

Bimekizumab Treatment Resulted in Rapid Response That Was Associated with Clinically Important Improvements in Patient-Reported Outcomes up to 3 Years in Patients with Psoriatic Arthritis

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Objective

To assess whether achieving stringent treatment responses at Week 16 in bimekizumab (BKZ)-treated patients with active psoriatic arthritis (PsA) was associated with clinically meaningful improvements in patient-reported outcomes (PROs) over 3 years.

Background

- PsA is a chronic inflammatory disease in which pain, fatigue and impaired functional capacity are among the most burdensome patient-reported symptoms, each contributing significantly to reduced health-related quality of life.¹⁻³
- Achieving an early and rapid response to treatment is an important goal to reduce symptoms and minimise disease impact.^{4,5}
- BKZ is a monoclonal IgG1 antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A.

Methods

- BE OPTIMAL (NCT03895203) and BE COMPLETE (NCT03896581) were phase 3 trials, both placebo-controlled to Week 16, which assessed subcutaneous BKZ 160 mg every 4 weeks (Q4W), in patients with active PsA who were biologic disease-modifying antirheumatic drug (bDMARD)-naïve or had prior intolerance or inadequate response to tumour necrosis factor inhibitors (TNFi-IR), respectively.
- Patients completing Week 52 in BE OPTIMAL or Week 16 in BE COMPLETE could enter BE VITAL (open-label extension; NCT04009499), where all patients received BKZ 160 mg Q4W.
- In this post hoc analysis, BKZ-randomised patients were classified as rapid responders or non-responders based on achievement of resolution of swollen joint count (SJC=0) or ≥50% improvement from baseline in American College of Rheumatology response criteria (ACR50) at Week 16.
- The proportion of BKZ-randomised patients reporting clinically meaningful improvements in the following PROs are presented to 3 years (Week 160/148 in BE OPTIMAL or Week 156 in BE COMPLETE), stratified by Week 16 SJC=0 or ACR50 response:
 - Pain50, defined as a substantial (≥50%) decrease from baseline in pain, measured by visual analogue scale (VAS; score range: 0 [no pain]–100 [most severe pain])⁶
 - FACIT-Fatigue MCID (Functional Assessment of Chronic Illness Therapy-Fatigue minimal clinically important difference; score range 0–52 [higher scores indicate less fatigue]), defined as ≥4-point increase from baseline in patients with FACIT-Fatigue score <48 at baseline
 - PsAID-12 (12-item Psoriatic Arthritis Impact of Disease; score range: 0–10) no symptom or disease impact, defined as PsAID-12 total score <1.15⁷
- Data are reported as observed case (OC) or using modified non-responder imputation (mNRI).
- mNRI considered all visits following discontinuation due to adverse events or lack of efficacy as non-response; all other missing data were imputed using multiple imputation and the response was derived from the imputed values.

Results

- 431 bDMARD-naïve and 267 TNFi-IR patients were randomised to BKZ in the BE OPTIMAL and BE COMPLETE studies, respectively.
- At Week 16, SJC=0 was achieved by 48.3% of bDMARD-naïve patients and 45.9% of TNFi-IR patients (mNRI; **Figure 1**). At Week 16, ACR50 was achieved by 44.8% of bDMARD-naïve patients and 43.5% of TNFi-IR patients (mNRI; **Figure 2**).
- Baseline characteristics were broadly comparable between responders and non-responders; responders were more likely overall to be younger and male (**Table**).
- Across both bDMARD-naïve and TNFi-IR patients, SJC=0 and ACR50 responders demonstrated greater improvements in PROs than non-responders at Week 16 (**Figures 1–2**).
- Improvements in PROs in responders at Week 16 were sustained or increased further to Year 3 (**Figures 1–2**).

