

Guselkumab Response and Inhibition of Structural Damage Progression in Active Psoriatic Arthritis Across APEX Participant Subgroups

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Background

Guselkumab (GUS), a fully-human monoclonal antibody able to bind to the CD64-receptor and simultaneously inhibit the IL-23p19 subunit, is indicated for moderate-to-severe plaque psoriasis, active psoriatic arthritis (PsA), and moderately-to-severely active Crohn's disease/ulcerative colitis

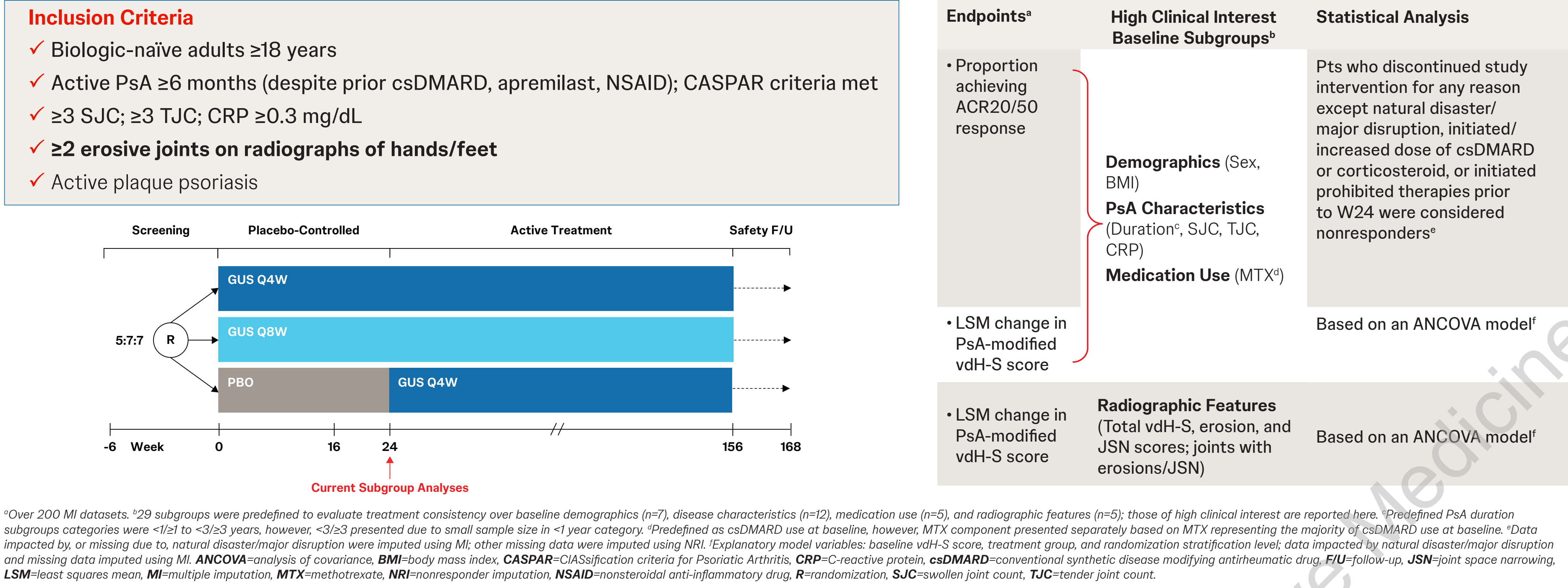
The ongoing phase 3b, randomized, double-blind, placebo (PBO)-controlled **APEX study (NCT04882098)** is further evaluating GUS effects on clinical and radiographic progression outcomes in **participants (pts) with active and erosive PsA**

APEX met primary (American College of Rheumatology ≥20% improvement (ACR20)) and major secondary (PsA-modified van der Heijde-Sharp (vdH-S) score change from baseline) endpoints, such that **GUS Q4W and Q8W demonstrated significantly higher rates of clinical improvement and significant inhibition of structural damage progression vs PBO at Week(W)24¹**

Objective

Evaluate consistency in GUS clinical response and radiographic progression inhibition across subgroups of pts of high clinical interest

