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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Key Takeaways

- **In the APEX population of pts with active and erosive PsA, GUS treatment significantly inhibited structural damage progression vs PBO at W24[2]**
- **Among pts receiving GUS Q4W and Q8W, achievement of clinical response was associated with less structural damage progression at W24 across PsA domains**
- **Additional analyses beyond W24 will determine the maintenance of structural damage inhibition among clinical responders and continue assessment of clinical nonresponders**

Background

Guselkumab 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
- Guselkumab (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) 24[2]

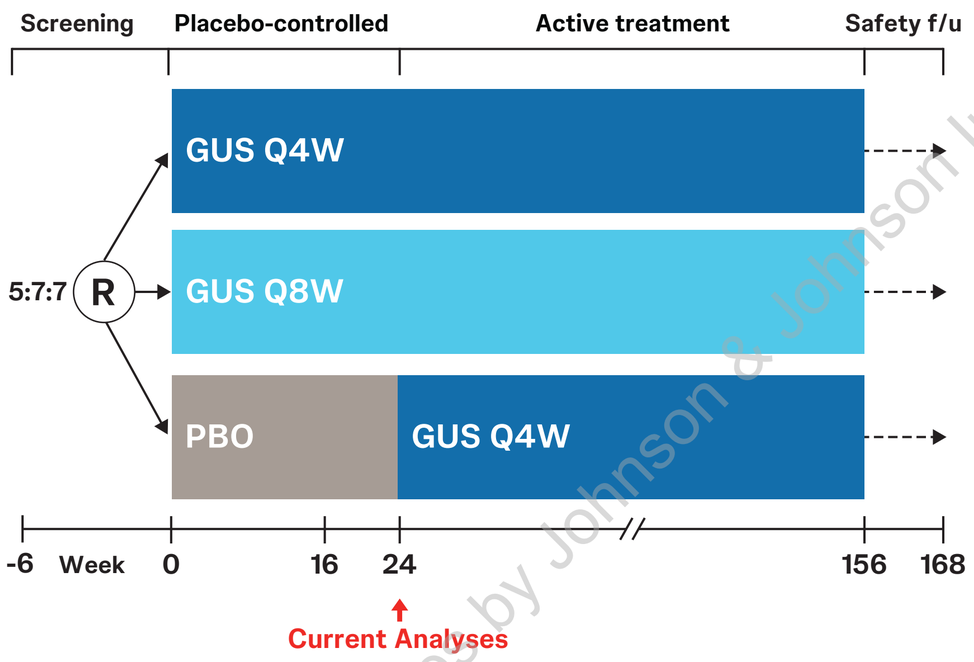
Objective

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

APEX Study Design and Methods

Inclusion Criteria

- ✓ Biologic-naive
- ✓ ≥18 years
- ✓ Active PsA ≥6 months (despite prior csDMARDs, apremilast, NSAIDs); CASPAR criteria met
- ✓ ≥3 SJC; ≥3 TJC; CRP ≥0.3 mg/dL
- ✓ **≥2 joints with erosions** on baseline radiographs of hands/foots (centrally read)
- ✓ Active plaque PsO (≥1 PsO plaque ≥2 cm and/or nail PsO)



Endpoints assessed at W24

LSM change from baseline in PsA-modified vdH-S score by clinical response status at W24, as assessed by:

- ACR20/50/70
- DAPSA LDA ≤14/REM ≤4[3]
- cDAPSA LDA ≤13/REM ≤4[3,4]
- MDA[5]
- HAQ-DI ≤0.5
- Pt-Reported Pain ≤15 mm on VAS

Statistical Analyses

- Pts were considered clinical nonresponders if they initiated/increased oral corticosteroids, csDMARDs, initiated protocol-prohibited PsA therapies, or discontinued study agent for any reason other than ND/MD
  - Data affected by ND/MD were not used
- For change in vdH-S scores, data affected by ND/MD were not used; missing data were imputed using MI

***ACR20/50/70**=≥20%/≥50%/≥70% improvement in the American College of Rheumatology criteria, **CASPAR**=CIASsification criteria for Psoriatic Arthritis, **cDAPSA**=clinical Disease Activity Index for PsA, **CRP**=C-reactive protein, **csDMARDs**=conventional synthetic disease modifying antirheumatic drugs, **DAPSA**=Disease Activity Index for PsA, **F/U**=follow-up, **GUS**=Guselkumab, **HAQ-DI**=Health Assessment Questionnaire-Disability Index, **LDA**=low disease activity, **LSM**=least squares mean, **MD**=major disruption (Ukraine/Russia Crisis), **MDA**=minimal disease activity, **MI**=multiple imputation, **ND**=natural disaster (COVID-19 site access restrictions), **NSAIDs**=nonsteroidal anti-inflammatory drug, **PBO**=placebo, **Pt**=participants, **PsA**=psoriatic arthritis, **PsO**=psoriasis, **Q4W/Q8W**=every 4/8 weeks, **R**=randomization, **REM**=remission, **SJC**=swollen joint count, **TJC**=tender joint count, **VAS**=visual analog scale, **vdH-S**=van der Heijde-Sharp.*

