

# Achievement of cDAPSA Low Disease Activity/Remission and Association With Structural Damage Progression in Guselkumab-Treated Participants With Active and Erosive Psoriatic Arthritis: Post Hoc Analysis Through Week 48 of the Phase 3b, Randomized, Double-Blind, Placebo-Controlled APEX Study

Christopher T Ritchlin,<sup>1</sup> Laura C Coates,<sup>2</sup> Philip J Mease,<sup>3,4</sup> Alexa P Kollmeier,<sup>5</sup> Weihong Hu,<sup>6</sup> Soumya D Chakravarty,<sup>7,8</sup> Stacey Fitch,<sup>7</sup> Karissa Lozenski,<sup>7</sup> Alexis Ogdie,<sup>9</sup> Proton Rahman<sup>10</sup>

<sup>1</sup>Department of Medicine, Allergy/Immunology and Rheumatology, University of Rochester Medical Center, Rochester, NY, USA; <sup>2</sup>Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences, University of Oxford, Botnar Research Centre, Oxford, UK; <sup>3</sup>Rheumatology Research, Providence Swedish Medical Center, Seattle, WA, USA; <sup>4</sup>University of Washington School of Medicine, Seattle, WA, USA; <sup>5</sup>Johnson & Johnson, San Diego, CA, USA; <sup>6</sup>Johnson & Johnson, Spring House, PA, USA; <sup>7</sup>Johnson & Johnson, Horsham, PA, USA; <sup>8</sup>Drexel University College of Medicine, Philadelphia, PA, USA; <sup>9</sup>University of Pennsylvania School of Medicine, Philadelphia, PA, USA; <sup>10</sup>Faculty of Medicine, Division of Rheumatology, Memorial University of Newfoundland, St. John's, NL, Canada

## Background

Guselkumab (GUS), a fully human, dual-acting,<sup>1</sup> monoclonal antibody that selectively inhibits the interleukin (IL)-23p19 subunit, has demonstrated multidomain efficacy and significantly inhibited structural damage progression in participants (pts) with active and erosive psoriatic arthritis (PsA) in the phase 3b APEX study<sup>2</sup>

The Disease Activity Index for PsA (DAPSA) is a composite score assessing joint symptoms, disease activity, pain, and C-reactive protein (CRP); the clinical DAPSA (cDAPSA) excludes CRP

DAPSA and cDAPSA are validated and perform similarly in pts with PsA<sup>3</sup>

Through Week (W) 24 of APEX, significantly greater proportions of GUS- vs placebo (PBO)-randomized pts achieved low disease activity (LDA) based on both DAPSA and cDAPSA assessments<sup>4</sup>

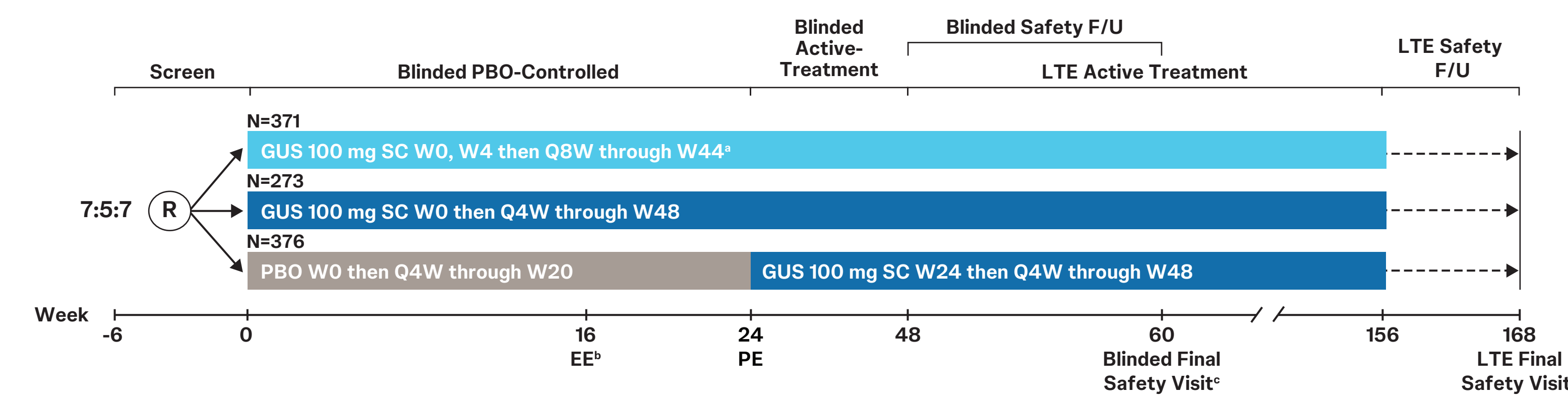
## Objective

Evaluate the relationship between structural damage progression at 1 year, measured by total PsA-modified van der Heijde-Sharp (vdH-S) score, and achievement of DAPSA/cDAPSA response through W24 in GUS-randomized pts in APEX

