Efficacy of Guselkumab Assessed by Composite Indices in Participants With Active and Erosive Psoriatic Arthritis: Analyses Through Week 24 of the Phase 3b, Randomized, Double-Blind, Placebo-Controlled APEX Study

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Key Takeaways

- **Through W24 of APEX, GUS-treated pts had greater response rates compared with PBO-treated pts for achieving low levels of disease activity across multiple PsA domains**
- **At W24, GUS treatment effect for both dosing regimens was consistent across stringent endpoints using composite measures of disease activity: MDA and VLDA**

Background

Psoriatic arthritis (PsA) is a heterogenous, chronic, inflammatory disease with clinical manifestations across peripheral arthritis, axial involvement, dactylitis, enthesitis, psoriatic skin, and nail disease

Guselkumab (GUS) is a fully human, dual-acting,[1] monoclonal antibody that selectively inhibits the interleukin (IL)-23p19 subunit and is approved to treat moderate-to-severe plaque psoriasis (PsO), active psoriatic arthritis (PsA), and moderately-to-severely active Crohn's disease and ulcerative colitis[2]

In the ongoing phase 3b, randomized, double-blind, placebo (PBO)-controlled APEX study, GUS demonstrated efficacy vs PBO in improving signs and symptoms of PsA and significantly inhibiting structural damage progression at Week (W) 24[3]

Objective

Evaluate multidomain efficacy of GUS through W24 in APEX using composite indices assessing PsA disease activity in pts with active and erosive PsA

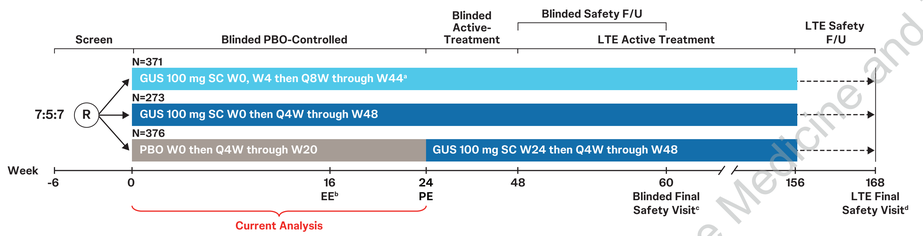
Methods

Key inclusion criteria:

- Biologic-naïve
- Age ≥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)

Endpoints through W24:

- DAPSA LDA ≤14/REM ≤4[4]
- cDAPSA LDA ≤13/REM ≤4[4,5]
- MDA[6]
- VLDA[6]



Statistical Analyses

- P-values (W4-24) based on GLMM were not multiplicity controlled, are considered nominal, and may not be used to claim statistical significance
- Pts were considered nonresponders at post-baseline visits (W4-24) if they had previously 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 and were accounted for in the analysis model (GLMM); other missing data were imputed using NRI
- Efficacy analyses included all randomized pts except those from Ukrainian sites unable to support key study operations (mFAS, N=1020).

[a]PBO SC W8 then Q8W through W48 administered to maintain blinding. [b]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. [c]Final safety visit for those who do not enter LTE. [d]Final safety visit for those who entered LTE. ***CASPAR****=ClASsification 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 Psoriatic Arthritis,* ***EE****=early escape,* ***F/U****=follow-up,* ***GLMM****=generalized linear mixed model,* ***LDA****=low disease activity,* ***LTE****=long-term extension,* ***MD****=major disruption: involving Ukraine and neighboring countries/territories beginning 24 February 2022,* ***MDA****=Minimal disease activity,* ***mFAS****=modified full analysis set,* ***ND****=natural disaster: site closure, site access restrictions, or lockdowns due to the COVID-19 pandemic,* ***NRI****=nonresponder imputation,* ***NSAIDs****=nonsteroidal anti-inflammatory drug,* ***PE****=primary endpoint,* ***PsA****=psoriatic arthritis,* ***PsO****=psoriasis,* ***Q4W/Q8W****=every 4/8 weeks,* ***R****=randomization,* ***REM****=remission,* ***SC****=subcutaneous,* ***SJC****=swollen joint count,* ***TJC****=tender joint count,* ***VLDA****=very low disease activity.*

Results

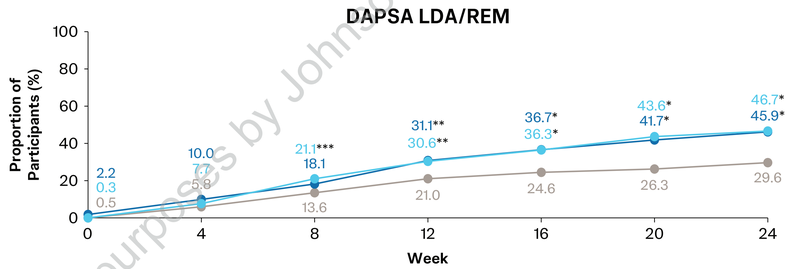
Baseline characteristics of pts with active and erosive PsA were balanced across treatment groups

