

Structural Damage Progression and Clinical Response to Guselkumab in Participants With Active and Erosive Psoriatic Arthritis: Post-hoc Analysis at Week 24 of the Phase 3b, Randomized, Double-Blind, Placebo-Controlled APEX Study

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Background

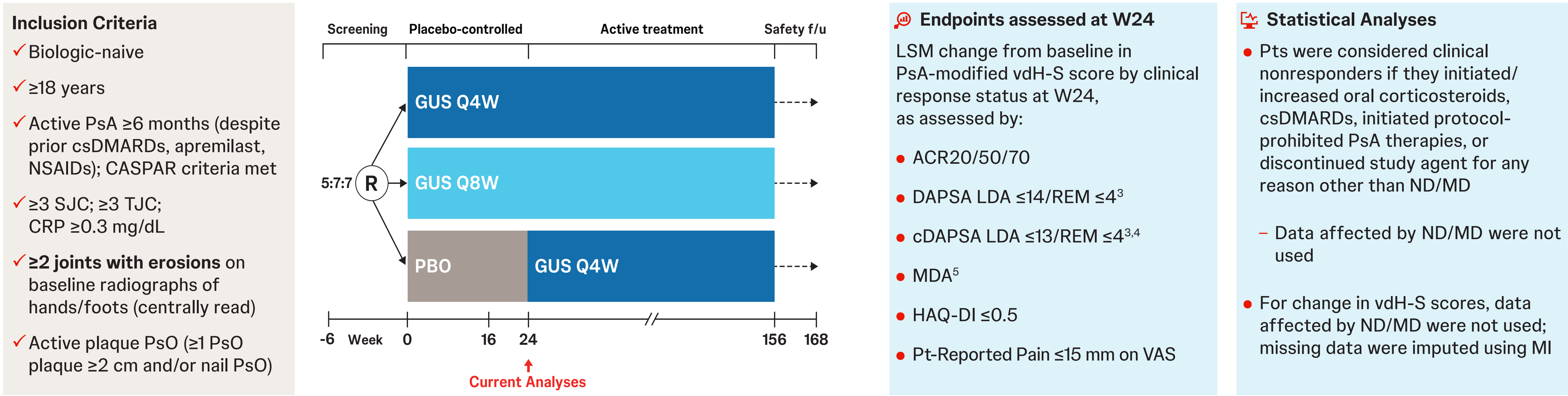
Guselkumab (GUS) inhibition of structural damage progression in psoriatic arthritis (PsA)

- Uncontrolled inflammation in PsA increases the risk of structural joint damage, which is associated with long-term disability and greater impairments in physical function and health-related quality of life
- GUS is a fully human, dual-acting,¹ monoclonal antibody that selectively inhibits the interleukin (IL)-23p19 subunit
- In the phase 3b APEX study, GUS demonstrated efficacy across PsA domains and significantly inhibited structural damage progression compared with placebo (PBO) in participants (pts) with active and erosive PsA at Week (W) 24²

Objective

Evaluate the relationship between clinical response status and structural damage progression at W24 among GUS-randomized pts in APEX

