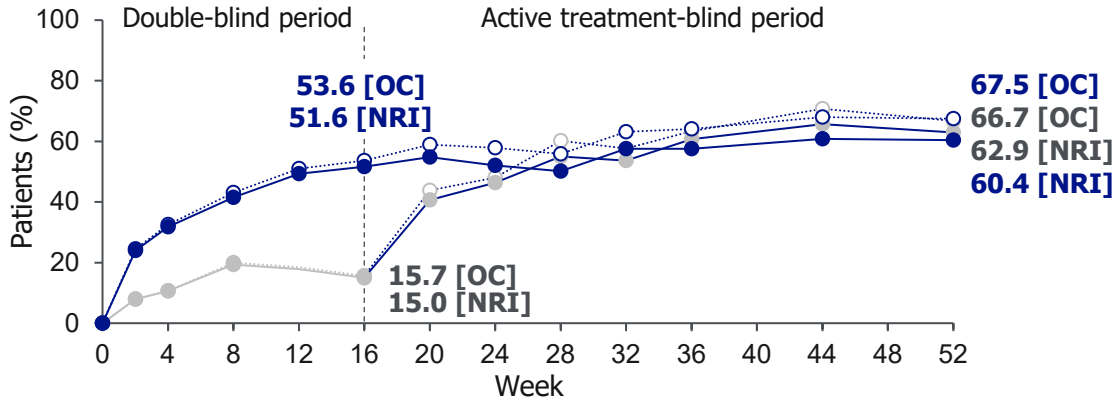
Pain VAS Improvements in Patients with Baseline Psoriasis BSA ≥3% to Week 52

BE OPTIMAL (bDMARD-naïve)

A) CfB (MI)



B) Substantial improvement: Pain VAS ≥50% improvement[a] (NRI/OC)

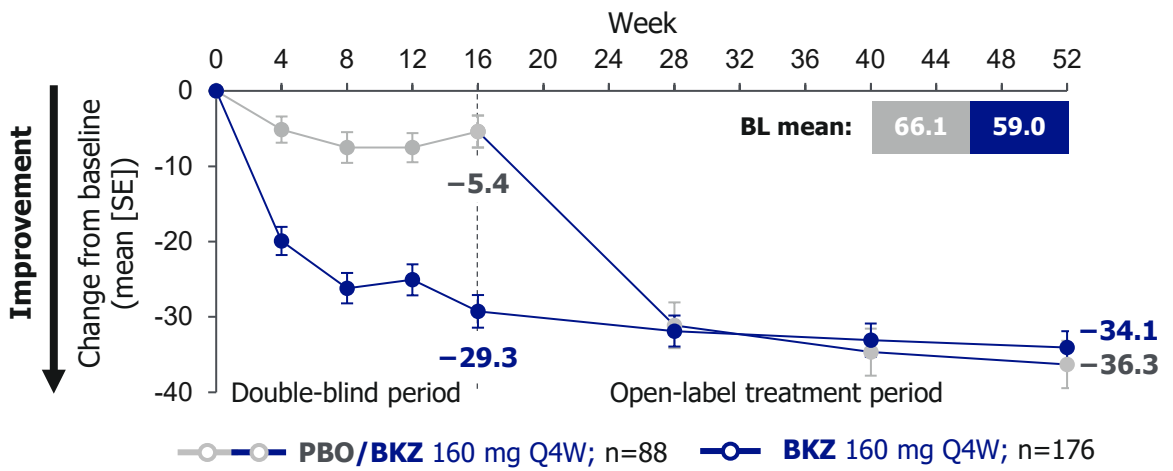


n (OC)			
PBO/BKZ	140	134	132
BKZ	217	209	194

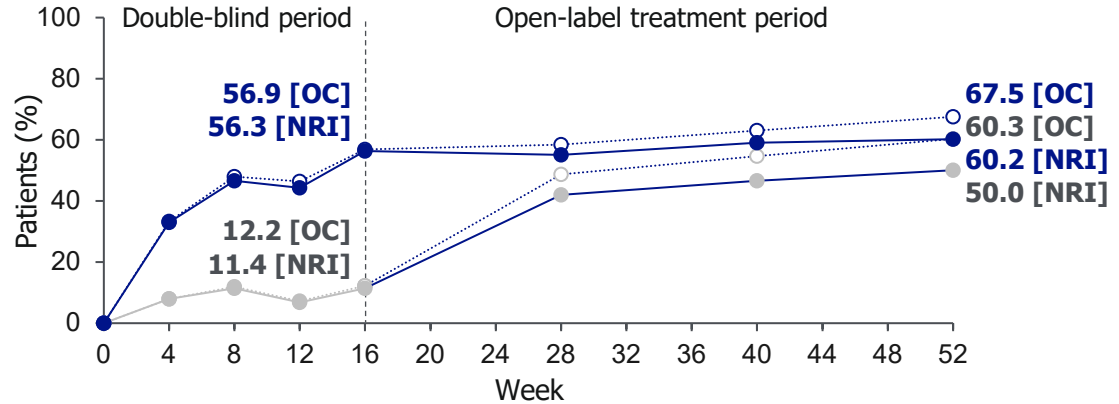
PBO/BKZ 160 mg Q4W; n=140 — BKZ 160 mg Q4W; n=217 — NRI — OC