APEX Study Design and Analysis Methods



Results

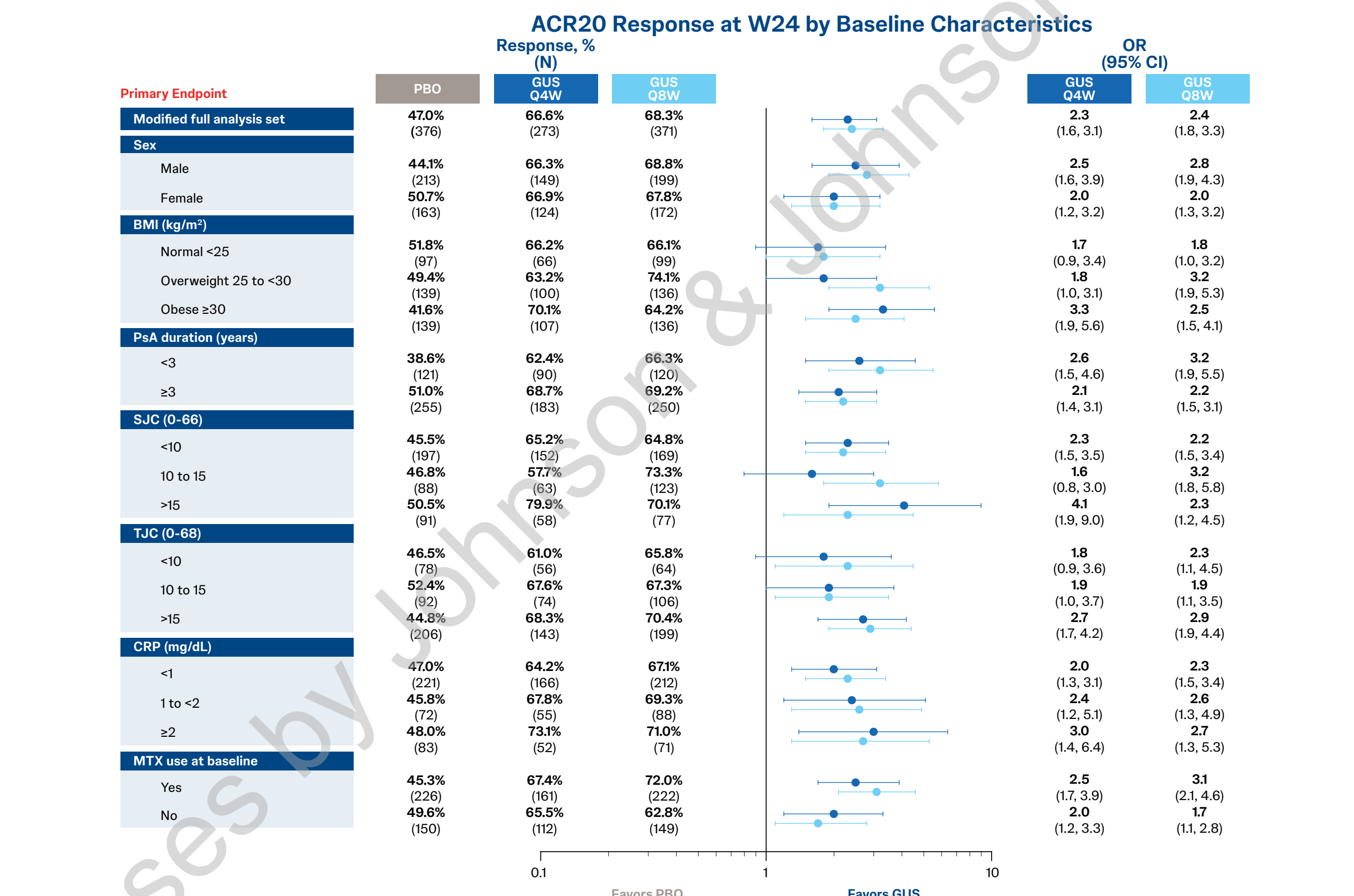
Similar proportions of pts comprised baseline characteristic subgroups across treatment arms

- Pts with active and erosive PsA: median disease duration=5 years, SJC=9, TJC=16, and CRP=0.8 mg/dL