APEX Study Design and Methods



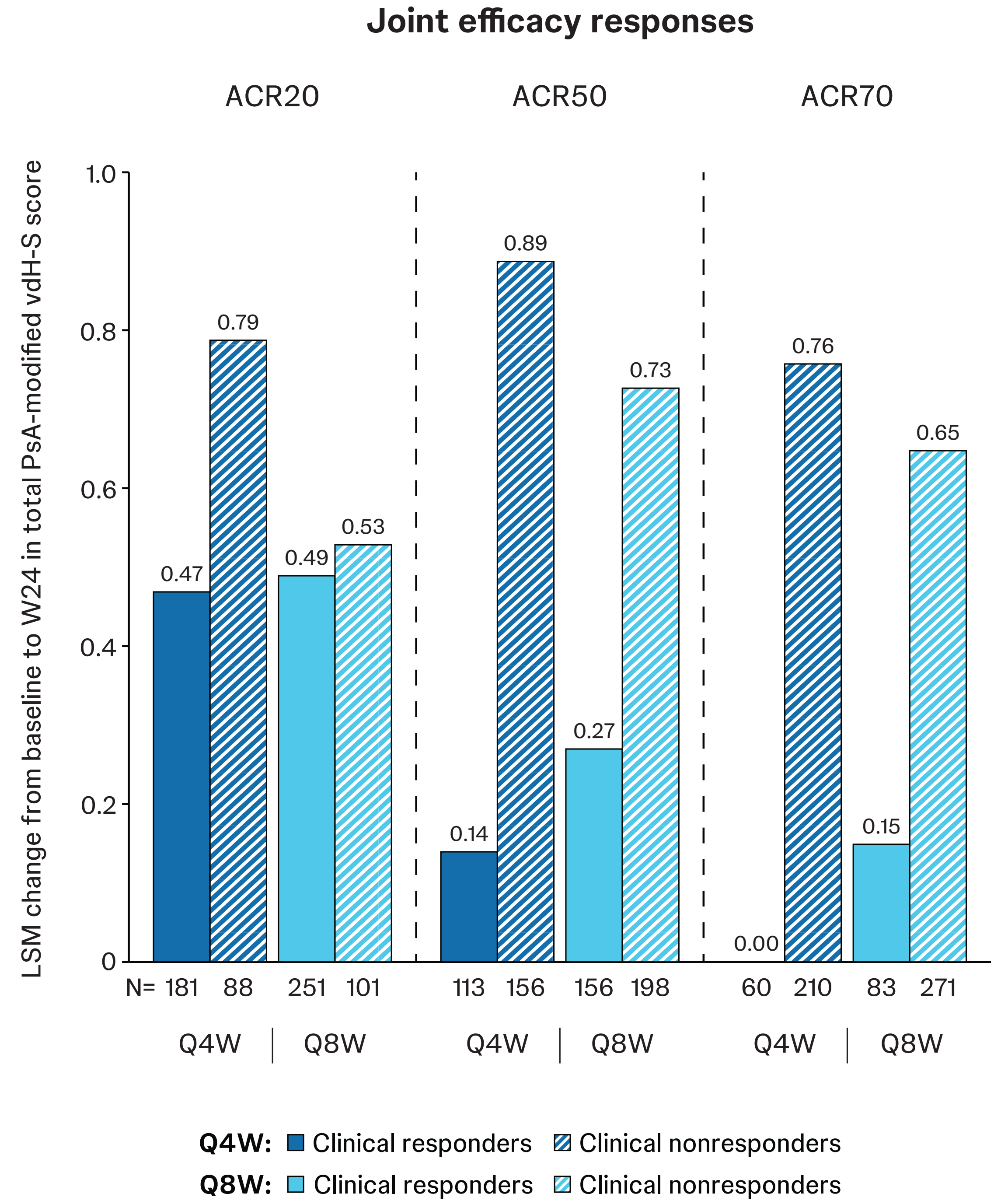
Results

Baseline characteristics were well balanced across treatment groups

	GUS Q4W (N=273)	GUS Q8W (N=371)	PBO (N=376)	Total (N=1020)
Demographics				
Age, years	52.2 (13.2)	53.2 (12.9)	53.5 (13.0)	53.0 (13.0)
Male	55%	54%	57%	55%
Weight, kg	85.6 (20.1)	83.2 (17.4)	83.1 (18.2)	83.8 (18.5)
BMI, kg/m ²	29.4 (6.0)	29.0 (5.6)	28.9 (5.7)	29.1 (5.7)
PsA Characteristics				
PsA Disease Duration, years	7.5 (7.1)	7.2 (7.6)	7.2 (6.9)	7.3 (7.2)
SJC [0–66]	11.6 (9.4)	12.1 (8.5)	11.8 (8.9)	11.9 (8.9)
TJC [0–68]	21.2 (14.6)	20.6 (13.4)	20.5 (13.9)	20.7 (13.9)
Pt-reported pain (VAS; 0–100 mm)	59.2 (22.2)	59.3 (21.0)	59.4 (20.6)	59.3 (21.1)