BE COMPLETE (TNFi-IR)

A) CfB (MI)



B) Substantial improvement: Pain VAS ≥50% improvement[a] (NRI/OC)



n (OC)			
PBO/BKZ	88	82	73
BKZ	176	174	157

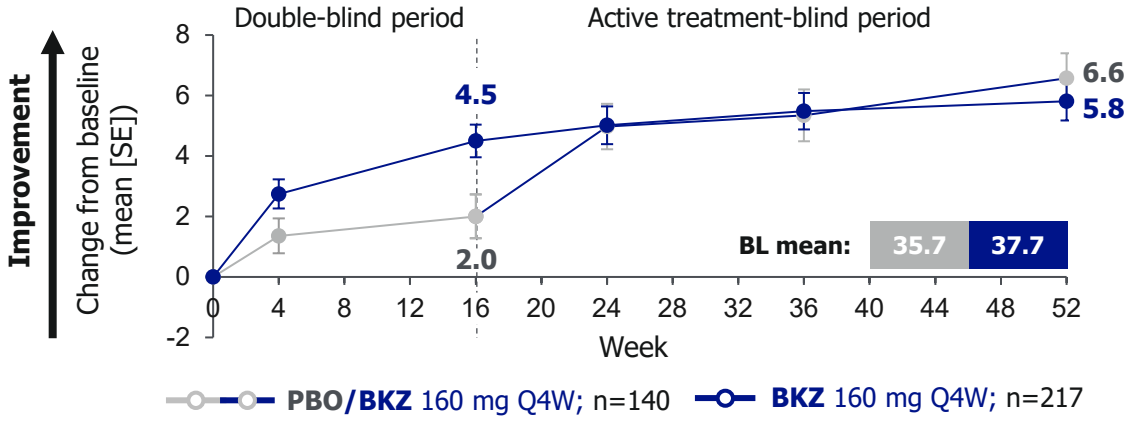
PBO/BKZ 160 mg Q4W; n=88 — BKZ 160 mg Q4W; n=176

1. Dworkin RH. J Pain 2008;9:105–21. Randomized set. Data are reported as observed case, and missing data imputed using non-responder imputation (discrete) or multiple responder imputation (continuous). [a] ≥50% improvement in pain represents clinically important improvement in patient-reported pain; [1] measured by ≥50% improvement in Patient Assessment of Arthritis Pain (pain VAS), with 0 representing "no pain" and 100 "most severe pain".
bDMARD-naïve: biologic disease-modifying antirheumatic drug naïve; BKZ: bimekizumab; BL: baseline; BSA: body surface area; CfB: change from baseline; MI: multiple imputation; NRI: non-responder imputation; OC: observed case; PBO: placebo; Q4W: every 4 weeks; SE: standard error; TNFi-IR: inadequate response or intolerance to tumor necrosis factor inhibitors; VAS: visual analogue scale.

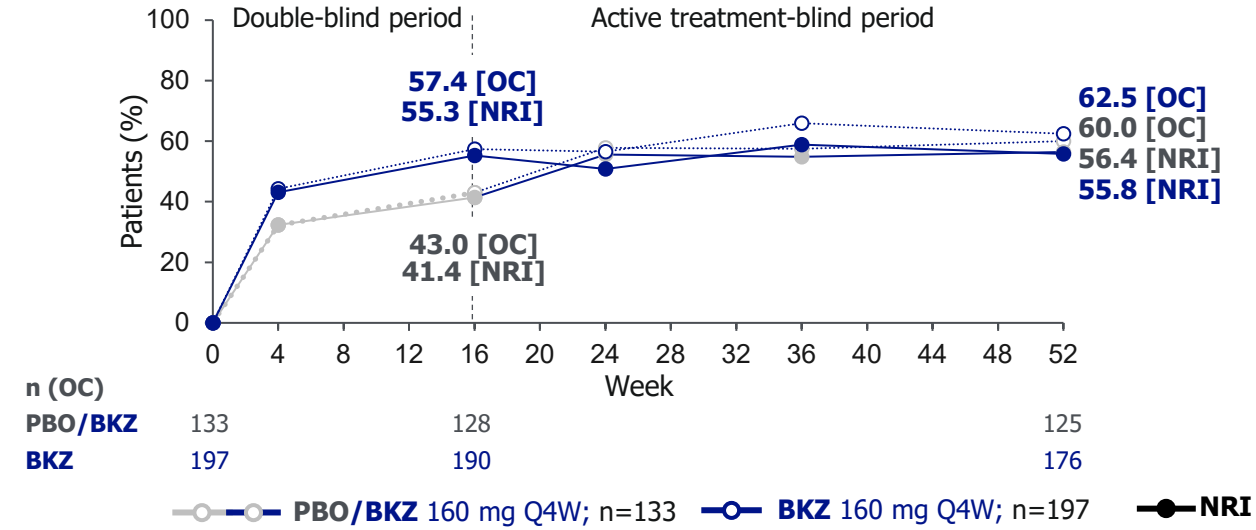
FACIT-Fatigue Improvements in Patients with Baseline Psoriasis BSA ≥3% to Week 52/40

