

APEX: Guselkumab Response and Inhibition of Structural Damage Progression in Active Psoriatic Arthritis by Participant Baseline Characteristics

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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 treatment effect was generally consistent across diverse subgroups of pts defined by baseline demographics, disease characteristics, and concomitant MTX use
 - Benefit in achieving ACR20, ACR50, PASI 90, and MDA was similar regardless of sex, BMI, PsA duration, joint involvement, CRP, and MTX use at baseline
 - Inhibition of structural damage progression was observed across subgroups

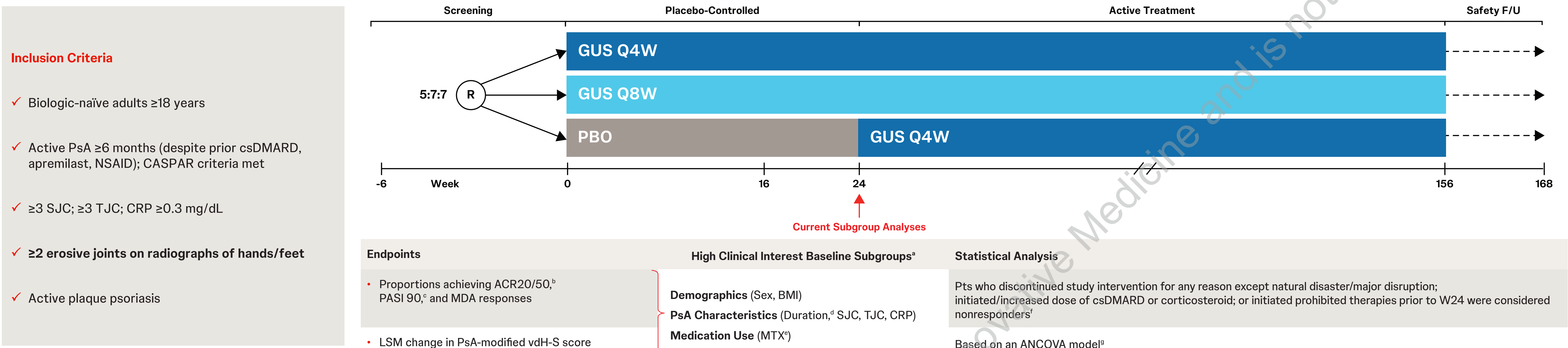
Background

- ✓ **Guselkumab (GUS)**, a fully-human monoclonal antibody able to bind to the CD64-receptor and simultaneously inhibit the interleukin (IL)-23p19 subunit, is approved for moderate-to-severe plaque psoriasis, active psoriatic arthritis (PsA), and moderately-to-severely active Crohn's disease and 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 every 4 weeks (Q4W) and every 8 weeks (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



¹29 subgroups were predefined to evaluate treatment consistency over baseline demographics (n=7), disease characteristics (n=12), and medication use (n=5); those of high clinical interest are reported here. ^aAverage proportion of pts over 200 MI datasets. ^bAmong pts who had ≥3% BSA psoriatic involvement and an IGA score of ≥2 (mild) at baseline. ^cPredefined PsA duration subgroups categories were <1st to <3rd years, however, <3rd presented due to small sample size in <1 year category. ^dPredefined as csDMARD use at baseline, however, MTX component presented separately based on MTX representing the majority of csDMARD use at baseline. ^eData impacted by, or missing due to, natural disaster/major disruption were imputed using MI (ACR20/50) or were not explicitly imputed (PASI 90/MDA); other missing data were imputed using NRI. ^fExploratory model variables: baseline vdH-S score, treatment group, and randomization stratification level; data impacted by natural disaster/major disruption and missing data imputed using MI. ^gACR20/50=American College of Rheumatology ≥20%/≥50% improvement, ^hANCOVA=analysis of covariance, ⁱBMI=body mass index, ^jBSA=body surface area, ^kCASPAR=Classification criteria for Psoriatic Arthritis, ^lCRP=C-reactive protein, ^mcsDMARD=conventional synthetic disease modifying antirheumatic drug, ⁿFU=follow-up, ^oGUS=guselkumab, ^pIGA=Investigator's Global Assessment, ^qLSM=least squares mean, ^rMDA=minimal disease activity, ^sMI=multiple imputation, ^tMTX=methotrexate, ^uNRI=nonresponder imputation, ^vNSAID=nonsteroidal anti-inflammatory drug, ^wPASI 90=90% improvement in Psoriasis Area and Severity Index, ^xPBO=placebo, ^yPsA=psoriatic arthritis, ^zPts=participants, ^{aa}Q4W/Q8W=every 4/8 weeks, ^{ab}R=randomization, ^{ac}SJC=swollen joint count, ^{ad}TJC=tender joint count, ^{ae}vdH-S=van der Heijde-Sharp, ^{af}W=week.