Conclusions

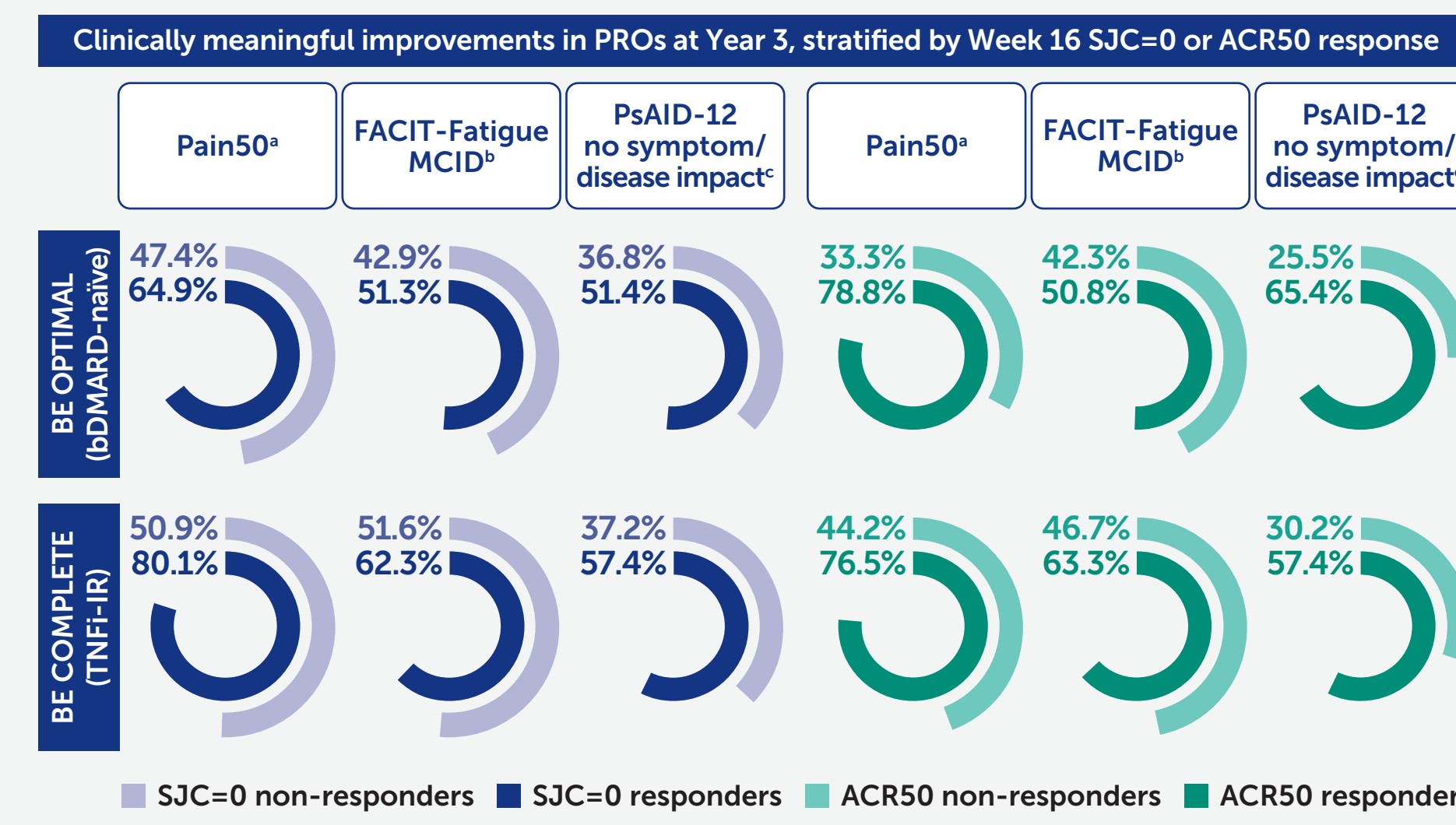
Patients with PsA treated with bimekizumab who were SJC=0 or ACR50 responders at Week 16 demonstrated greater and sustained improvements in pain, fatigue and reduced disease impact over 3 years compared to non-responders, both in bDMARD-naïve and TNFi-IR patients.

Interpretation should consider the post hoc design and potential confounding factors, including pain VAS being a component of the ACR response criteria.

These data suggest that rapid and high clinical responses may lead to long-term improvements in PROs, reinforcing the importance of timely intervention with effective therapy for optimal PsA management.

Summary

This post hoc analysis assessed whether the achievement of stringent treatment responses at Week 16 with bimekizumab, was associated with sustained, clinically meaningful improvements in patient-reported outcomes up to 3 years, in patients with active psoriatic arthritis.



Among bDMARD-naïve and TNFi-IR patients with PsA treated with bimekizumab, those achieving SJC=0 or ACR50 at Week 16 experienced greater and sustained reductions in pain, fatigue and overall disease impact up to 3 years than non-responders, highlighting the value of prompt, effective intervention to optimise long-term outcomes in PsA.

Data reported using mNRI. [a] Defined as a substantial (≥50%) decrease from baseline in pain VAS; [b] Defined as a ≥4-point increase from baseline in patients with FACIT-Fatigue score <48 at baseline; [c] Defined as PsAID-12 total score <1.15.

Table Baseline demographics and characteristics by Week 16 SJC=0 and ACR50 response