## Methods

### Key inclusion criteria:

- Biologic-naïve
- ≥18 years
- Active PsA (≥3 SJC; ≥3 TJC; CRP ≥0.3 mg/dL) for ≥6 months (despite prior csDMARDs, apremilast, NSAIDs); CASPAR criteria met
- ≥2 erosive joints on hand/foot radiographs
- Active plaque PsO (≥1 PsO, plaque ≥2 cm and/or nail PsO)



<sup>1</sup>PBO SC W8 then Q8W through W48 administered to maintain blinding. <sup>2</sup>EE if <20% improvement from baseline in both TJC and SJC at W16. EE pts may initiate/increase dose of permitted medication up to the maximum dose at the investigator's discretion. <sup>3</sup>Final safety visit for those who do not enter LTE. <sup>4</sup>Final safety visit for those who entered LTE. CASPAR=Classification criteria for Psoriatic Arthritis, BL=baseline, CRP=C-reactive protein, csDMARDs=conventional synthetic disease modifying antirheumatic drugs, EE=early escape, F/U=follow-up, GLMM=generalized linear mixed model, HDA=high disease activity, LTE=long-term extension, MD=major disruption: involving Ukraine and neighboring countries/territories beginning 24 February 2022, mFAS=modified full analysis set, MI=multiple imputation, ModDA=moderate disease activity, ND=natural disaster: site closure, site access restrictions, or lockdowns due to the COVID-19 pandemic, NSAIDs=nonsteroidal anti-inflammatory drug, PE=primary endpoint, PsO=psoriasis, Q4W/Q8W=every 4/8 weeks, R=randomization, REM=remission, SC=subcutaneous, SJC=swollen joint count, TJC=tender joint count, VAS=visual analog scale.

### Outcomes:

- Achievement of DAPSA LDA ≤14/REM ≤4 and cDAPSA LDA ≤13/REM ≤4 at W8, W24, and W48 among pts with DAPSA ModDA >14-≤28/HDA >28 or cDAPSA ModDA >13-≤27/HDA >27 at BL
  - DAPSA components: TJC (0-68), SJC (0-66), CRP level (mg/dL), pt VAS for pain (0-10), pt VAS for global disease activity (0-10)
  - cDAPSA components: TJC (0-68), SJC (0-66), pt VAS for pain (0-10), pt VAS for global disease activity (0-10)
- Maintenance of DAPSA/cDAPSA response from W24 to W48
- Changes in PsA-modified vdH-S scores at W48 by the time of DAPSA/cDAPSA response

### Statistical Analyses:

- Pts were considered clinical nonresponders through W24 if they initiated/increased oral corticosteroids or csDMARDs or initiated protocol-prohibited PsA therapies, and through W48 if they discontinued study agent for any reason other than ND/MD. Data affected by ND/MD were not used and were accounted for in the analysis model (GLMM). P-values are nominal.
- For change in vdH-S scores, data affected by ND/MD were not used; missing data were imputed using MI.

