Guselkumab Efficacy on MDA Components and Structural Damage Progression in Participants With Active and Erosive Psoriatic Arthritis

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Key Takeaways

- **In APEX, GUS-treated pts had numerically greater response rates for achieving individual MDA components and resolution of SJC/TJC vs PBO pts at W24 with continued improvement through W48**
- **Achievement of MDA criteria, as early as W12, was associated with reduced structural damage progression at W48 for both GUS dosing regimens**

Background

- Guselkumab (GUS) is a fully human, dual-acting[1] monoclonal antibody that selectively inhibits the interleukin-23p19 subunit and is approved for patients with active psoriatic arthritis (PsA)
- In APEX, GUS demonstrated multidomain efficacy and significantly inhibited structural damage progression vs placebo (PBO) at Week (W) 24 in participants (pts) with active & erosive PsA[2]
- Minimal disease activity (MDA) is a composite measure that evaluates low levels of disease activity across multiple PsA domains: peripheral joint activity, psoriatic skin disease, pain, patient global assessment, physical function, and health-related quality of life[3]

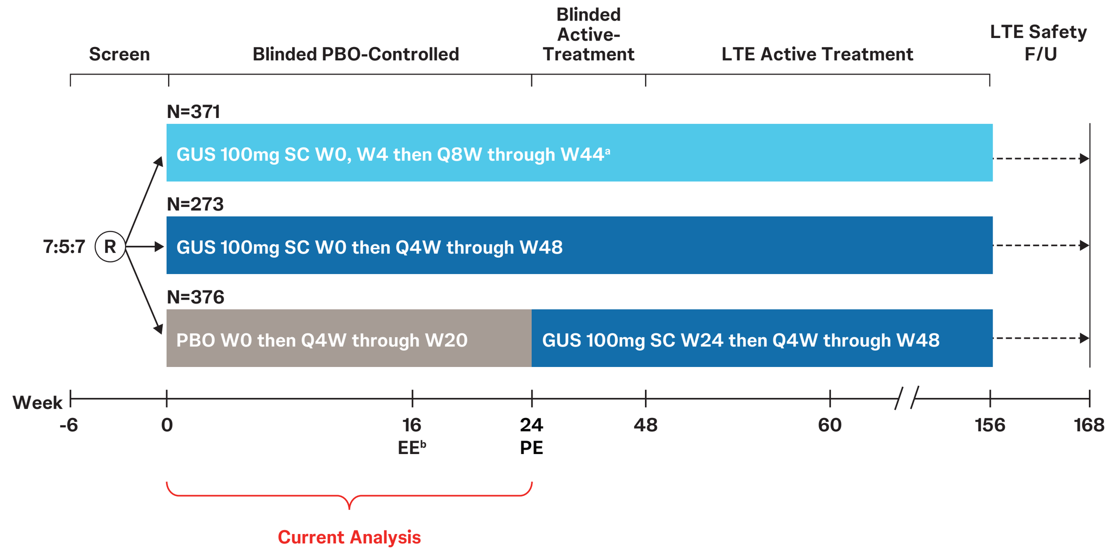
Objective

Evaluate the efficacy of GUS in achieving individual components of MDA and their association with structural damage progression through W48

Methods

Inclusion Criteria

- ✓ Biologic-naive
- ✓ Age ≥18 years
- ✓ Active PsA ≥6 months (despite prior csDMARD, apremilast, NSAID); CASPAR criteria met
- ✓ ≥3 SJC; ≥3 TJC; CRP ≥0.3 mg/dL
- ✓ **≥2 erosive joints on hand/foot radiographs**



Screen
Blinded PBO-Controlled
Blinded Active-Treatment
LTE Active Treatment
LTE Safety F/U
N=371
GUS 100mg SC W0, W4 then Q8W through W44ᵃ
7:5:7 R
N=273
GUS 100mg SC W0 then Q4W through W48
N=376
PBO W0 then Q4W through W20
GUS 100mg SC W24 then Q4W through W48
Week -6 0 16 24 48 60 156 168
EEᵇ
PE
Current Analysis