Baseline Characteristics	GUS Q4W (N=273)	GUS Q8W (N=371)	PBO (N=376)
Demographics			
Age, years	52.2 (13.2)	53.2 (12.9)	53.5 (13.0)
Female, n (%)	124 (45.4)	172 (46.4)	163 (43.4)
PsA Characteristics			
PsA disease duration, years	7.5 (7.1)	7.2 (7.6)	7.2 (6.9)
SJC [0-66]	11.6 (9.4)	12.1 (8.5)	11.8 (8.9)
TJC [0-68]	21.2 (14.6)	20.6 (13.4)	20.5 (13.9)
HAQ-DI [0-3]	1.2 (0.7)	1.2 (0.6)	1.2 (0.6)
Patient assessment of pain [VAS; 0-10cm]	5.9 (2.2)	5.9 (2.1)	5.9 (2.1)
Patient's global assessment [VAS; 0-10cm]	5.9 (2.2)	5.9 (2.1)	5.9 (2.0)
Physician's global assessment [VAS; 0-10cm]	6.4 (1.6)	6.4 (1.6)	6.2 (1.7)
CRP, mg/dL	1.7 (2.9)	1.5 (2.0)	1.7 (2.5)
Dactylitis [1-60]	10.8 (11.5)[a]	11.0 (12.8)[b]	10.2 (10.5)[c]
Enthesitis LEI [1-6]	3.2 (1.8)[d]	3.0 (1.7)[e]	3.0 (1.6)[f]
DAPSA	46.4 (24.3)	46.1 (22.1)	46.0 (22.8)
cDAPSA	44.7 (23.5)	44.6 (21.6)	44.3 (22.3)
PsO Characteristics			
BSA, n (%)	15.0 (19.2)	16.5 (21.9)	16.3 (21.5)
PASI [0-72]	7.6 (8.3)	8.3 (10.1)	8.2 (9.5)

Values are reported as mean (standard deviation) unless otherwise noted. [a]N=119. [b]N=143. [c]N=167. [d]N=157. [e]N=214. [f]N=218. ***BSA****=body surface area,* ***LEI****=Leeds Enthesitis Index,* ***VAS****=Visual analog scale.*

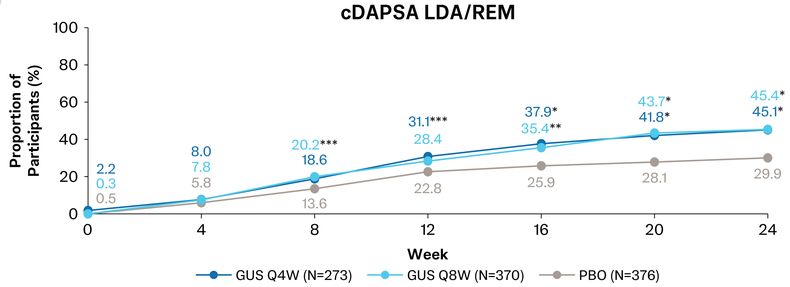
At W24, greater proportions of GUS-treated pts achieved DAPSA LDA/REM vs PBO

- Separation from PBO observed as early as W12



*P-values are nominal. *ps≤0.001, **ps<0.01, ***ps<0.05. P-values and adjusted response rates were determined using GLMM including data from post-baseline visits (W4-24); observed data are reported for W0 (GUS Q4W N=273; GUS Q8W N=369; PBO N=375). DAPSA LDA (≤14) and DAPSA REM (≤4) are calculated as the sum of the following components: TJC (0–68), SJC (0–66), CRP level (mg/dL), patient assessment of pain (VAS 0–10), and patient global assessment of disease activity (arthritis, VAS 0-10).[4,5] VAS=visual analog scale.*

Greater proportions of GUS-treated pts achieved cDAPSA LDA/REM vs PBO at W24



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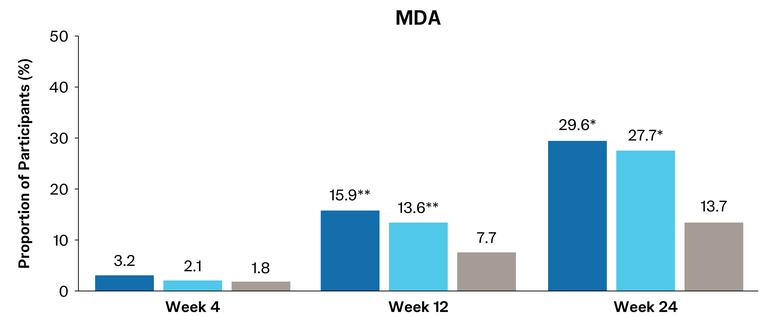
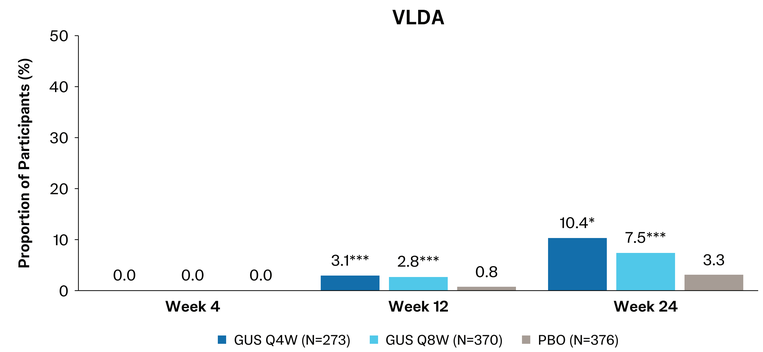
GUS-treated pts had greater response rates vs PBO for achieving MDA and VLDA across PsA domains at W12 and W24





*P-values are nominal. *ps≤0.001, **ps≤0.01, ***p<0.05. MDA (≤5/7 of the following) and VLDA (all 7): TJC ≤1; SJC ≤1; psoriasis activity and severity index ≤1; patient pain VAS (0-100) score ≤15; patient global assessment of disease activity (arthritis and psoriasis, VAS 0-100) score of ≤20; HAQ-DI score ≤0.5; and ≤1 tender entheseal point.[6]*

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