Results

Similar proportions of pts comprised baseline characteristic subgroups across treatment arms

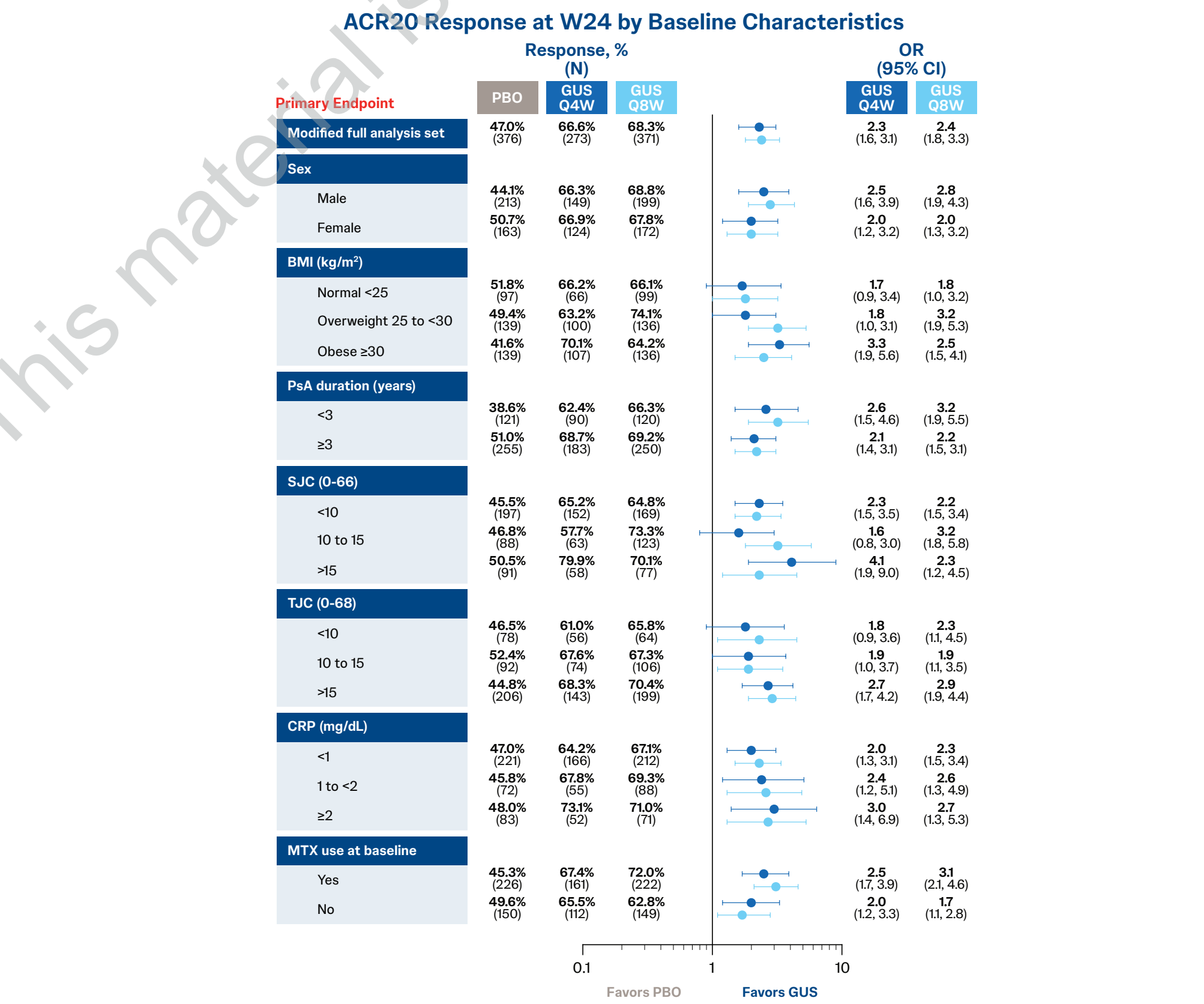
- Pts had active and erosive PsA: median disease duration=5 years, SJC=9, TJC=16, and CRP=0.8 mg/dL