BE OPTIMAL (bDMARD-naïve)

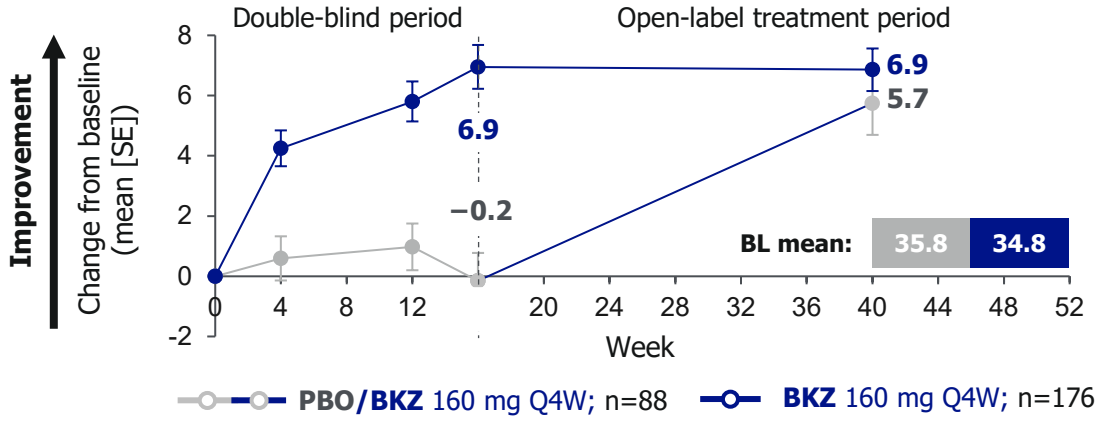
A) CfB (MI)

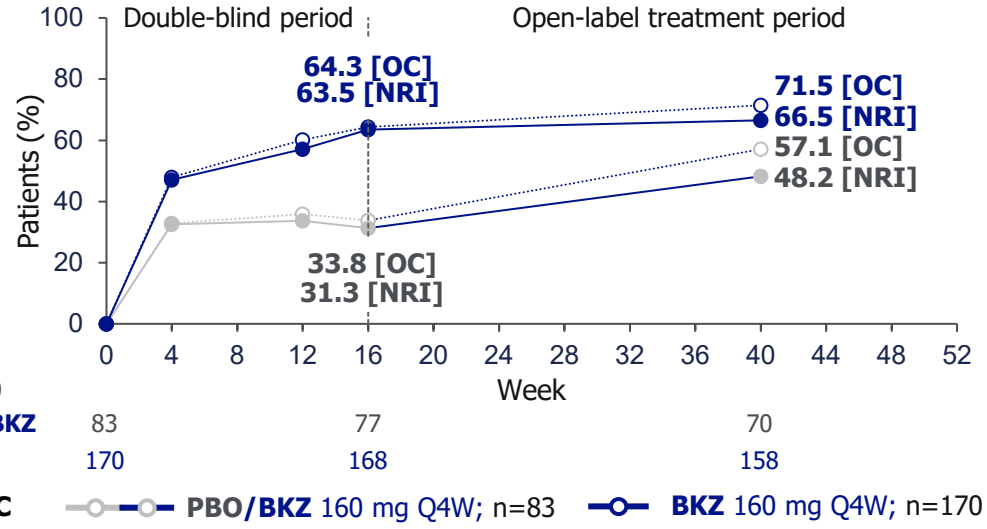


B) MCID (score increase from baseline ≥4)[b] (NRI/OC)



BE COMPLETE[a] (TNFi-IR)





Randomized set. Data are reported as observed case, and missing data imputed using non-responder imputation (discrete) or multiple responder imputation (continuous). [a] For BE COMPLETE, FACIT-Fatigue values were not collected at Week 52; only up to Week 40; [b] FACIT-Fatigue MCID defined as score increase from BL ≥4 in patients with FACIT-Fatigue ≤48 at BL. bDMARD-naïve: biologic disease-modifying antirheumatic drug naïve; BKZ: bimekizumab; BL: baseline; CfB: change from baseline; FACIT-Fatigue: Functional Assessment of Chronic Illness Therapy – Fatigue; MCID: minimum clinically important difference; MI: multiple imputation; NRI: non-responder imputation; OC: observed case; PBO: placebo; Q4W: every 4 weeks; SE: standard error; TNFi-IR inadequate response or intolerance to tumor necrosis factor inhibitors.

CONCLUSIONS:

- Bimekizumab treatment demonstrated sustained or greater clinically meaningful improvements in patient-reported pain and fatigue from Week 16 up to 1 year in patients with PsA and baseline psoriasis.
- Improvements in pain and fatigue were consistent between bimekizumab-treated patients who were bDMARD-naïve or had inadequate response or intolerance to TNFi.

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