Bimekizumab Maintained Efficacy Responses Through 52 Weeks in Biologic Disease-Modifying Antirheumatic Drug-Naïve Patients with Psoriatic Arthritis who were Responders at Week 16: Results from a Phase 3, Active Reference Study

Objective

To report the maintenance of response in efficacy outcomes assessing joints and skin, including composite disease activity measures, to Week 52 in bimekizumab (BKZ)-treated patients with psoriatic arthritis (PsA) who were responders at Week 16 of the BE OPTIMAL study.

Background

- PsA is a chronic, long-term condition; thus, it is important that therapies sustain high levels of disease control
- Assessing the maintenance of response in patients that achieve treatment targets is of interest, particularly as patients can experience loss of response with long-term therapy.¹
- BKZ, a monoclonal IgG1 antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A, has demonstrated rapid, statistically significant and clinically meaningful efficacy responses at Week 16 versus placebo in patients with PsA.^{2,3}
- Week 16 efficacy was sustained to Week 52 in the phase 3 BE OPTIMAL trial.⁴

Methods

- BE OPTIMAL (NCT03895203) included a 16-week, double-blind, placebo-controlled period, and a 36-week active treatment-blind period. An active reference adalimumab (ADA) arm was included to provide a reference for the benefit-risk profile of BKZ. The ADA arm was not powered for statistical comparison to BKZ or placebo.
- Maintenance of response is reported as the percentage of Week 16 responders who met the response criteria at subsequent study visits. This analysis is shown for visits from Week 16 to Week 52 for American College of Rheumatology (ACR)20/50/70, Psoriasis Area and Severity Index (PASI)75/90/100, minimal and very low disease activity (MDA, VLDA), Disease Activity Index for Psoriatic Arthritis (DAPSA) remission or low disease activity (REM+LDA; score of \leq 14) and remission (REM; score \leq 4), and composite ACR50+PASI100 responses.
- Week 16 responders are reported using non-responder imputation (NRI); Week 52 maintenance data are reported using NRI and observed case (OC).
- The number of treatment-emergent adverse events (TEAEs) to Week 52 are reported for patients who received ≥ 1 dose of BKZ, including patients who switched from placebo to BKZ at Week 16.