Modified full analysis set ^a	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%

^aAll randomized pts except those from Ukraine sites rendered unable to support key study operations due to major disruptions (N=1020). ^bBMI=body mass index, ^cCRP=C-reactive protein, ^dGUS=guselkumab, ^eMTX=methotrexate, ^fPBO=placebo, ^gPsA=psoriatic arthritis, ^hPts=participants, ⁱQ4W/Q8W=every 4/8 weeks, ^jSJC=swollen joint count, ^kTJC=tender joint count, ^lyrs=years.

GUS treatment effect on joint disease activity was consistent across subgroups

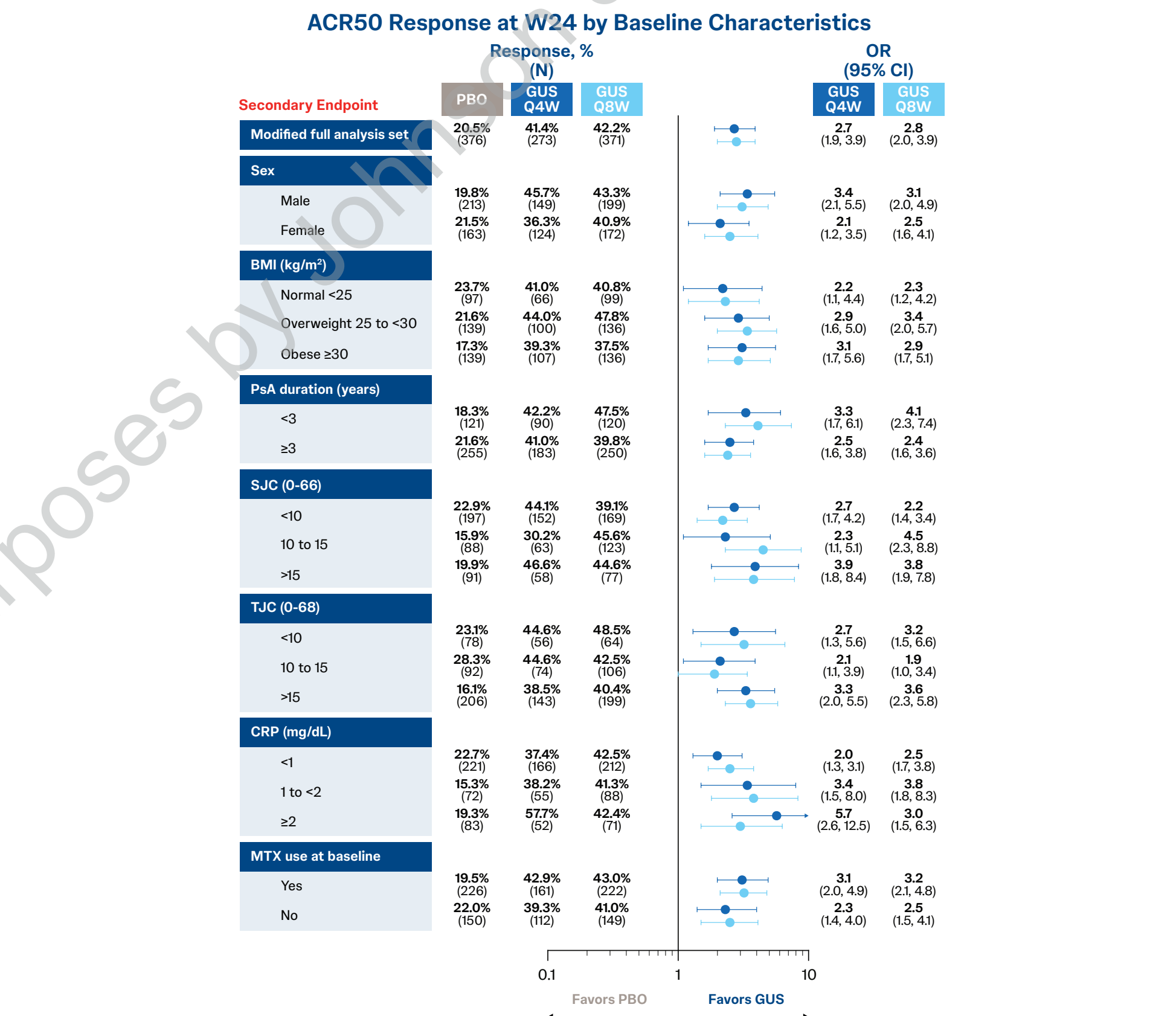
- Aligned with primary endpoint results, GUS-treated pts had approximately 2- to 4-times higher odds of achieving ACR20 response than PBO-treated pts