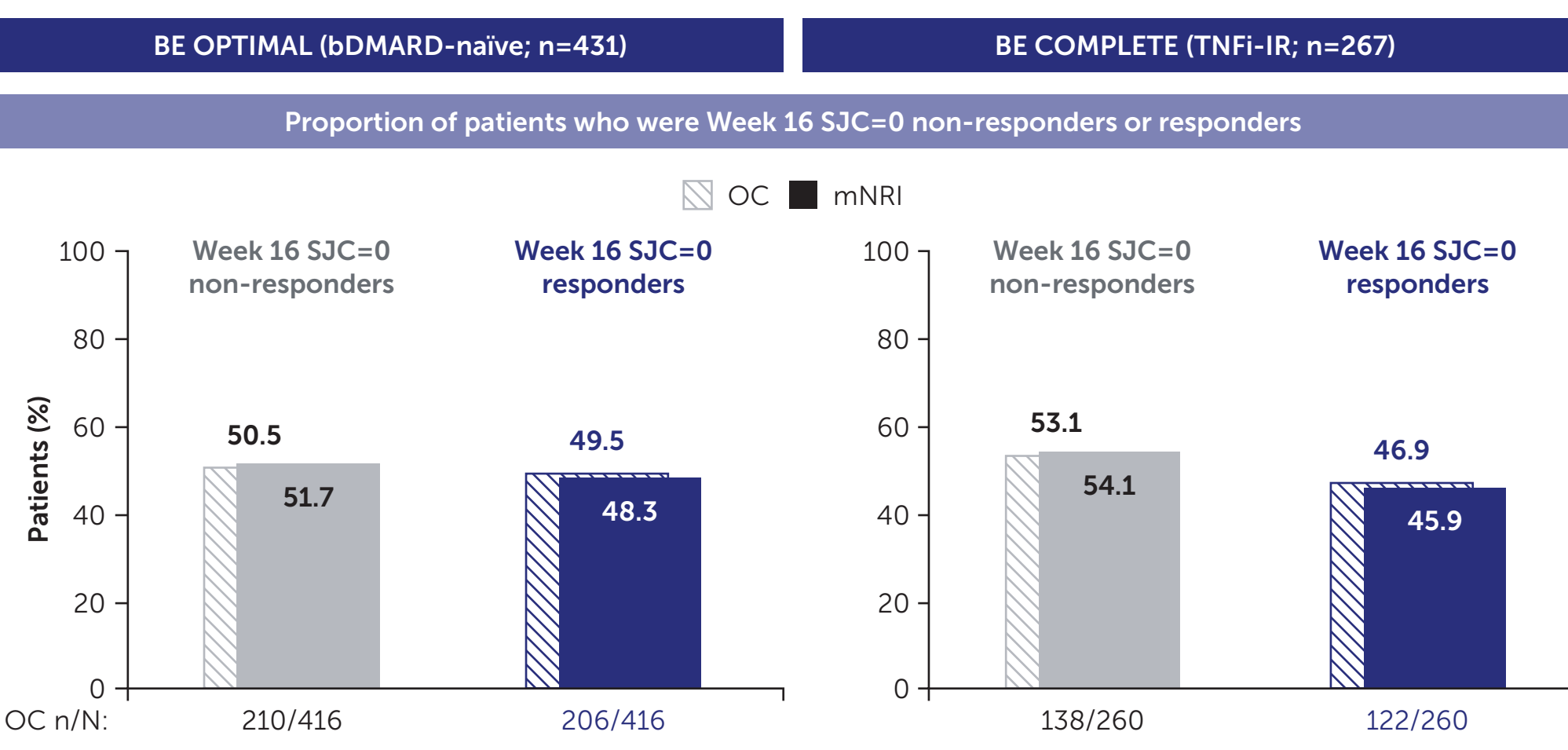
	BE OPTIMAL (bDMARD-naïve; n=431)		BE COMPLETE (TNFi-IR; n=267)	
	Week 16 SJC=0 non-responders (n=210)	Week 16 SJC=0 responders (n=206)	Week 16 SJC=0 non-responders (n=138)	Week 16 SJC=0 responders (n=122)
Mean (SD), unless otherwise stated				
Age, years	50.1 (13.1)	46.3 (11.4)	51.6 (11.7)	48.6 (12.8)
Sex, male, n (%)	87 (41.4)	109 (52.9)	70 (50.7)	56 (45.9)
BMI, kg/m ²	30.0 (7.4)	28.7 (6.0)	30.9 (7.3)	29.2 (5.4)
Time since PsA diagnosis, years	6.0 (7.5) ^a	6.1 (7.3) ^a	10.1 (10.3)	9.1 (9.3) ^a
SJC (of 68 joints)	8.7 (7.0)	8.2 (5.3)	10.6 (7.6)	8.2 (6.8)
TJC (of 68 joints)	18.0 (12.7)	15.2 (10.1)	19.4 (14.0)	16.9 (12.6)
BSA affected by psoriasis ≥3%, n (%)	93 (44.3)	117 (56.8)	83 (60.1)	89 (73.0)
PASI score ^b	7.3 (6.2) ^a	9.1 (7.4) ^a	10.2 (10.6) ^a	9.7 (6.7) ^a
Enthesitis (LEI >0), n (%)	83 (39.5)	53 (25.7)	66 (47.8)	36 (29.5)
LEI score ^c	2.4 (1.4)	2.6 (1.4)	2.5 (1.4)	2.8 (1.7)
Dactylitis (LDI >0), n (%)	31 (14.8)	23 (11.2)	23 (16.7)	10 (8.2)
LDI score ^d	54.6 (68.7)	35.0 (23.5)	90.2 (134.8)	36.5 (33.4)
hs-CRP, mg/L, median (Q1, Q3)	3.9 (1.4, 9.3)	3.4 (1.6, 11.8)	6.7 (2.0, 20.2)	3.7 (1.5, 10.1)
Pain VAS ^e	54.3 (23.3)	53.0 (25.1) ^a	59.3 (24.4)	57.2 (24.3)
FACIT-Fatigue ^f	37.4 (10.1)	38.4 (8.7) ^a	34.2 (10.7)	36.8 (10.2)
PsAID-12 total score ^g	4.0 (1.9)	3.9 (1.9) ^a	4.6 (2.1)	4.3 (2.0)

Randomised set, in patients randomised to BKZ at baseline. [a] n=205; [b] n=203; [c] n=121; [d] In patients with baseline psoriasis ≥3% BSA; [e] n=93; [f] n=117; [g] n=83; [h] n=89. [i] In patients with enthesitis at baseline (LEI >0); [j] In patients with dactylitis at baseline (LDI >0); [k] Pain was assessed using Patient's Assessment of Arthritis Pain VAS (score range: 0 [no pain] to 100 [most severe pain]); [l] FACIT-Fatigue scores range from 0–52; higher scores indicate less fatigue; [m] PsAID-12 total scores range from 0–10; higher scores indicate worse status; [n] n=220; [o] n=186; [p] n=114; [q] n=105; [r] n=104; [s] n=90; [t] n=82.