Endpoints

The proportion of pts achieving the following outcomes through W48:

- Individual MDA components: SJC ≤1, TJC ≤1, Pt Pain ≤15, PASI ≤1, PtGA ≤20, HAQ-DI ≤0.5, LEI ≤1
- SJC=0
- TJC=0

LSM changes in PsA modified vdH-S score at W24 and W48 among GUS-randomized pts were analyzed by W12, W24, and W48 response status (achievement of individual MDA components and SJC=0/TJC=0)

Statistical Analyses

- NRI was used for:
 - Pts who initiated/increased csDMARDs or oral corticosteroids or initiated protocol-prohibited medication/therapies through W24
 - Pts who discontinued study intervention for any reason other than ND/MD through W48
- Data affect by ND/MD were not used
- Other missing data were accounted in the model (GLMM), followed by NRI
- Response rates for each outcome were assessed in pts with a baseline score greater than the relative response threshold
- For change in vdH-S scores, data affected by ND/MD were not used; missing data were imputed using MI

*ᵃPBO SC W8 then Q8W through W48 administered to maintain blinding. ᵇEE 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. **CASPAR**=ClASsification criteria for Psoriatic ARthritis, **CRP**=C-reactive protein, **csDMARD**=conventional synthetic disease modifying antirheumatic drug, **EE**=early escape, **F/U**=follow-up, **GLMM**=Generalized Linear Mixed Model, **HAQ-DI**=Health Assessment Questionnaire-Disability Index, **LEI**=Leeds Enthesitis Index (tender entheseal points), **LSM**=least squares mean, **LTE**=long-term extension, **MD**=major disruption (Ukraine/Russia crisis), **MI**=multiple imputation, **ND**=natural disaster (COVID-19 site access restrictions), **NRI**=nonresponder imputation, **NSAID**=nonsteroidal anti-inflammatory drug, **PASI**=Psoriasis Area and Severity Index, **PE**=primary endpoint, **Pt Pain**=Patient-reported Pain, **PtGA**=Patient Global Assessment of disease activity (arthritis and psoriasis), **Q4W/Q8W**=every 4/8 weeks, **R**=randomization, **SC**=subcutaneous, **SJC**=swollen joint count, **TJC**=tender joint count, **vdH-S**=van der Heijde-Sharp.*

Results

Baseline demographics were well balanced among treatment groups

- Mean baseline disease characteristics were consistent 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%
White	85%	82%	83%	83%
BMI, kg/m²	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)
PASI (0-72)	7.6 (8.3)[a]	8.3 (10.1)[b]	8.2 (9.5)[c]	8.1 (9.4)[d]
Pt Pain (VAS; 0-10 cm)	5.9 (2.2)	5.9 (2.1)	5.9 (2.1)	5.9 (2.1)
PtGA (VAS; 0-10 cm)	5.9 (2.2)	5.9 (2.1)	5.9 (2.0)	5.9 (2.1)
HAQ-DI (0-3)	1.2 (0.7)	1.2 (0.6)	1.2 (0.7)	1.2 (0.7)
LEI (1-6)	3.2 (1.8)[e]	3.0 (1.7)[f]	3.0 (1.6)[g]	3.1 (1.7)[h]
CRP, mg/dL	1.7 (2.9)	1.5 (2.0)	1.7 (2.5)	1.6 (2.5)

*[a]N=269, [b]N=364, [c]N=369, [d]N=1002, [e]N=271, [f]N=365, [g]N=372, [h]N=1008. Data shown are mean (SD) unless otherwise noted. **BMI**=body mass index, **VAS**=visual analog scale.*

Response rates were greater for GUS-randomized pts compared to PBO-randomized pts at W24

- The separation of response rates for GUS-randomized vs PBO-randomized pts occurred as early as W8 (nominal p<0.05)
- Response rates continued to increase through W48

Proportions of Pts Achieving Individual MDA Components and SJC=0/TJC=0 Through W48