Modified full analysis set*	PBO (N=376)	GUS Q4W (N=273)	GUS Q8W (N=371)	Total (N=1020)
Sex				
Male	57%	55%	54%	55%
Female	43%	45%	46%	45%
BMI, kg/m²				
Normal <25	26%	24%	27%	26%
Overweight ≥25 to <30	37%	37%	37%	37%
Obese ≥30	37%	39%	37%	37%
PsA disease duration, yrs				
<3	32%	33%	32%	32%
≥3	68%	67%	68%	68%
SJC (0–66)				
<10	52%	56%	46%	51%
10 to 15	23%	23%	33%	27%
>15	24%	21%	21%	22%
TJC (0–68)				
<10	21%	21%	17%	19%
10 to 15	24%	27%	29%	27%
>15	55%	52%	54%	54%
CRP, mg/dL				
<1	59%	61%	57%	59%
1 to <2	19%	20%	24%	21%
≥2	22%	19%	19%	20%
MTX use at baseline				
Yes	60%	59%	60%	60%
No	40%	41%	40%	40%

GUS treatment effect on joint disease activity was consistent across subgroups

- Aligned with primary endpoint results, GUS-treated pts had approximately 2- to 4-times higher odds of achieving ACR20 response than PBO-treated pts



ACR=American College of Rheumatology; BMI=body mass index; CI=confidence interval; CRP=C-reactive protein; GUS=guselkumab; MTX=methotrexate; OR=odds ratio; PBO=placebo; PsA=psoriatic arthritis; pts=participants; Q4W=every 4 weeks; Q8W=every 8 weeks; SJC=swollen joint count; TJC=tender joint count; W=week.

GUS effect on the more stringent ACR50 response was also consistent across subgroups

- Aligned with overall ACR50 results, GUS-treated pts had approximately 2- to 6-times higher odds of achieving ACR50 response than PBO-treated pts



ACR=American College of Rheumatology; BMI=body mass index; CI=confidence interval; CRP=C-reactive protein; GUS=guselkumab; MTX=methotrexate; OR=odds ratio; PBO=placebo; PsA=psoriatic arthritis; Q4W=every 4 weeks; Q8W=every 8 weeks; SJC=swollen joint count; TJC=tender joint count; W=week.



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Key Takeaways

✓ **GUS-treated biologic-naïve pts with active and erosive PsA demonstrated significantly greater clinical improvement and significant inhibition of structural damage progression vs PBO at W24**