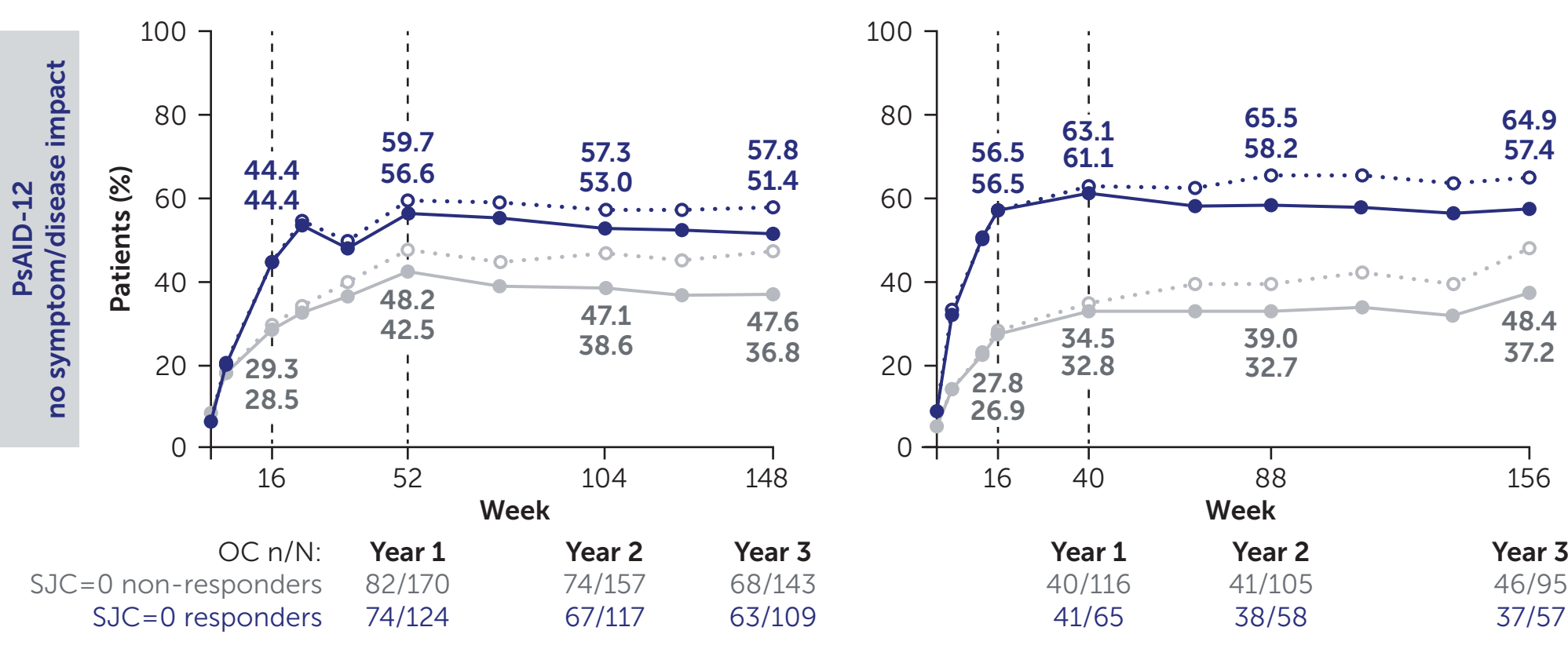
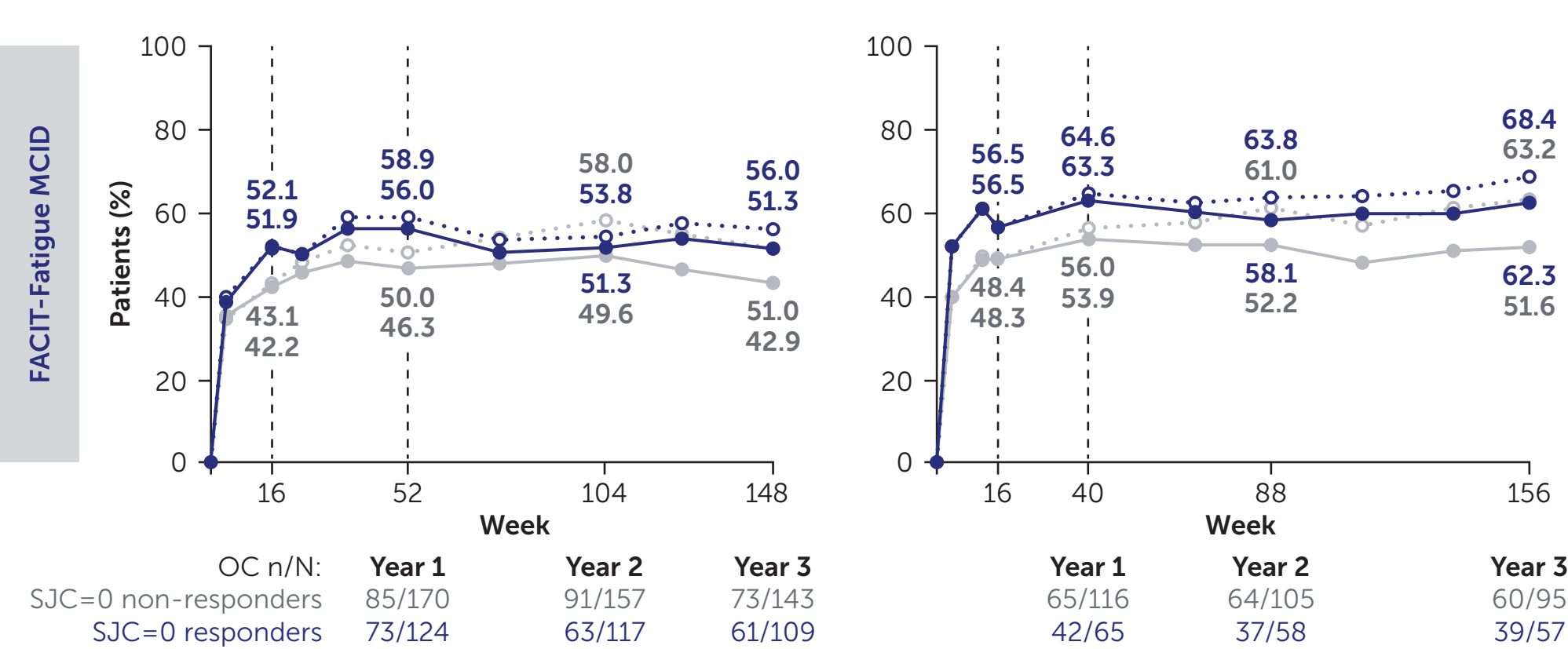
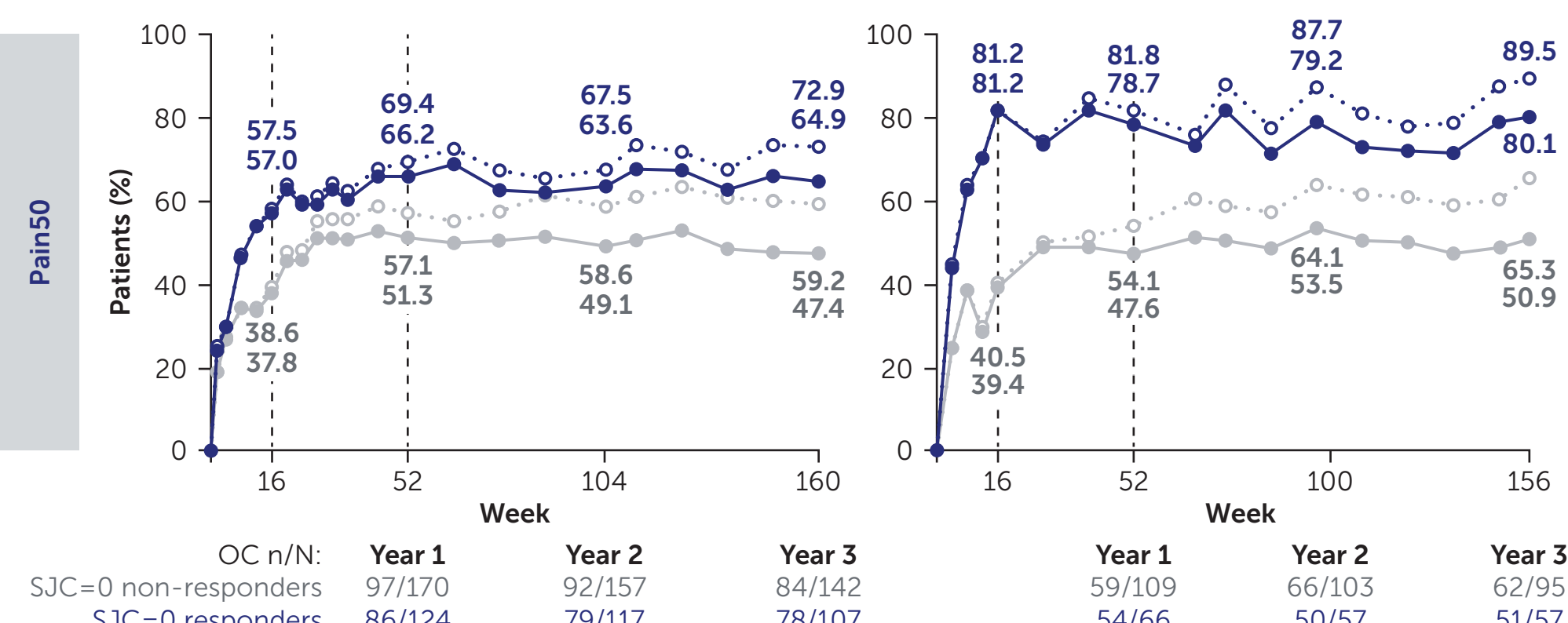
ACR: American College of Rheumatology; ACR50: ≥50% improvement from baseline in ACR response criteria; bDMARD: biologic disease-modifying antirheumatic drug; BKZ: bimekizumab; BMI: body mass index; BSA: body surface area; FACIT-Fatigue: Functional Assessment of Chronic Illness Therapy-Fatigue; hs-CRP: high-sensitivity C-reactive protein; ILI: interleukin; LDI: Leeds Dactylitis Index; LEI: Leeds Enthesitis Index; MCID: minimal clinically important difference; mNRI: modified non-responder imputation; OC: observed case; Pain50: ≥50% decrease from baseline in pain VAS; PASI: Psoriasis Area and Severity Index; PsA: psoriatic arthritis; PsAID-12: 12-item Psoriatic Arthritis Impact of Disease; PRO: patient-reported outcome; Q1: first quartile; Q3: third quartile; Q4W: every 4 weeks; SD: standard deviation; SJC: swollen joint count; TJC: tender joint count; TNFi-IR: prior inadequate response or intolerance to tumour necrosis factor inhibitors; VAS: visual analogue scale.

