Effects of Guselkumab on Patient-Reported Outcomes in Biologic-Naïve Participants With Active and Erosive Psoriatic Arthritis: Results 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 experienced greater improvements in FACIT-Fatigue and PsAID-12 compared with PBO as early as W12**
- **In addition to demonstrating efficacy in clinical outcomes, inhibition of structural damage progression, and improvement in physical function,[3] GUS treatment was associated with meaningful improvements in fatigue and overall HRQoL**

Background

Guselkumab (GUS) is a fully human, dual-acting,[1] monoclonal antibody inhibiting the interleukin (IL)-23p19 subunit and is approved for treating patients with active psoriatic arthritis (PsA)[2]

In the ongoing, phase 3b, multicenter, randomized, double-blind, placebo (PBO)-controlled APEX study of participants (pts) with active and erosive PsA, GUS demonstrated efficacy across clinical endpoints, inhibition of structural damage progression, and improvements in physical function at Week (W) 24[3]

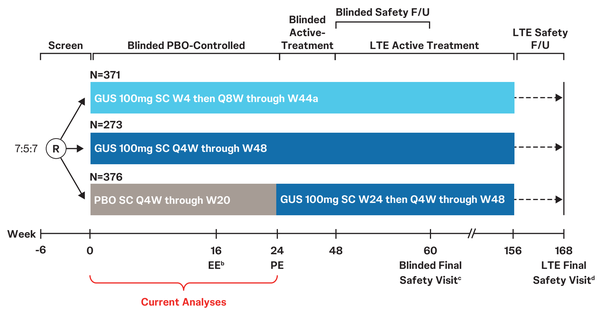
Objective

Summarize the efficacy of GUS through W24 of APEX using patient-reported outcomes (PROs) to evaluate fatigue and the impact of PsA on mental and physical aspects of health-related quality of life (HRQoL)

APEX Study Design and Methods

Key Inclusion Criteria

- ✓ Biologic-naïve
- ✓ ≥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)



Assessments

FACIT-Fatigue
- 13-item questionnaire evaluating fatigue level and its impact on daily functioning over the previous 7 days (0-52; lower scores reflect more severe fatigue)
- **CMI: ≥4**

PsAID-12
- 12-item questionnaire assessing physical and psychological domains of PsA: pain, fatigue, skin, work and/or leisure activities, function, discomfort, sleep, coping, anxiety, embarrassment, social life, and depression
- **CMI: ≥3**
- **PASS:** Indicates patient satisfaction with their current symptoms (score: ≤4)[4]

W24 Statistical Analysis
- LS mean change from baseline
- % achieving **≥4-point improvement**
- LS mean change from baseline
- % achieving **≥3-point improvement**
- % achieving PASS

- P-values were not multiplicity controlled, are considered nominal, and may not be used to claim statistical significance
- Pts were considered nonresponders for binary endpoints and to have had no improvement (change=0) for continuous endpoints at a visit 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. After applying these rules, missing data due to ND/MD were accounted for in the analysis model (LS Mean change: MMRM; Response Rates: GLMM). For binary endpoints, other missing data were imputed using NRI
- Efficacy analyses include 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=*CASsification criteria for Psoriatic Arthritis*, ***CMI***=*clinically meaningful improvement*, ***CRP***=*C-reactive protein*, ***csDMARDs***=*conventional synthetic disease modifying antirheumatic drugs*, ***EE***=*early escape*, ***FACIT-Fatigue***=*Functional Assessment of Chronic Illness Therapy-Fatigue*, ***F/U***=*follow-up*, ***GLMM***=*generalized linear mixed model*, ***LS***=*least squares*, ***LTE***=*long-term extension*, ***MD***=*major disruption: involving Ukraine and neighboring countries/territories beginning 24 February 2022*, ***mFAS***=*modified full analysis set*, ***MMRM***=*Mixed Model for Repeated Measures*, ***ND***=*natural disaster: site closure, site access restrictions, or lockdowns due to the COVID-19 pandemic*, ***NRI***=*nonresponder imputation*, ***NSAIDs***=*nonsteroidal anti-inflammatory drugs*, ***PASS***=*Patient Acceptable Symptom State*, ***PE***=*primary endpoint*, ***PsA***=*psoriatic arthritis*, ***PsAID-12***=*Psoriatic Arthritis Impact of Disease: 12-item questionnaire*, ***PsO***=*psoriasis*, ***Q4W/Q8W***=*every 4/8 weeks*, ***R***=*randomization*, ***SC***=*subcutaneous*, ***SJC***=*swollen joint count*, ***TJC***=*tender joint count*.