GUS Q4W

Week	4	8	12	16	20	24	28	36	48
SJC ≤1	7.5	19.0	26.9‡	35.4†	41.7*	47.6*	51.5	54.1	59.0
TJC ≤1	1.7	5.1	9.3‡	12.1	15.9‡	19.1†	22.7	24.1	28.0
PASI ≤1	13.4	N/A	46.4*	N/A	N/A	71.2*	81.5	N/A	83.4
Pt Pain ≤15	4.6	11.1	18.1	23.9	28.8†	29.5†	29.9	34.9	35.3
PtGA ≤20	8.5	17.0‡	25.5†	30.5†	33.8*	40.5*	42.1	44.6	46.8
HAQ-DI ≤0.5	12.7‡	15.9	16.3	21.0	23.3	26.5‡	28.2	30.1	32.8
LEI ≤1	39.9‡	N/A	54.0	N/A	N/A	58.4	66.6	66.6	65.0
SJC=0	3.8	13.6‡	18.5‡	24.0‡	28.7†	36.7*	39.8	44.2	48.3
TJC=0	1.3	2.2	4.8	6.5	9.8‡	12.1†	15.8	15.1	21.4

GUS Q8W

Week	4	8	12	16	20	24	28	36	48
SJC ≤1	7.9	19.0‡	25.8‡	32.5‡	38.7†	43.5*	46.4	51.1	53.0
TJC ≤1	1.5	5.9	8.5	11.8	13.7	17.4†	21.2	22.2	29.2
PASI ≤1	13.0	N/A	47.4*	N/A	N/A	63.5*	70.6	N/A	76.3
Pt Pain ≤15	6.7	15.1‡	19.7‡	25.1‡	29.7*	30.0†	34.0	38.8	42.1
PtGA ≤20	7.9	18.7†	22.7†	33.0*	36.2*	37.1*	43.9	45.9	48.9
HAQ-DI ≤0.5	12.5†	11.5	21.2	26.6†	29.0*	28.0†	32.6	34.6	35.9
LEI ≤1	37.8	N/A	52.8	N/A	N/A	60.1	56.4	61.4	68.2
SJC=0	4.4	12.2‡	18.4‡	24.5†	30.5*	32.2*	36.2	42.4	44.0
TJC=0	0.7	1.9	3.4	6.8	7.5	12.0†	14.5	14.8	18.6

PBO (W4–W24); PBO→GUS Q4W (W28–W48)