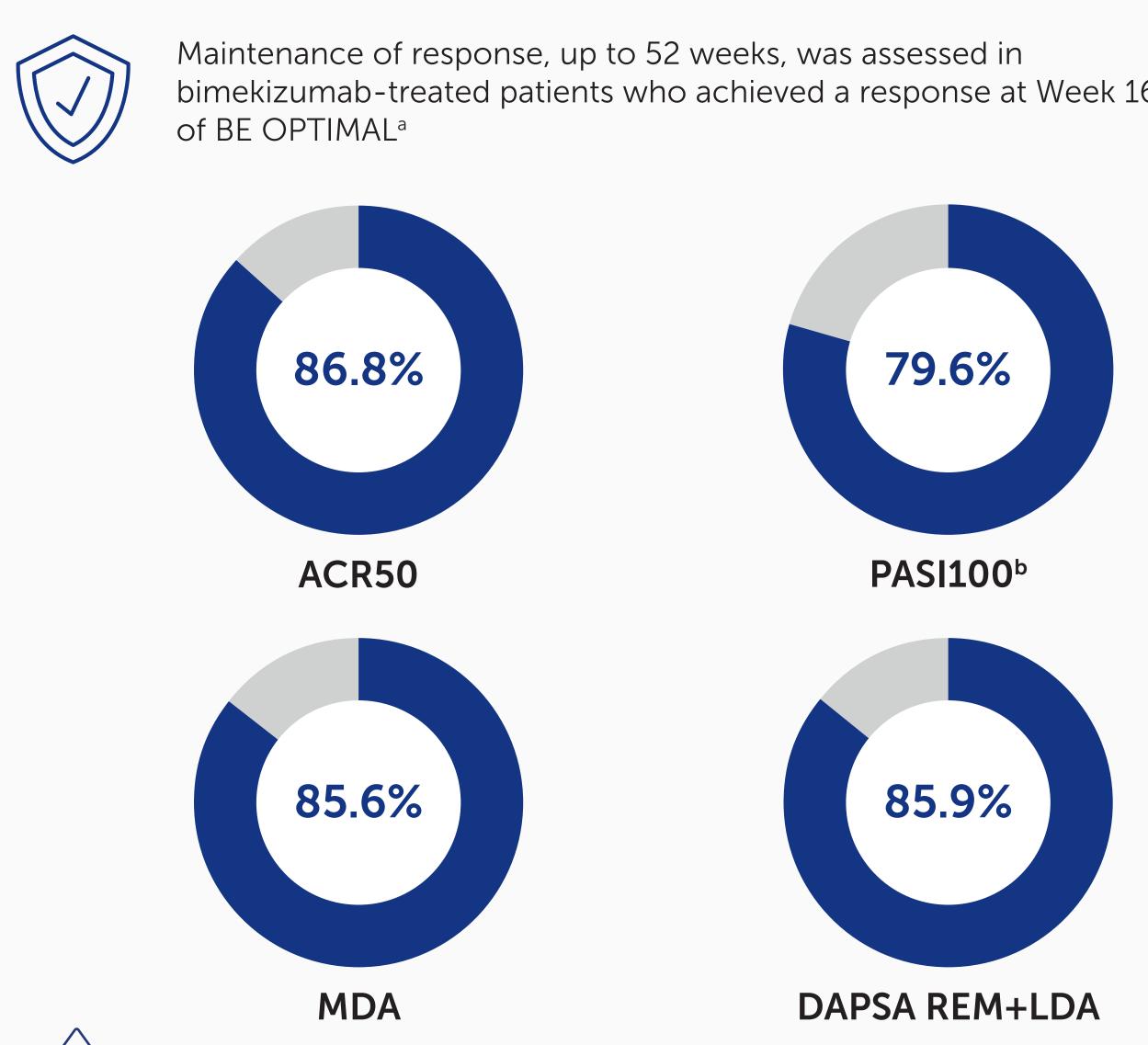
Results

- At baseline, 431 and 140 patients were randomized to BKZ 160 mg every 4 weeks (Q4W) and ADA 40 mg every 2 weeks (Q2W), respectively. 217/431 (50.3%) BKZ- and 68/140 (48.6%) ADA-randomized patients had psoriasis affecting \geq 3% body surface area (BSA). Week 16 completers: 414/431 (96.1%) BKZ, 136/140 (97.1%) ADA; Week 52 completers: 383/431 (88.9%) BKZ, 123/140 (87.9%) ADA.
- Baseline demographics and disease characteristics for the groups randomized to BKZ and ADA are reported in **Table 1**.
- At Week 16, 189 (43.9%; NRI) BKZ-treated patients achieved ACR50. Of those responders, 86.8% (NRI) and 91.1% (OC) maintained ACR50 response at Week 52 (Figure 1). Similar results were seen across other ACR endpoints: ACR20/70 was achieved by 268 (62.2%) and 105 (24.4%) patients, respectively, at Week 16 (NRI). At Week 52, ACR20/70 was maintained by 88.4%/82.9% (NRI) and 92.9%/87.9% (OC) of patients.
- Of 217 BKZ-treated patients with psoriasis affecting \geq 3% BSA at baseline, 133 (61.3%; NRI) and 103 (47.5%; NRI) achieved PASI90/100 at Week 16. Robust maintenance of response was observed in high proportions (>79%) of these patients to Week 52 (Figure 2). 168 (77.4%) achieved PASI75; 88.1% maintained response to Week 52 (NRI).
- A high proportion of Week 16 BKZ-treated responders for MDA, DAPSA REM+LDA and ACR50+PASI100 maintained their responses to Week 52 (Figures 3–5).
- Response was maintained to Week 52 for 79.4% (NRI) and 86.2% (OC) of patients that achieved VLDA at Week 16. 68.1% (NRI) of the 47 (10.9%) patients that achieved DAPSA REM at Week 16 maintained response to Week 52.
- To Week 52, 555/702 (79.1%) patients reported \geq 1 TEAE whilst receiving BKZ; 46 (6.6%) reported serious TEAEs.

Conclusions

A high proportion of bimekizumab-treated patients who responded at Week 16 maintained robust efficacy responses to Week 52. Efficacy measures spanned joint, skin, disease activity, and composite efficacy outcomes. The safety profile of bimekizumab was consistent with previous reports.^{2,3}

Summary





[a] Values shown here are NRI; [b] In patients with psoriasis affecting \geq 3% BSA at baseline.

Age, years, mean (SD **Male**, n (%)

BMI, kg/m², mean (SE

Time since first PsA Methotrexate at base

BSA affected by psor

PASI score,^d mean (S TJC (of 68 joints), m

SJC (of 66 joints), m

Enthesitis (LEI>0),^e r

LEI score, mean (SE **Dactylitis**,^f n (%)

LDI score, mean (S

hs-CRP ≥6 mg/L, n HAQ-DI, mean (SD)

PtAAP,^g mean (SD)

Randomized set. [a] Listed as time since first diagnosis of PsA; [b] n=423; [c] n=139; [d] In patients with psoriasis affecting >3% BSA at baseline; [e] LEI >0; [f] LDI >0; [g] PtAAP VAS 0 (no symptoms) – 100 (severe symptoms); [h] n=430.