## Results

Baseline characteristics were well balanced across treatment groups

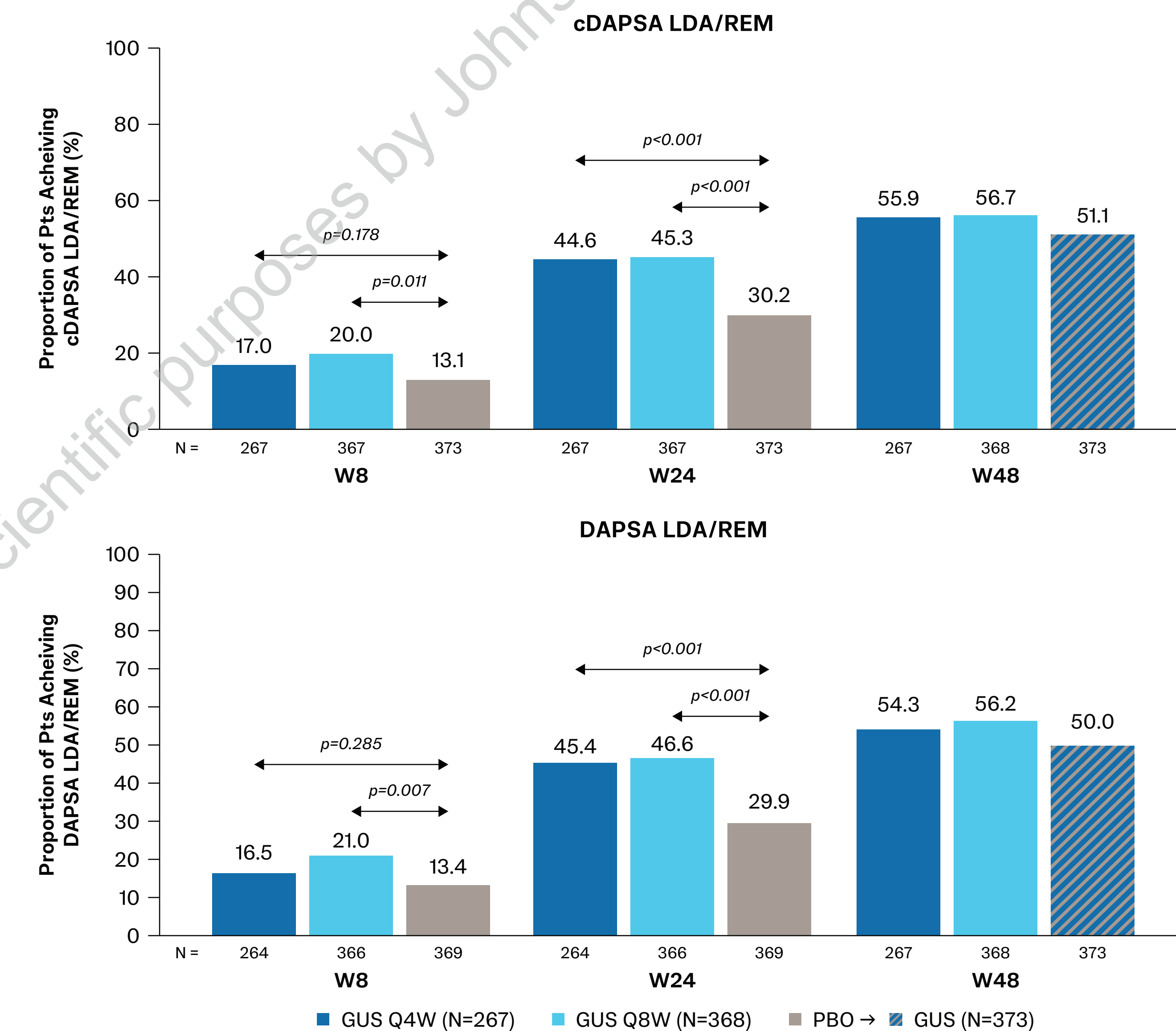
|  | GUS Q4W<br>N=273 | GUS Q8W<br>N=371 | PBO<br>N=376 | Total<br>N=1020 |
|--|------------------|------------------|--------------|-----------------|
| <b>Baseline Demographics</b>           |                  |                  |              |                 |
| Age, years                             | 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 <sup>2</sup>                 | 29.4 (6.0)       | 29.0 (5.6)       | 28.9 (5.7)   | 29.1 (5.7)      |
| <b>PsA Characteristics</b>             |                  |                  |              |                 |
| 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's assessment of pain [VAS; 0-10 cm] | 5.9 (2.2)        | 5.9 (2.1)        | 5.9 (2.1)    | 5.9 (2.1)       |
| HAQ-DI [0-3]                           | 1.2 (0.7)        | 1.2 (0.6)        | 1.2 (0.7)    | 1.2 (0.7)       |
| <b>DAPSA</b>                           |                  |                  |              |                 |
| ModDA/HDA                              | 46.4 (24.3)      | 46.1 (22.1)      | 46.0 (22.8)  | 46.1 (22.9)     |
| cDAPSA                                 | 44.7 (23.5)      | 44.6 (21.7)      | 44.3 (22.3)  | 44.5 (22.4)     |
| ModDA/HDA                              | 20%/78%          | 18%/82%          | 20%/79%      | 19%/80%         |
| CRP, mg/dL                             | 1.7 (2.9)        | 1.5 (2.0)        | 1.7 (2.5)    | 1.6 (2.5)       |
| <b>Radiographic Characteristics</b>    |                  |                  |              |                 |
| PsA-modified vdH-S total score [0-528] | 27.7 (47.6)      | 26.7 (43.4)      | 26.8 (42.2)  | 27.0 (44.1)     |
| Erosion subscore [0-320]               | 13.7 (24.3)      | 13.4 (21.9)      | 13.4 (20.7)  | 13.5 (22.1)     |
| JSN subscore [0-208]                   | 14.0 (24.2)      | 13.3 (22.8)      | 13.4 (22.4)  | 13.5 (23.0)     |