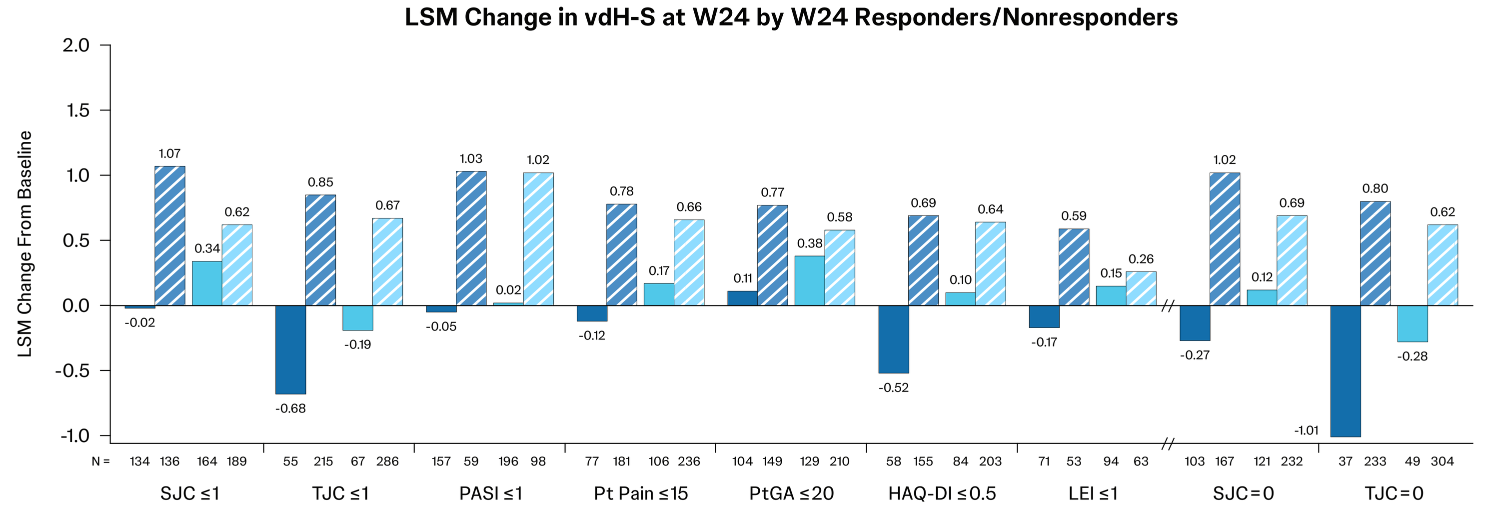
Week	4	8	12	16	20	24	28	36	48
SJC ≤1	5.5	13.8	19.0	24.7	28.1	28.1	34.2	43.0	50.0
TJC ≤1	2.0	3.5	5.0	8.3	9.3	10.1	11.6	17.4	22.4
PASI ≤1	9.1	N/A	19.6	N/A	N/A	27.5	36.8	N/A	74.2
Pt Pain ≤15	3.8	9.7	13.5	17.8	17.5	19.5	24.1	33.5	40.4
PtGA ≤20	6.8	10.5	14.8	19.8	20.9	21.2	29.1	42.7	47.0
HAQ-DI ≤0.5	6.2	10.1	17.3	17.8	17.1	18.7	22.0	28.0	31.4
LEI ≤1	28.6	N/A	46.8	N/A	N/A	53.3	63.1	66.2	70.2
SJC=0	3.3	7.4	11.7	15.9	18.8	19.3	22.8	35.1	38.5
TJC=0	0.5	1.4	2.6	5.5	5.5	5.5	6.2	11.0	13.2

0% 20% 40% 60% 80% 100%

*Nominal *p<0.001, †p<0.01, ‡p<0.05 vs PBO. P-values are based on GLMM, are considered nominal, and may not be used to claim statistical significance. **N/A**=not available; the assessment was not collected at this time point.*

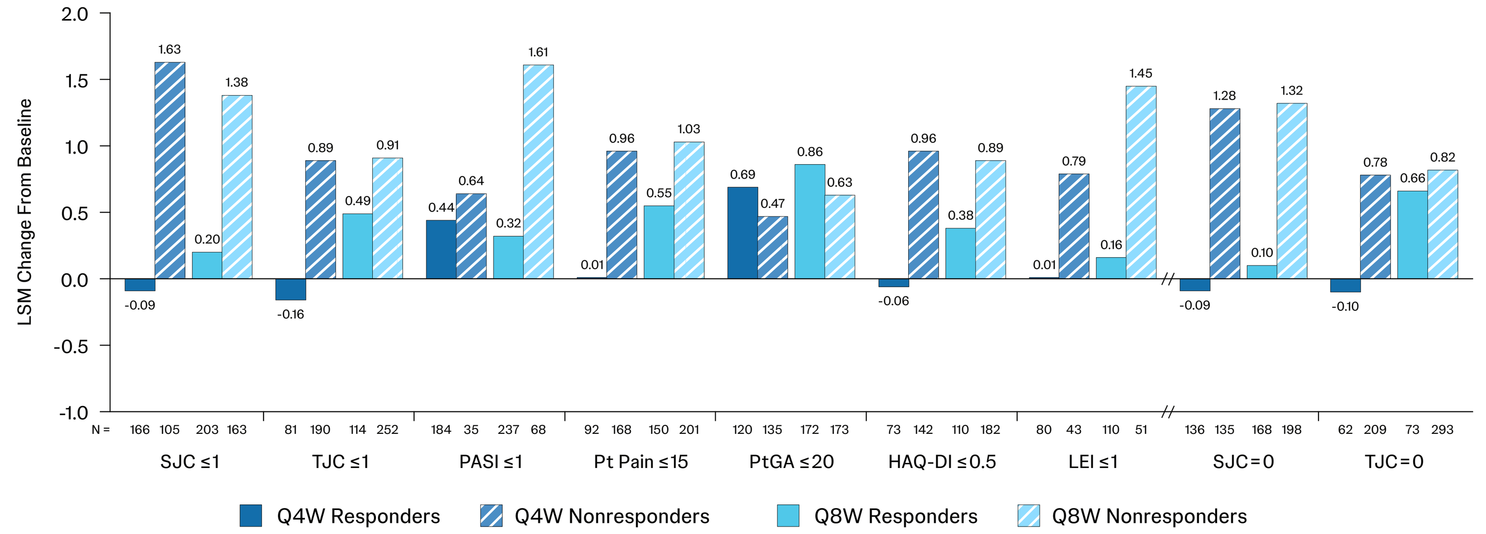
Among GUS-randomized pts, pts achieving response at W24 or W48 had less structural damage progression compared with nonresponders across endpoints