^aACR20=American College of Rheumatology ≥20% improvement, ^bBMI=body mass index, ^cCI=confidence interval, ^dCRP=C-reactive protein, ^eGUS=guselkumab, ^fMTX=methotrexate, ^gOR=odds ratio, ^hPBO=placebo, ⁱPsA=psoriatic arthritis, ^jQ4W/Q8W=every 4/8 weeks, ^kSJC=swollen joint count, ^lTJC=tender joint count, ^mW=week.

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

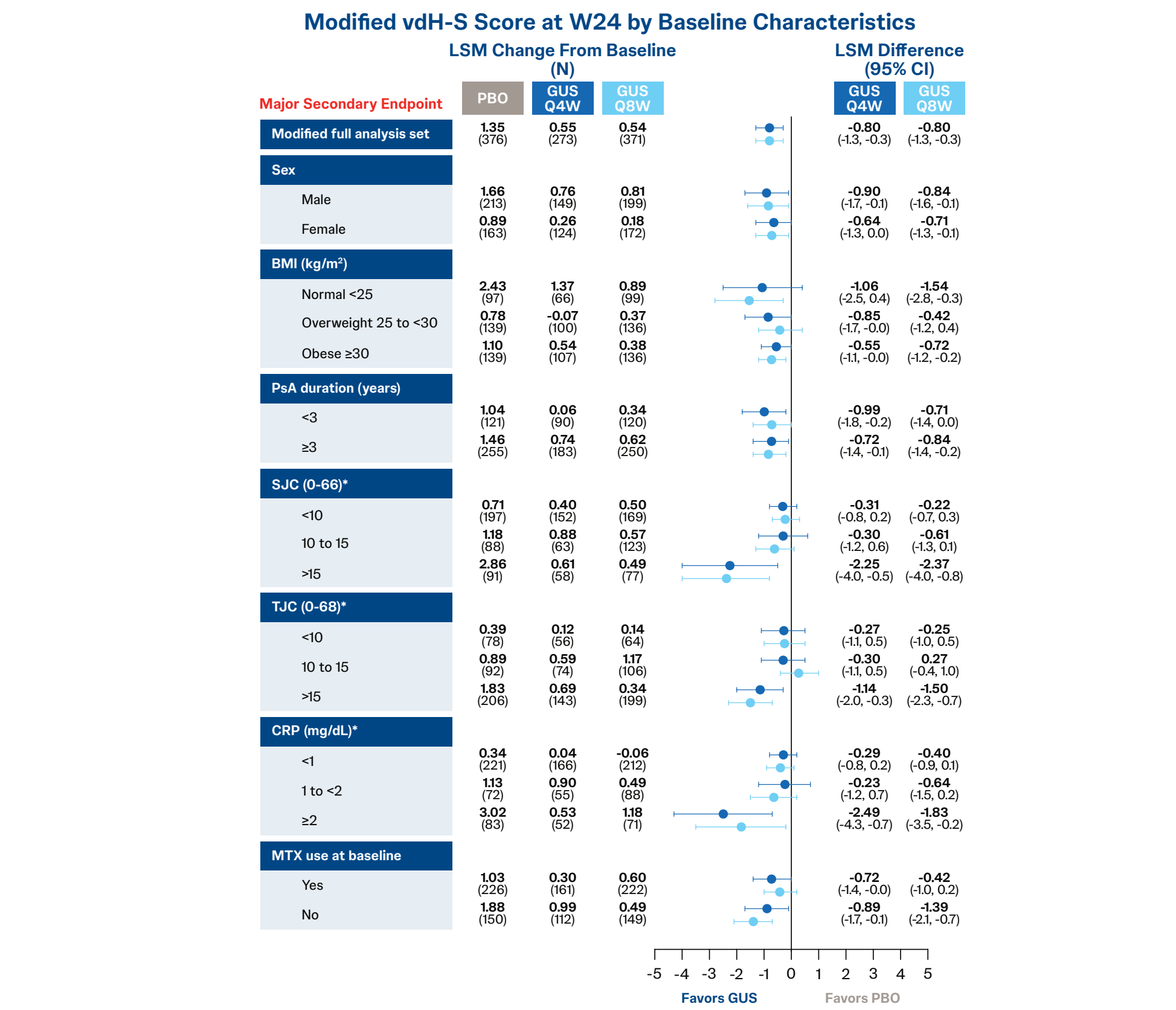
- Aligned with overall ACR50 results, GUS-treated pts had approximately 2- to 6-times higher odds of achieving ACR50 response than PBO-treated pts