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Figure 1 Clinically meaningful improvements in PROs to 3 years by Week 16 SJC=0 response (mNRI, OC)

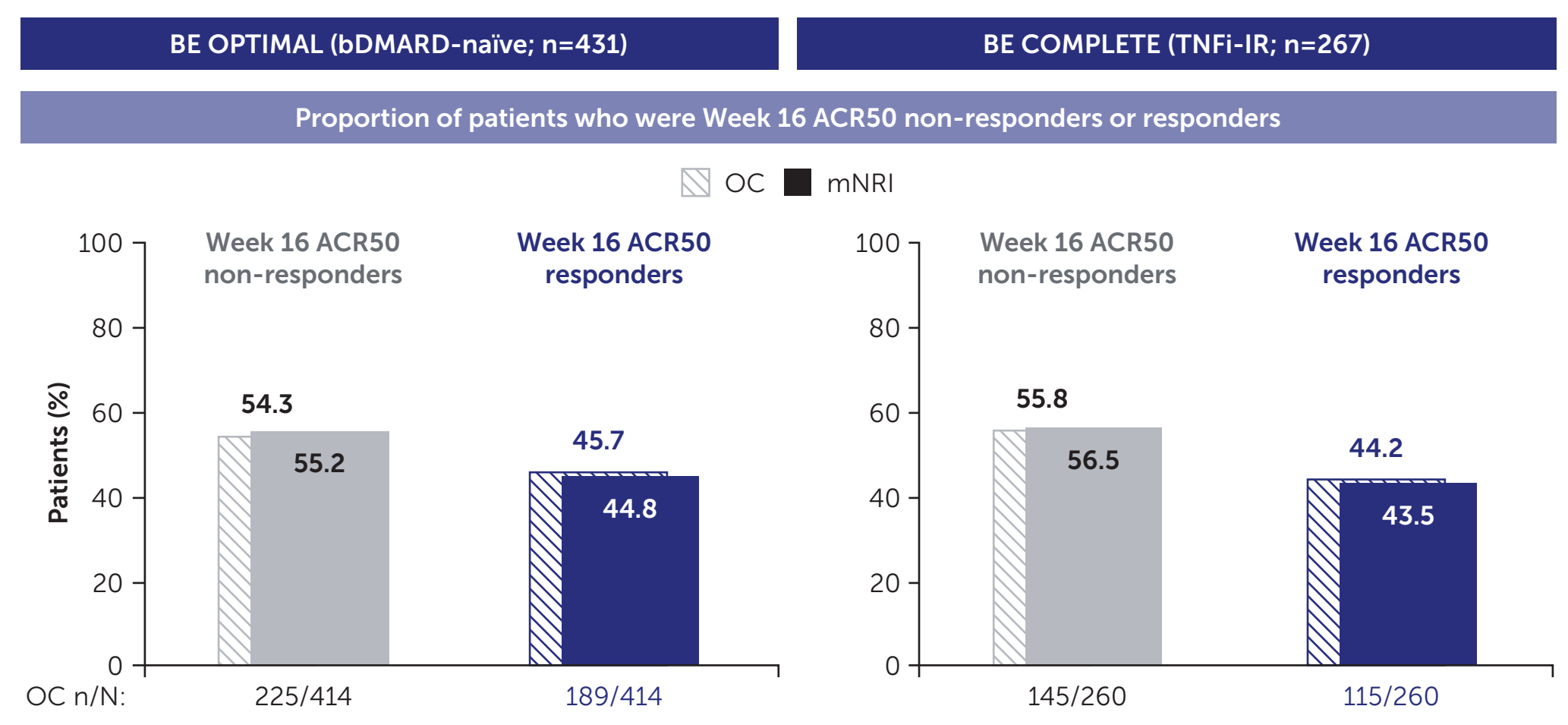


Clinically meaningful improvements in PROs by Week 16 SJC=0 response

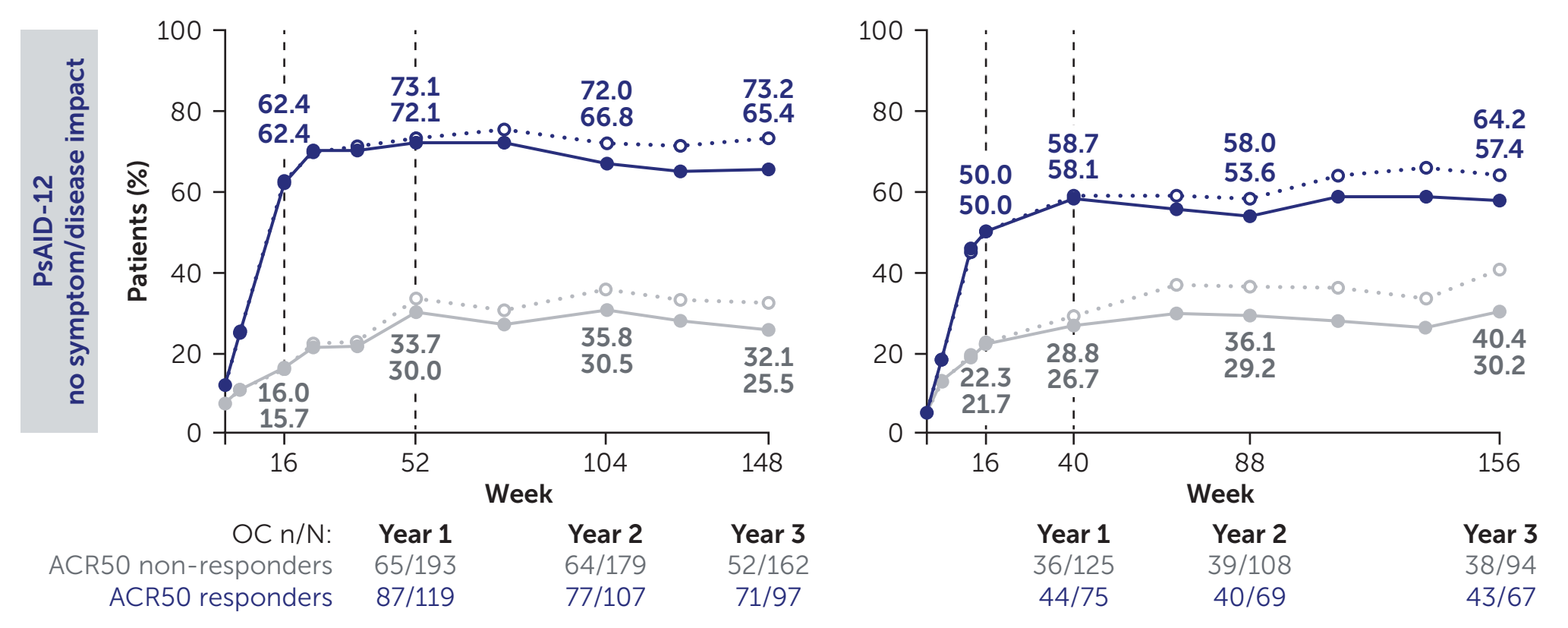
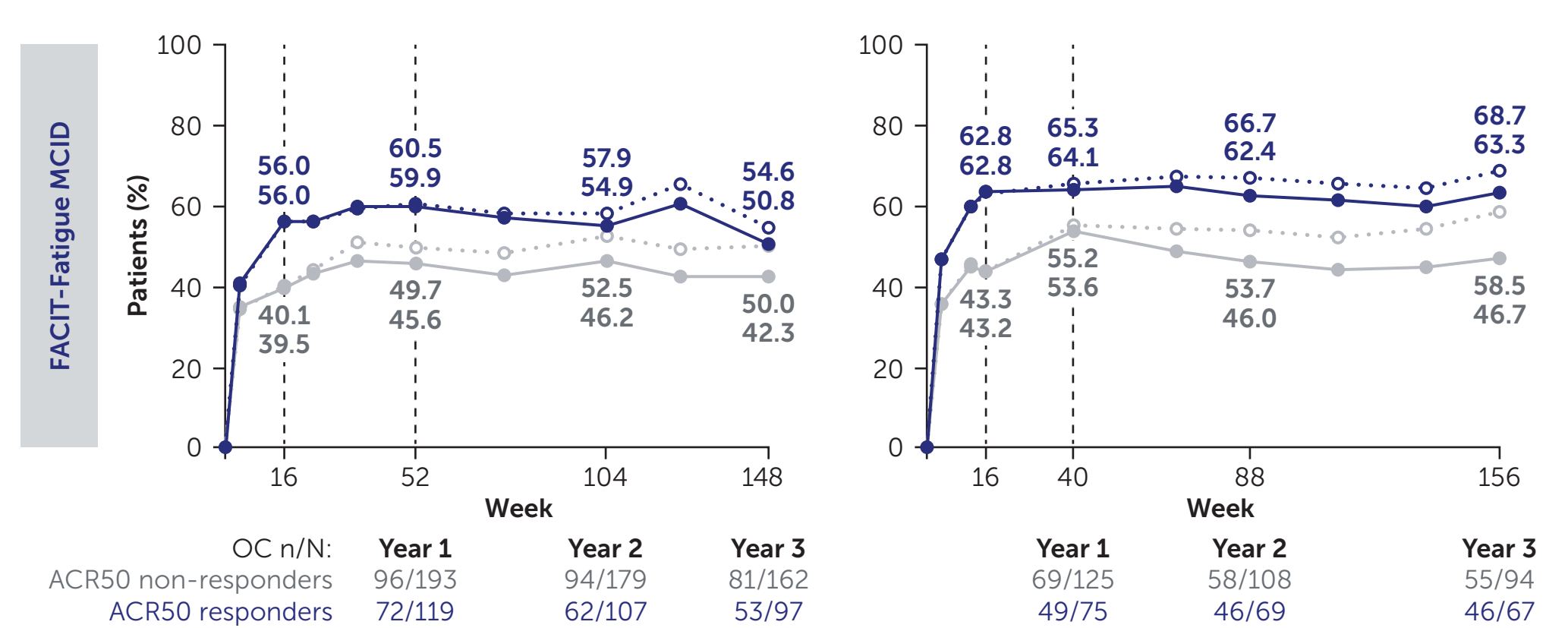
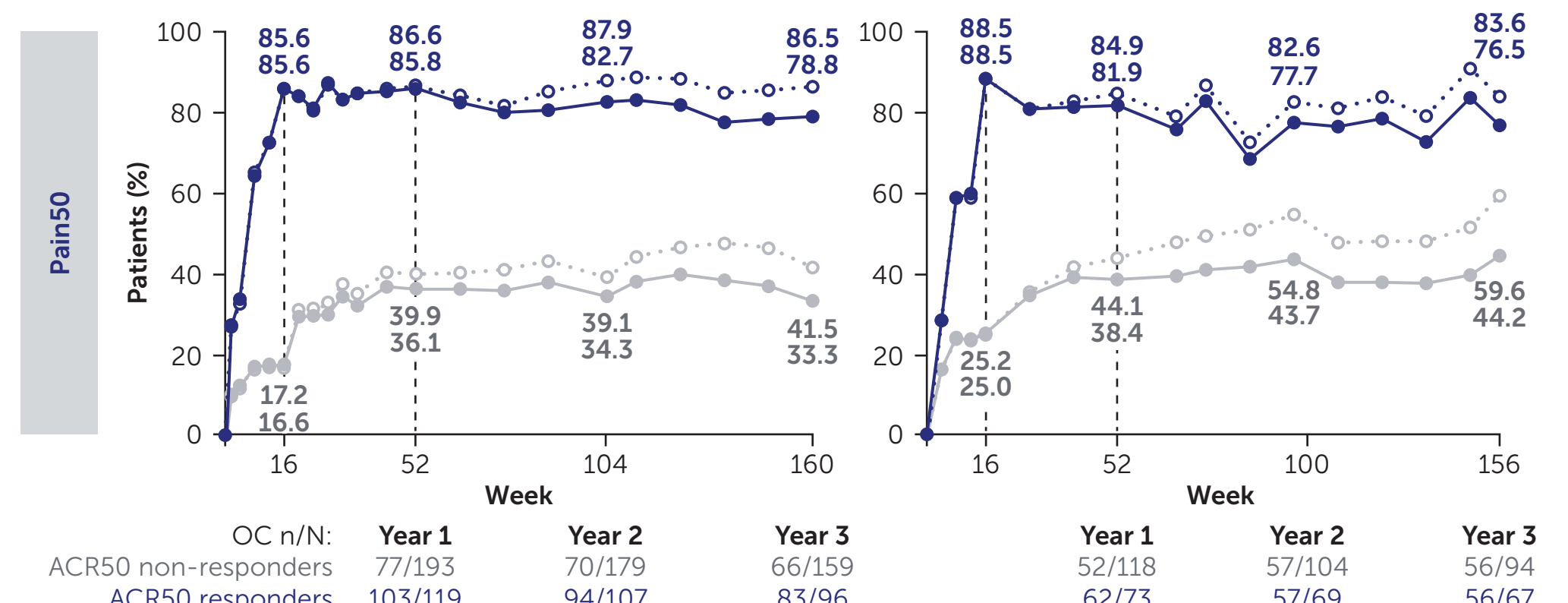


Randomised set, in patients randomised to BKZ at baseline. Data reported through Year 1 (Week 52 in BE OPTIMAL and Week 52/40 in BE COMPLETE), Year 2 (Week 104 in BE OPTIMAL and Week 100/148 in BE COMPLETE) and Year 3 (Week 160/148 in BE OPTIMAL and Week 156 in BE COMPLETE).

Figure 2 Clinically meaningful improvements in PROs to 3 years by Week 16 ACR50 response (mNRI, OC)



Clinically meaningful improvements in PROs by Week 16 ACR50 response



Randomised set, in patients randomised to BKZ at baseline. Data reported through Year 1 (Week 52 in BE OPTIMAL and Week 52/40 in BE COMPLETE), Year 2 (Week 104 in BE OPTIMAL and Week 100/148 in BE COMPLETE) and Year 3 (Week 160/148 in BE OPTIMAL and Week 156 in BE COMPLETE).

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