LSM Change in vdH-S at W24 by W24 Responders/Nonresponders



LSM Change From Baseline
SJC ≤1
TJC ≤1
PASI ≤1
Pt Pain ≤15
PtGA ≤20
HAQ-DI ≤0.5
LEI ≤1
SJC=0
TJC=0

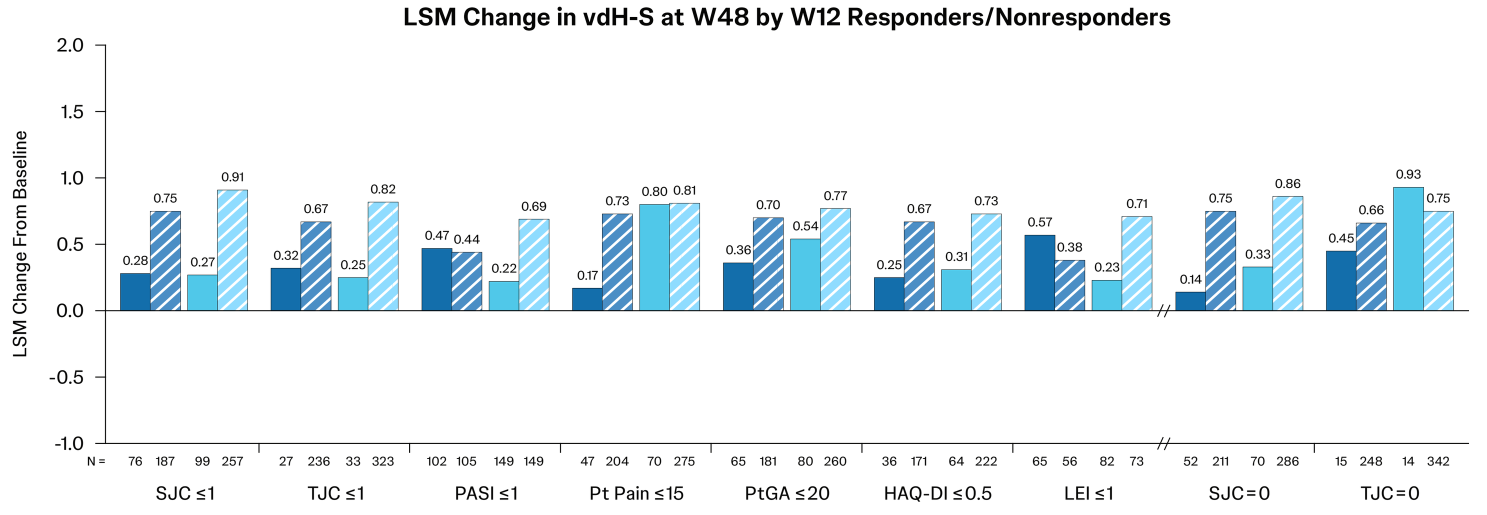
LSM Change in vdH-S at W48 by W48 Responders/Nonresponders