^aACR50=American College of Rheumatology ≥50% improvement, ^bBMI=body mass index, ^cCI=confidence interval, ^dCRP=C-reactive protein, ^eGUS=guselkumab, ^fMTX=methotrexate, ^gOR=odds ratio, ^hPBO=placebo, ⁱPsA=psoriatic arthritis, ^jQ4W/Q8W=every 4/8 weeks, ^kSJC=swollen joint count, ^lTJC=tender joint count, ^mW=week.

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

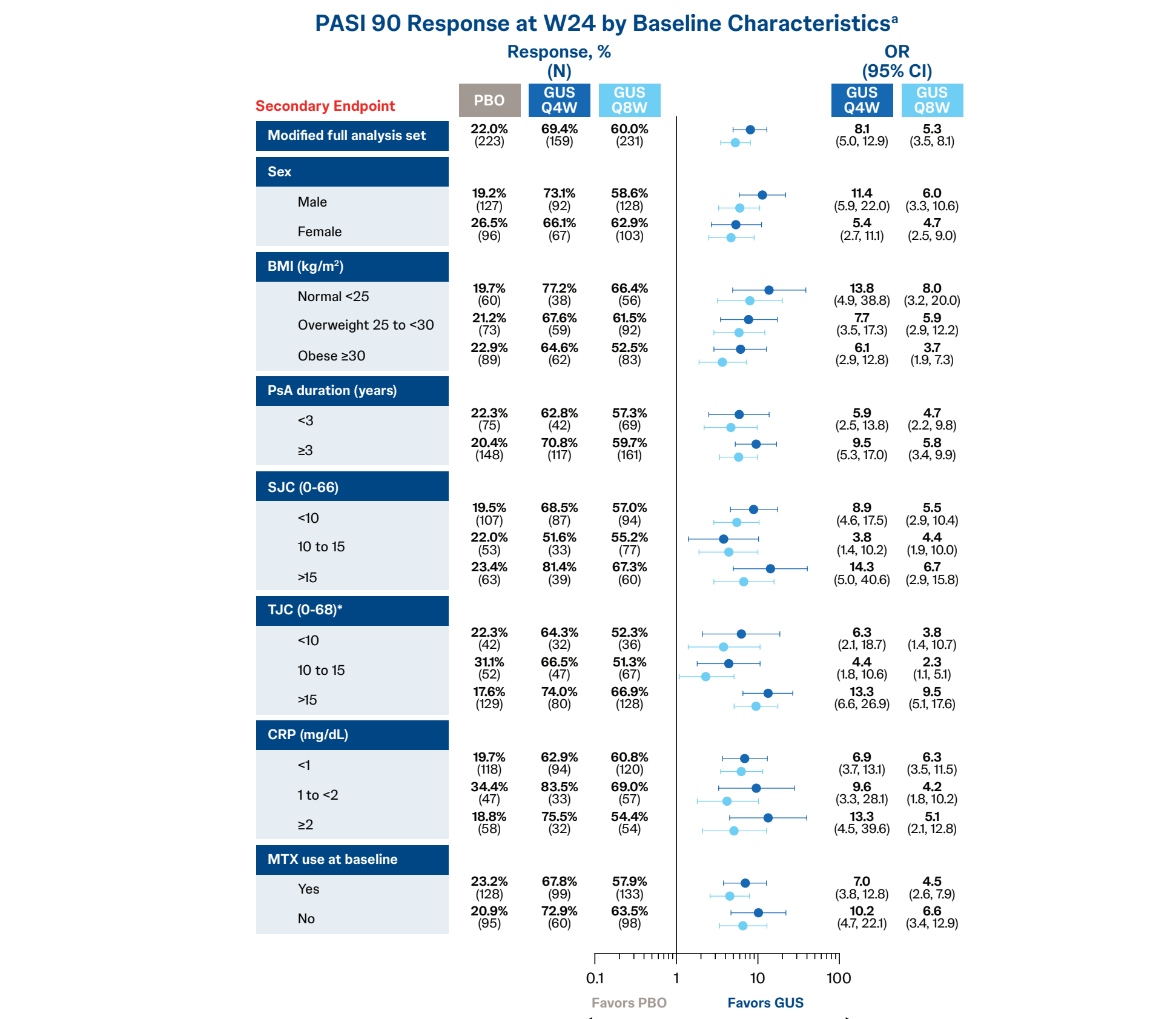
- Concordant with known risk factors, PBO-treated pts with SJC >15 & CRP ≥2 mg/dL exhibited notably higher degrees of structural damage progression, leading to even more robust GUS effects in these groups