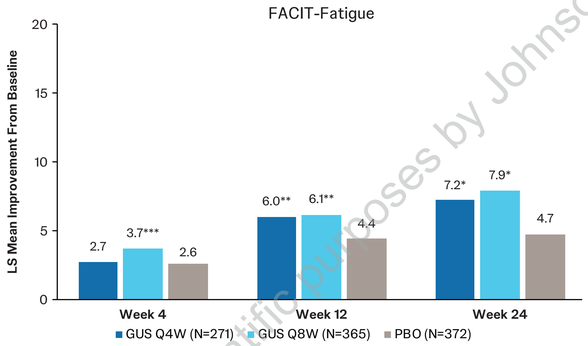
Results

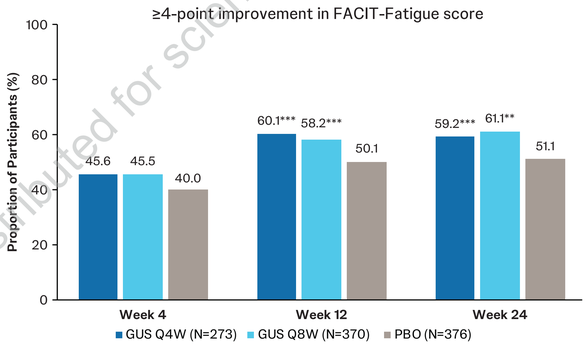
Baseline characteristics of pts with active and erosive PsA were balanced across treatment groups

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]
FACIT-Fatigue	30.8 (11.3)	31.1 (10.2)	31.2 (11.0)
PsAID-12	5.1 (2.2)	5.2 (2.0)	5.1 (2.1)
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*.

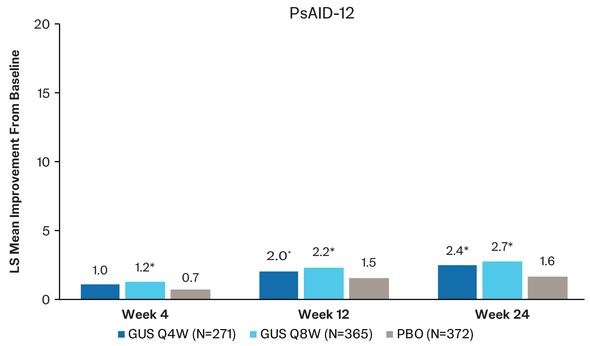
GUS-treated pts exhibited greater LS mean improvements in fatigue and greater proportions achieved clinically meaningful improvement vs PBO at W12 and W24

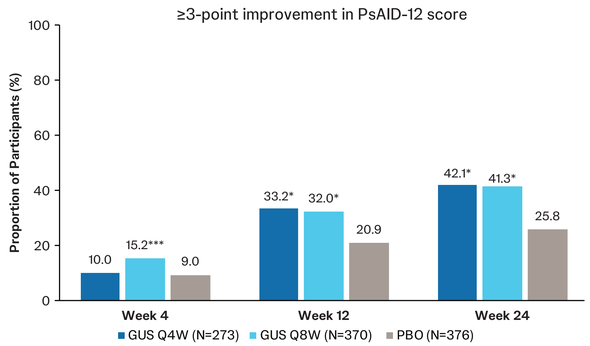




*P-values are nominal. *p<0.001, **p<0.01, ***p<0.05*

Through W24, GUS-treated pts exhibited greater LS mean improvements from baseline in physical and psychological aspects of PsA vs PBO and greater response rates for achieving meaningful improvement in PsAID-12 score and the PsAID-12 PASS





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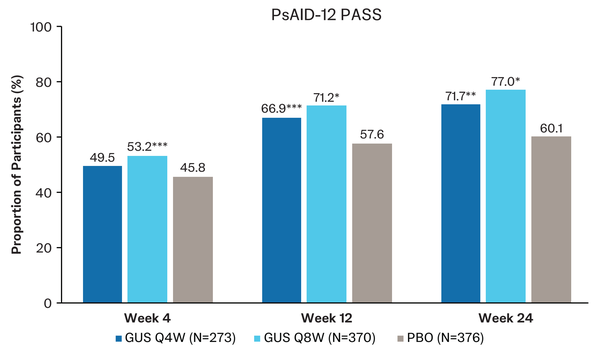

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