LSM Change From Baseline
SJC ≤1
TJC ≤1
PASI ≤1
Pt Pain ≤15
PtGA ≤20
HAQ-DI ≤0.5
LEI ≤1
SJC=0
TJC=0
Q4W Responders
Q4W Nonresponders
Q8W Responders
Q8W Nonresponders

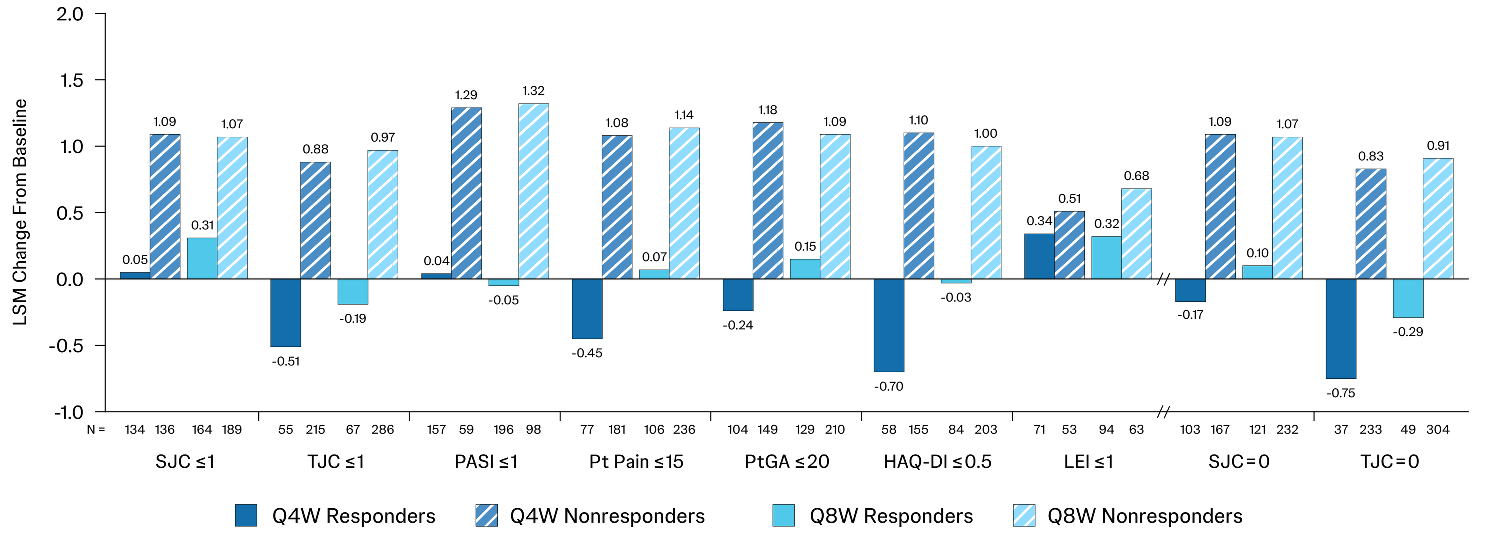
Among GUS-randomized pts, clinical response at W12 or W24 was associated with less structural damage progression at W48 compared with nonresponders

LSM Change in vdH-S at W48 by W12 Responders/Nonresponders



LSM Change From Baseline
SJC ≤1
TJC ≤1
PASI ≤1
Pt Pain ≤15
PtGA ≤20
HAQ-DI ≤0.5
LEI ≤1
SJC=0
TJC=0

LSM Change in vdH-S at W48 by W24 Responders/Nonresponders



LSM Change From Baseline
SJC ≤1
TJC ≤1
PASI ≤1
Pt Pain ≤15
PtGA ≤20
HAQ-DI ≤0.5
LEI ≤1
SJC=0
TJC=0
Q4W Responders
Q4W Nonresponders
Q8W Responders
Q8W Nonresponders

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