HAQ-DI [0–3]	1.2 (0.7)	1.2 (0.6)	1.2 (0.7)	1.2 (0.7)
DAPSA	46.4 (24.3)	46.1 (22.1)	46.0 (22.8)	46.1 (22.9)
cDAPSA	44.7 (23.5)	44.6 (21.6)	44.3 (22.3)	44.5 (22.4)
CRP, mg/dL	1.7 (2.9)	1.5 (2.0)	1.7 (2.5)	1.6 (2.5)
Enthesitis / Dactylitis	58% / 44%	59% / 39%	59% / 45%	58% / 43%
Mean LEI [1–6]/DSS [1–60]	3.2 / 10.8	3.0 / 11.0	3.0 / 10.2	3.1 / 10.6
Radiographic Characteristics				
PsA-modified vdH-S score [0–528]	27.7 (47.6)	26.7 (43.4)	26.8 (42.2)	27.0 (44.1)
Erosion score [0–320]	13.7 (24.3)	13.4 (21.9)	13.4 (20.7)	13.5 (22.1)
JSN score [0–208]	14.0 (24.2)	13.3 (22.8)	13.4 (22.4)	13.5 (23.0)

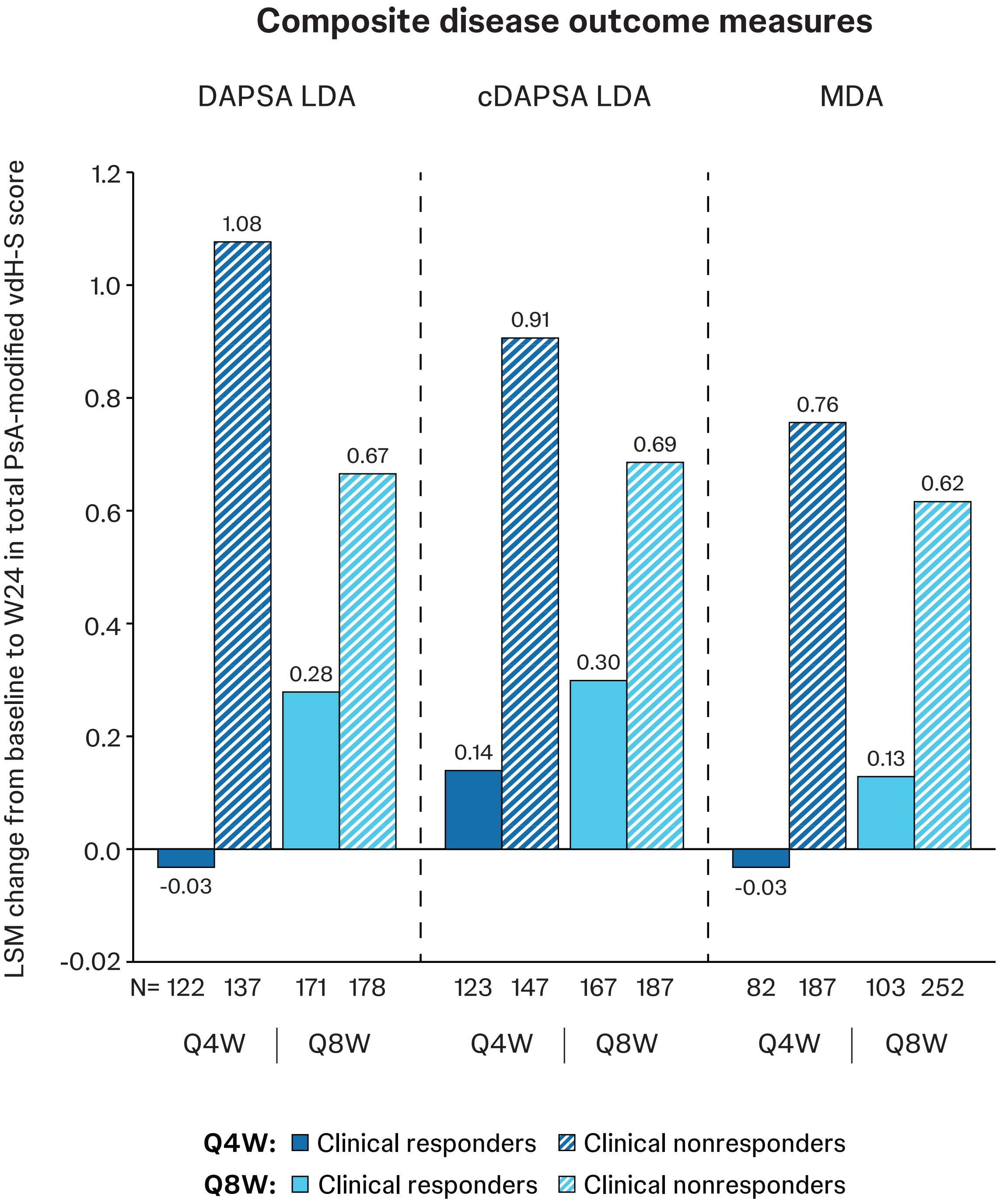
Values are reported as mean (SD) for pts with nonmissing data unless otherwise noted. **BMI** = body mass index. **cDAPSA** = clinical Disease Activity Index for Psoriatic Arthritis. **CRP** = C-reactive protein. **DAPSA** = Disease Activity Index for Psoriatic Arthritis. **DSS** = Disability Severity Score. **GUS** = guselkumab. **HAQ-DI** = Health Assessment Questionnaire-Disability Index. **JSN** = joint space narrowing. **LEI** = Leishman-Entrez index. **PBO** = placebo. **PsA** = psoriatic arthritis. **Pts** = participants. **Q4W** = every 4 weeks. **Q8W** = every 8 weeks. **SD** = standard deviation. **SJC** = swollen joint count. **TJC** = tender joint count. **VAS** = visual analog scale. **vdH-S** = van der Heijde-Sharp. **W** = week.