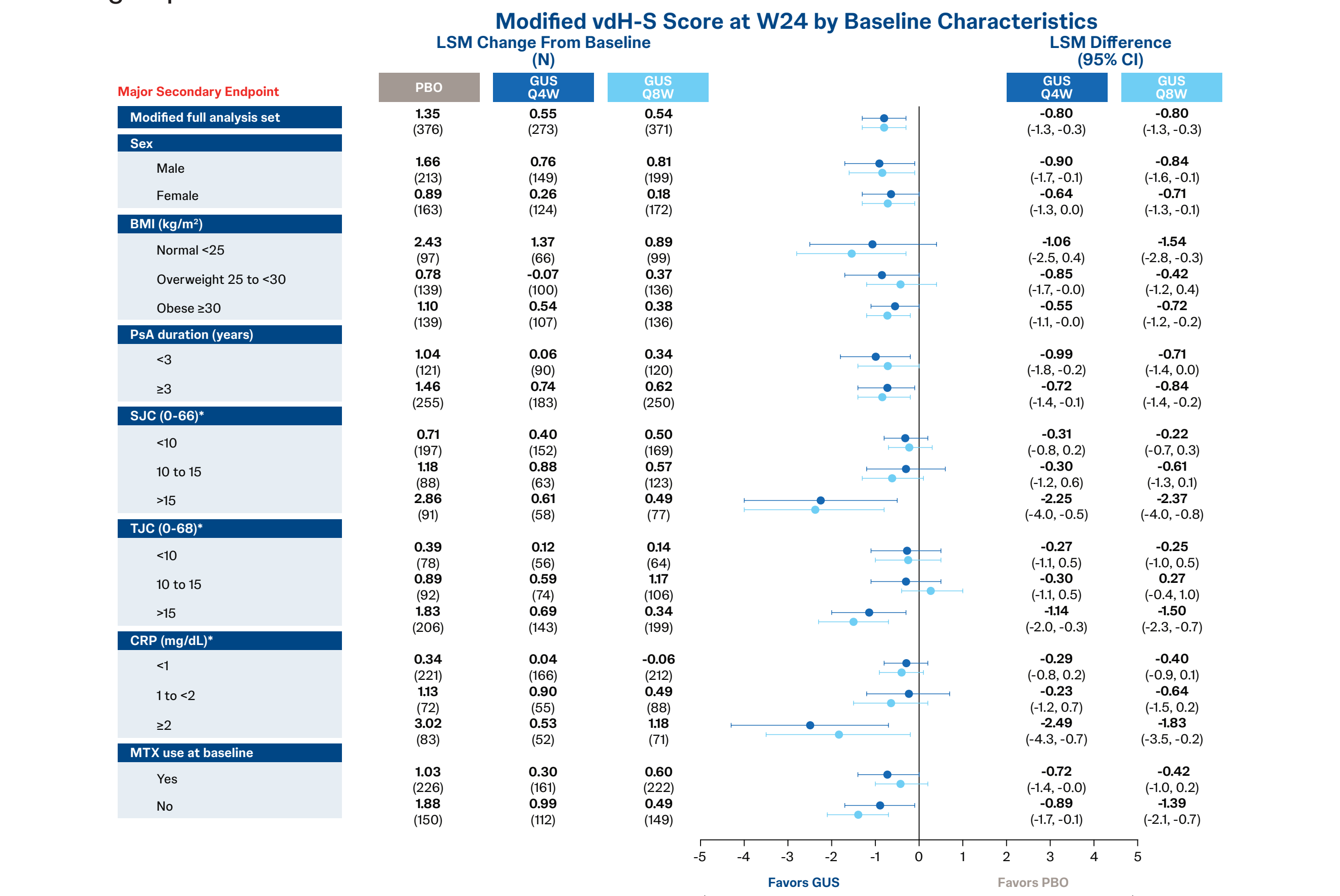
✓ **GUS effects were generally consistent across diverse subgroups of pts defined by baseline demographics, disease characteristics, medication use, and radiographic features of interest**

- Benefit in ACR20/50 clinical improvement was similar regardless of sex, BMI, PsA duration, joint involvement, CRP, and MTX use at baseline

- Inhibition of radiographic progression observed across clinical and radiographic feature subgroups

Significant inhibition of structural damage progression with GUS was generally consistent across baseline pts subgroups

- Concordant with known risk factors, PBO-treated pts with SJC >15 & CRP ≥2 mg/dL exhibited notably higher degrees of radiographic progression, leading to even more robust GUS effects in these groups



*Interaction p-value <0.05 for SJC GUS Q4W and Q8W; TJC GUS Q8W; CRP GUS Q4W. BMI=body mass index; CI=confidence interval; CRP=C-reactive protein; GUS=guselkumab; LSM=least squares mean; MTX=methotrexate; PBO=placebo; PsA=psoriatic arthritis; pts=participants; Q4W=every 4 weeks; Q8W=every 8 weeks; SJC=swollen joint count; TJC=tender joint count; vdH-S=van der Heijde-Sharp; W=week.

Baseline radiographic joint damage was of moderate degree and similar across treatment groups

	PBO (N=374)	GUS Q4W (N=271)	GUS Q8W (N=371)	Total (N=1016)
Baseline Radiographic Features				
Total vdH-S score [0–528]	11.5 [5.0–27.5]	11.0 [4.5–26.5]	11.0 [4.5–25.0]	11.0 [5.0–26.5]
Erosion score [0–320]	6.0 [2.5–13.0]	5.5 [2.5–13.0]	6.0 [2.5–14.0]	6.0 [2.5–13.5]
JSN score [0–208]	5.0 [1.5–14.0]	5.5 [1.5–14.9]	5.0 [1.0–14.5]	5.0 [1.5–14.5]

Values are median [interquartile range]. GUS=guselkumab; JSN=joint-space narrowing; N=number of participants; PBO=placebo; Q4W=every 4 weeks; Q8W=every 8 weeks; vdH-S=van der Heijde-Sharp.

Inhibition of structural damage progression with GUS was largely consistent regardless of baseline radiographic features

- PBO-treated pts with a vdH-S erosion score >6 and >4.5 erosive joints at baseline had the most radiographic progression at W24