^aInteraction p-value <0.05 for SJC GUS Q4W and Q8W; TJC GUS Q8W; CRP GUS Q4W; BMI=body mass index, ^bCI=confidence interval, ^cCRP=C-reactive protein, ^dGUS=guselkumab, ^eLSM=least squares mean, ^fMTX=methotrexate, ^gPBO=placebo, ^hPsA=psoriatic arthritis, ⁱQ4W/Q8W=every 4/8 weeks, ^jSJC=swollen joint count, ^kTJC=tender joint count, ^lvdH-S=van der Heijde-Sharp, ^mW=week.

Treatment effect of GUS on achieving PASI 90 response was generally consistent across subgroups

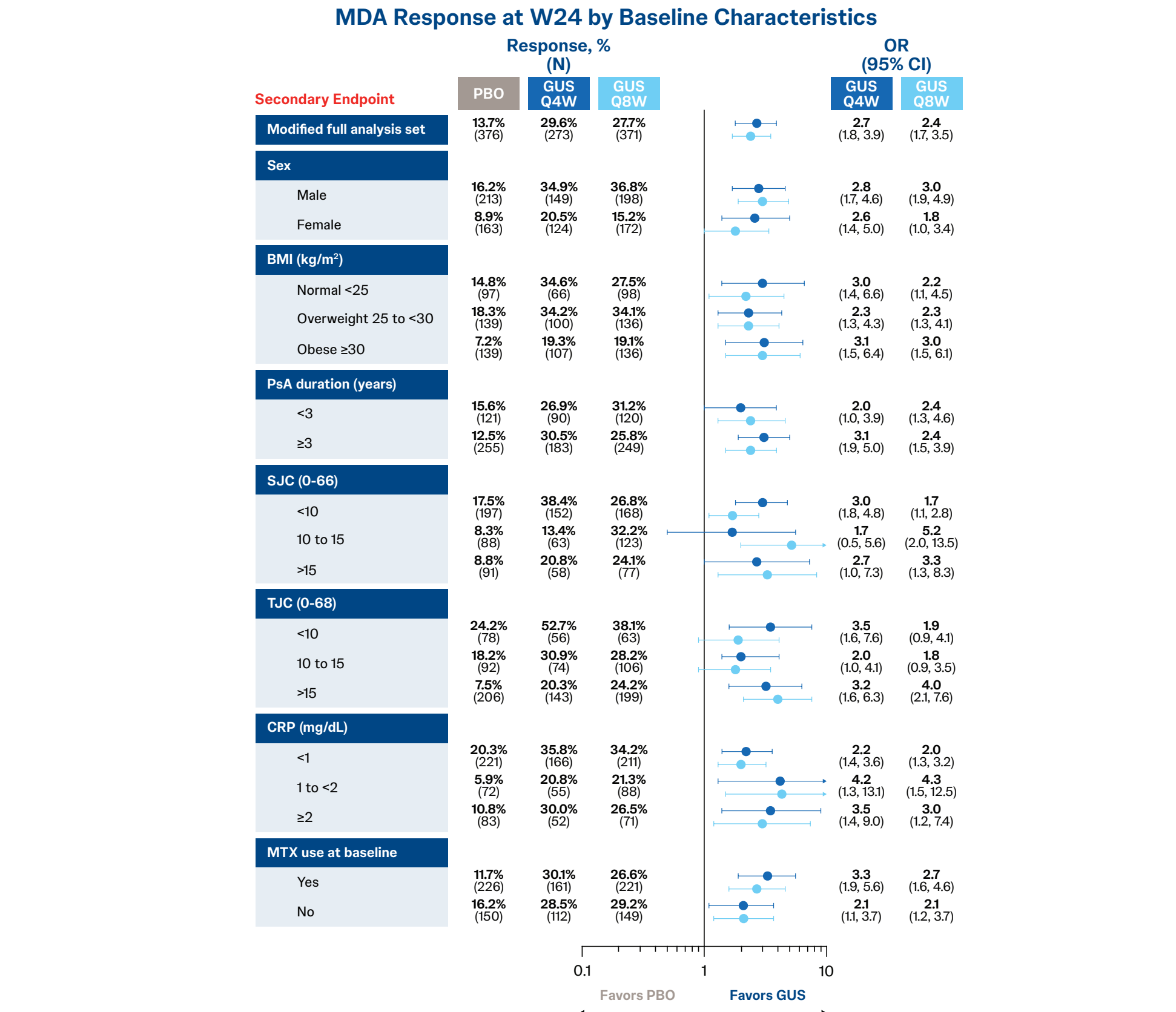
- Comparable to overall PASI 90 results, GUS-treated pts had approximately 2- to 14-times higher odds of achieving PASI 90 response than PBO-treated pts



^aAmong pts who had ≥3% BSA psoriatic involvement and an IGA score of ≥2 (mild) at baseline. ^bInteraction p-value <0.05 for TJC GUS Q8W, BMI=body mass index, ^cBSA=body surface area, ^dCI=confidence interval, ^eCRP=C-reactive protein, ^fGUS=guselkumab, ^gIGA=Investigator's Global Assessment, ^hMTX=methotrexate, ⁱPASI 90=90% improvement in Psoriasis Area and Severity Index, ^jPBO=placebo, ^kPsA=psoriatic arthritis, ^lOR=odds ratio, ^mQ4W/Q8W=every 4/8 weeks, ⁿSJC=swollen joint count, ^oTJC=tender joint count, ^pvdH-S=van der Heijde-Sharp, ^qW=week.

GUS effect on achievement of the MDA composite endpoint remained consistent across subgroups

- Aligned with overall MDA results, GUS-treated pts had approximately 2- to 5-times higher odds of achieving MDA than PBO-treated pts



^aBMI=body mass index, ^bCI=confidence interval, ^cCRP=C-reactive protein, ^dGUS=guselkumab, ^eIGA=Investigator's Global Assessment, ^fMDA=minimal disease activity, ^gMTX=methotrexate, ^hPASI 90=90% improvement in Psoriasis Area and Severity Index, ⁱPBO=placebo, ^jPsA=psoriatic arthritis, ^kOR=odds ratio, ^lQ4W/Q8W=every 4/8 weeks, ^mSJC=swollen joint count, ⁿTJC=tender joint count, ^ovdH-S=van der Heijde-Sharp, ^pW=week.

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