<BA: body surface area; BA: body surface area; BA: biological disease activity; LDI: Leeds Enthesitis Index; BA: body surface area; BA: b PASI: Psoriasis Area and Severity Index; PASI75/90/100: >75/90/100: >75/90/100% improvement in PASI; PsA: psoriatic arthritis; PtAAP: Patient Assessment of Arthritis Pain; REM: remission; SD: standard deviation; SJC: swollen joint count; TEAE: treatment-emergent adverse event; TJC: tender joint count; Co

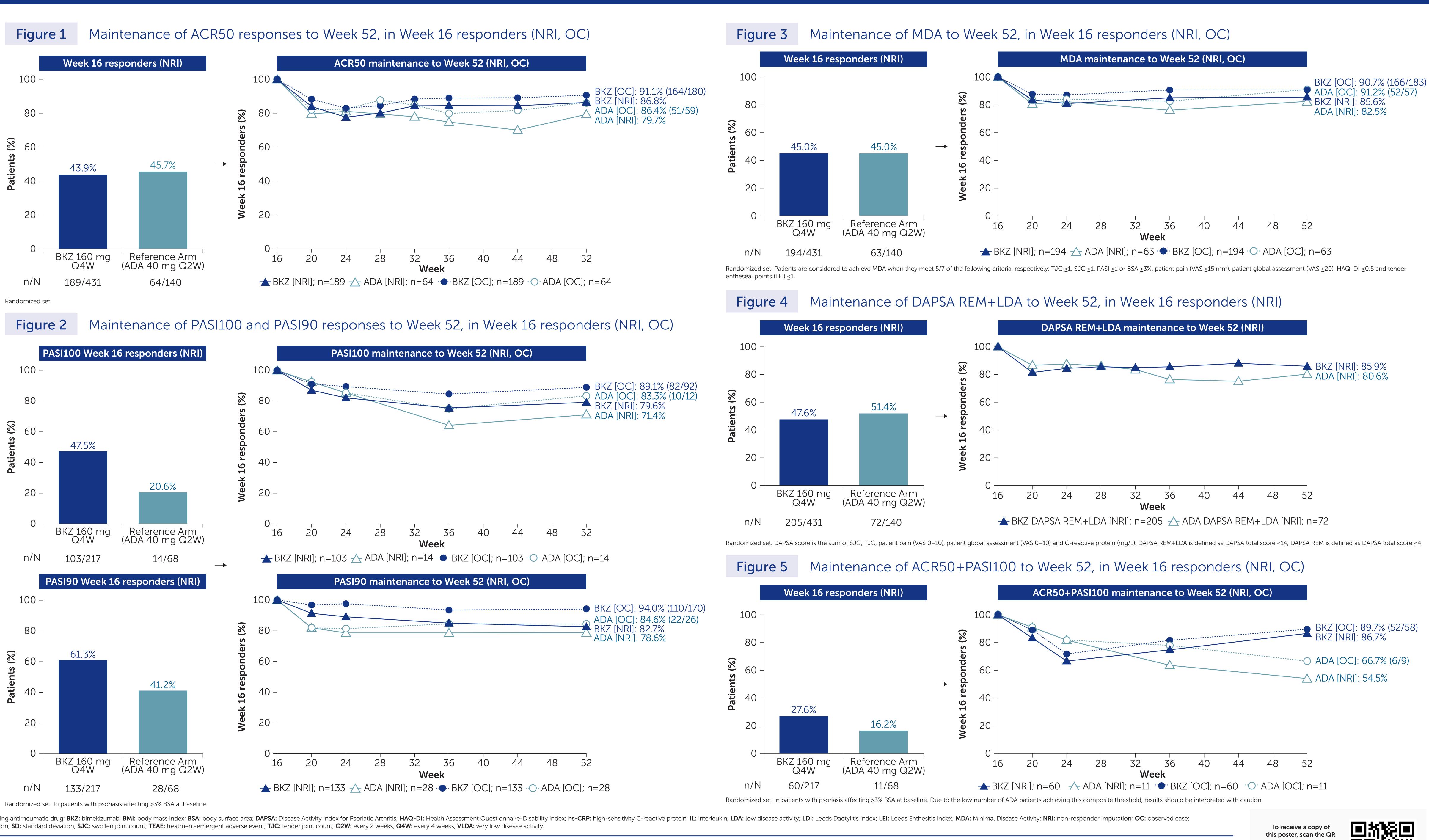
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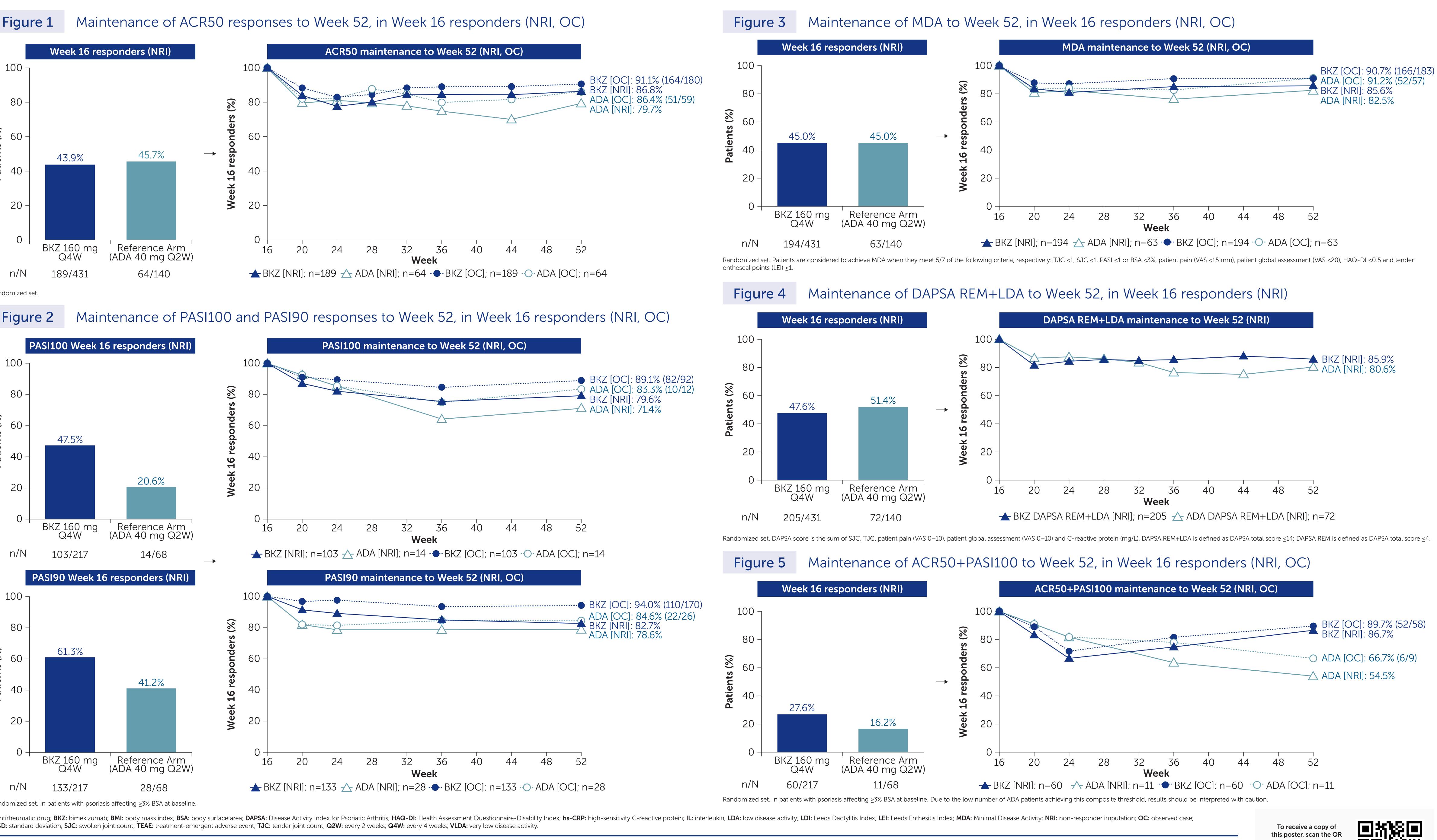
-treated patients who achieved a response at Week 16

A high proportion of patients who responded to treatment of bimekizumab at Week 16 maintained their response to Week 52 across multiple domains

Table 1Baseline characteristics

-	BKZ 160 mg Q4W n=431	ADA 40 mg Q2W n=140
D)	48.5 (12.6)	49.0 (12.8)
 	201 (46.6)	71 (50.7)
SD)	29.2 (6.8)	28.4 (5.9)
diagnosis , ^a years, mean (SD)	6.0 ^b (7.3)	6.1° (6.8)
seline, n (%)	252 (58.5)	82 (58.6)
oriasis >3% , n (%)	217 (50.3)	68 (48.6)
SD)	8.2 (6.8)	8.6 (7.6)
nean (SD)	16.8 (11.8)	17.5 (13.1)
nean (SD)	9.0 (6.2)	9.7 (7.1)
า (%)	143 (33.2)	36 (25.7)
5D)	2.5 (1.5)	2.3 (1.6)
	56 (13.0)	11 (7.9)
SD)	46.7 (54.3)	49.7 (31.9)
(%)	158 (36.7)	44 (31.4)
	0.82 (0.59)	0.86 (0.54)
	53.6 (24.3) ^h	56.7 (23.9)







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