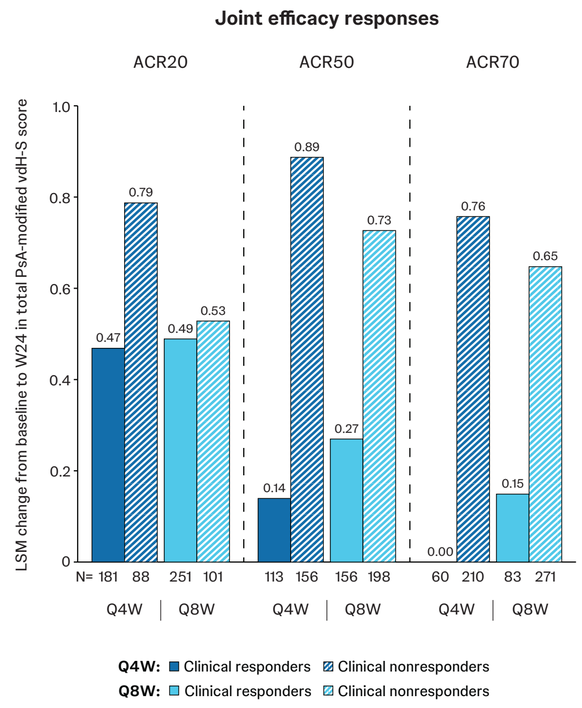
Results

Baseline characteristics were well balanced across treatment groups

	GUS Q4W (N=273)	GUS Q8W (N=371)	PBO (N=376)	Total (N=1020)
Demographics				
Age, yrs	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, yrs	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 PsA, **DSS**=Dactylitis Severity Score, **GUS**=guselkumab, **HAQ-DI**=Health Assessment Questionnaire–Disability Index, **JSN**=joint space narrowing, **LEI**=Leeds Enthesitis Index, **PBO**=placebo, **PsA**=psoriatic arthritis, **Pt**=participants, **Q4W/Q8W**=every 4/8 weeks, **SD**=standard deviation, **SJC**=swollen joint count, **TJC**=tender joint count, **VAS**=visual analog scale, **vdH-S**=van der Heijde–Sharp score*

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



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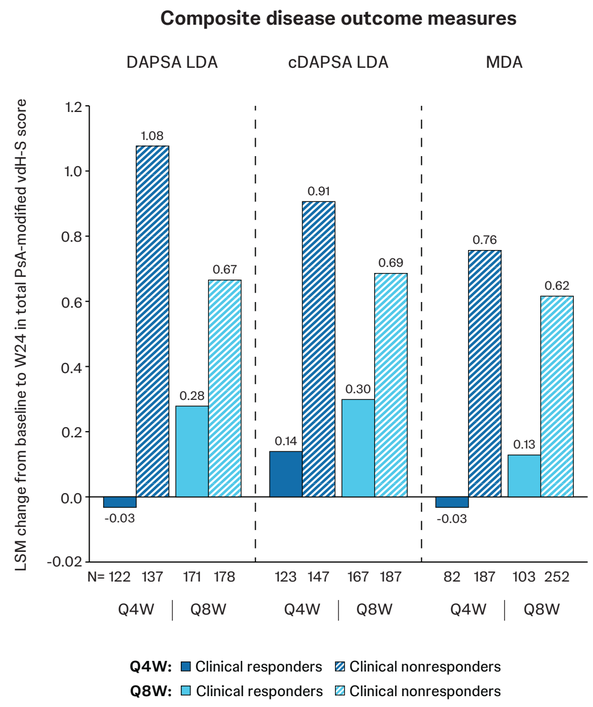
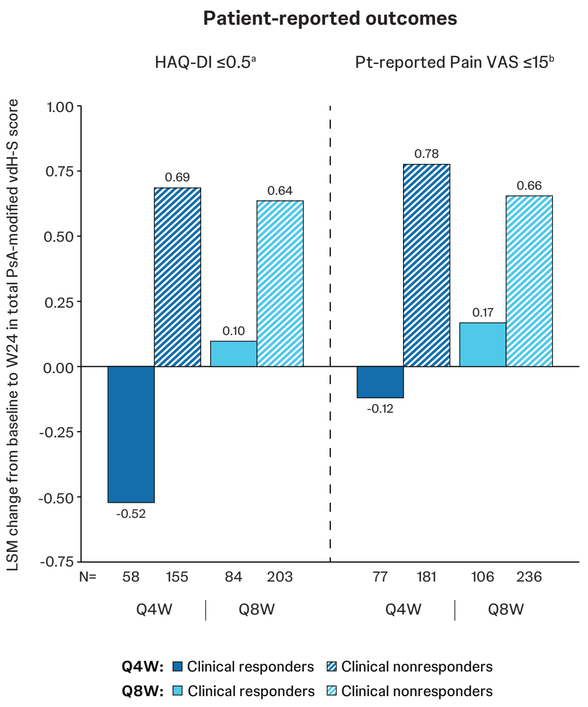
At W24, GUS-randomized pts who achieved low or minimal disease activity by composite indices had numerically lower levels of structural damage progression



***DAPSA**=Disease Activity Index for PsA, **GUS**=Guselkumab, **LSM**=least square mean, **PsA**=Psoriasis, **Q4W/Q8W**=every 4/8 weeks, **vdH-S**=van der Heijde-Sharp, **W**=week.*

At W24, GUS-randomized pts who achieved normalized physical function and minimal pain had numerically lower levels of structural damage progression



*[a]Among pts who had HAQ-DI score >0.5 at baseline. [b]Among pts who had pt-reported pain VAS >15 at baseline. **HAQ-DI**=Health Assessment Questionnaire-Disability Index, **GUS**=Guselkumab, **LDA**=low disease activity, **LSM**=least square mean, **PsA**=Psoriasis, **Pt**=participant, **Q4W/Q8W**=every 4/8 weeks, **VAS**=visual analog scale, **vdH-S**=van der Heijde-Sharp, **W**=week.*

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