At W24, GUS-randomized pts who achieved response in joint efficacy measures had numerically lower levels of structural damage progression



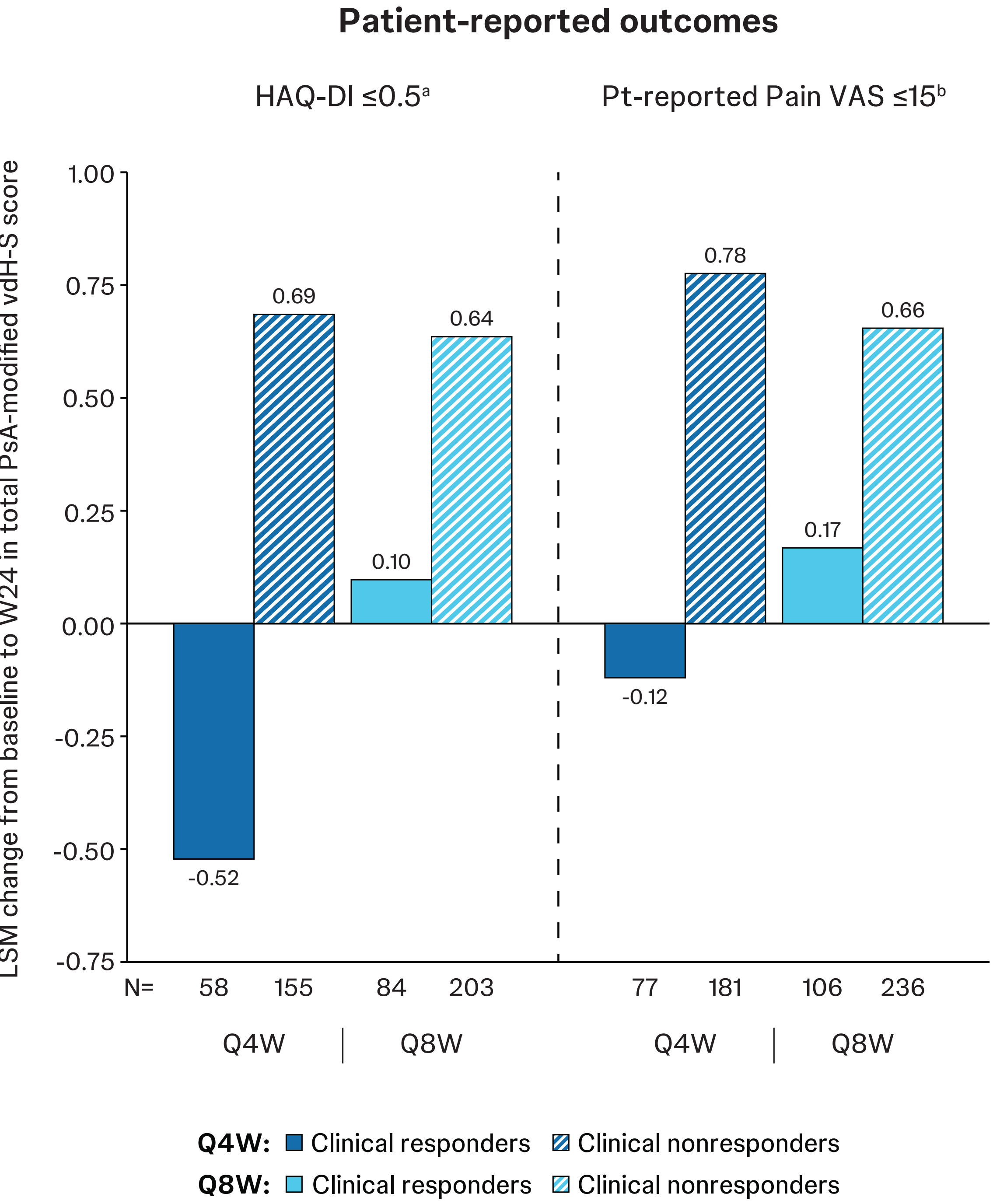
ACR20/50/70 = ≥20%/≥50%/≥70% improvement in the American College of Rheumatology criteria. **LSM** = least squares mean. **PsA** = psoriatic arthritis. **Q4W** = every 4 weeks. **Q8W** = every 8 weeks. **vdH-S** = van der Heijde-Sharp. **W** = week.

At W24, GUS-randomized pts who achieved low or minimal disease activity by composite indices had numerically lower levels of structural damage progression



cDAPSA = clinical Disease Activity Index for Psoriatic Arthritis. **DAPSA** = Disease Activity Index for Psoriatic Arthritis. **LDA** = low disease activity. **LSM** = least squares mean. **MDA** = minimal disease activity. **PsA** = psoriatic arthritis. **Q4W** = every 4 weeks. **Q8W** = every 8 weeks. **vdH-S** = van der Heijde-Sharp. **W** = week.

At Week 24, GUS-randomized pts who achieved normalized physical function and minimal pain had numerically lower levels of structural damage progression



^aAmong pts who had HAQ-DI score ≤0.5 at baseline. ^bAmong pts who had Pt-reported pain VAS ≤15 at baseline. **HAQ-DI** = Health Assessment Questionnaire-Disability Index. **LSM** = least squares mean. **PsA** = psoriatic arthritis. **Pts** = participants. **Q4W** = every 4 weeks. **Q8W** = every 8 weeks. **VAS** = visual analog scale. **vdH-S** = van der Heijde-Sharp. **W** = week.