Concomitant PsA medication use and study agent completion through W24 (96-97%) were consistent across treatment groups

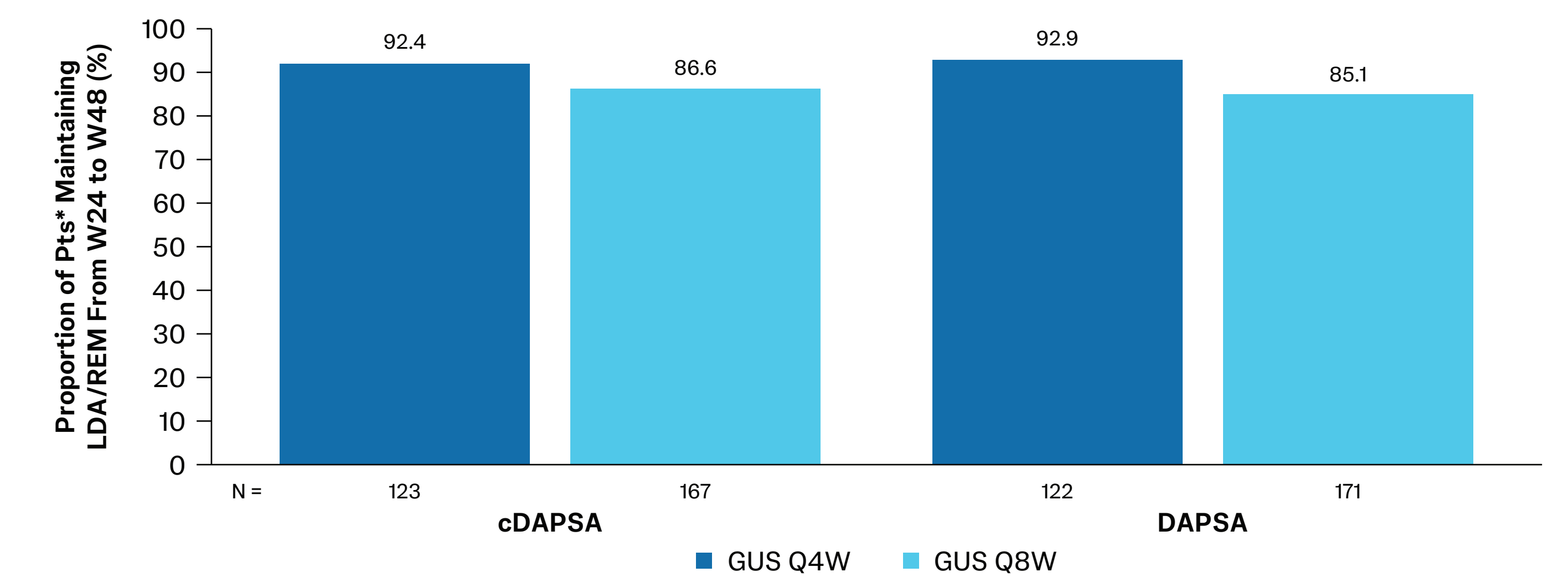
Values are reported as mean (standard deviation) for pts with non-missing data unless otherwise noted. BMI=body mass index, JSN=joint space narrowing.

Among pts with ModDA/HDA at BL, response rates for achieving cDAPSA and DAPSA LDA/REM were greater in the GUS Q4W and Q8W than PBO groups at W24, with separation from PBO seen at W8

• Response rates increased at W48 with both GUS dosing regimens



Most GUS-randomized pts who achieved LDA/REM by W24 maintained response at W48



\*Among pts who achieved cDAPSA or DAPSA LDA/REM at W24.

Among GUS-randomized pts, achievement of cDAPSA or DAPSA LDA/REM at W4-W8 or W16-W24 was associated with less structural damage progression vs nonresponse through W24

