Efficacy and Safety of Guselkumab in Participants With Active Psoriatic Arthritis and Inadequate Response/Intolerance to One Prior Tumor Necrosis Factor Inhibitor Through 1 Year of the SOLSTICE Study

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Background

- Guselkumab (GUS) is a fully human dual-acting[1] monoclonal antibody inhibiting 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]
- PsA is a chronic, heterogeneous, inflammatory disease primarily affecting the joints and skin[3,4]
- In SOLSTICE, a phase 3b, multicenter, randomized, placebo (PBO)-controlled study, GUS 100 mg every 4 weeks (Q4W) and Q8W significantly improved PsA signs and symptoms through week (W) 24 in participants (pts) with inadequate response (IR; inadequate efficacy or intolerance) to 1 prior tumor necrosis factor inhibitor (TNFi)[5]

Objective

Report efficacy and safety findings for GUS Q4W and Q8W through W52 of SOLSTICE in a dedicated TNFi-IR pt population with active PsA

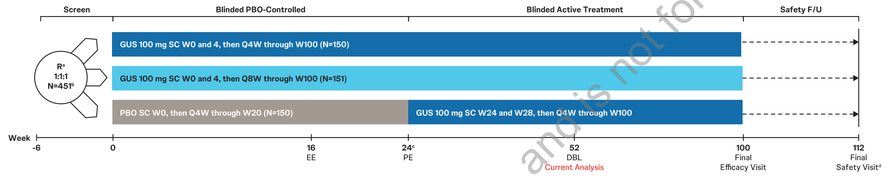
Methods

Key inclusion criteria:

- Age ≥18 years
- Active PsA (≥3 SJC; ≥3 TJC; CRP ≥0.3 mg/dL); CASPAR criteria met
- Inadequate efficacy and/or intolerance to 1 prior TNFi therapy
- History of or active PsO (≥1 plaque ≥2 cm and/or nail PsO)

Endpoints at W52:

- ACR20
- ACR50
- ACR70
- IGA 0/1 response: score 0 or 1 plus ≥2-grade improvement
- PASI 90
- MDA



Statistical Analyses

- Pts were considered nonresponders through W24 if they increased dose/initiated csDMARDs or oral corticosteroids or initiated protocol-prohibited PsA therapies, and through W52 if they discontinued study agent for any reason other than ND/MD.
- Data impacted by ND/MD were imputed using MI; other missing data were imputed using NRI. Response rates shown are the average proportion achieving response, over 200 MI datasets.

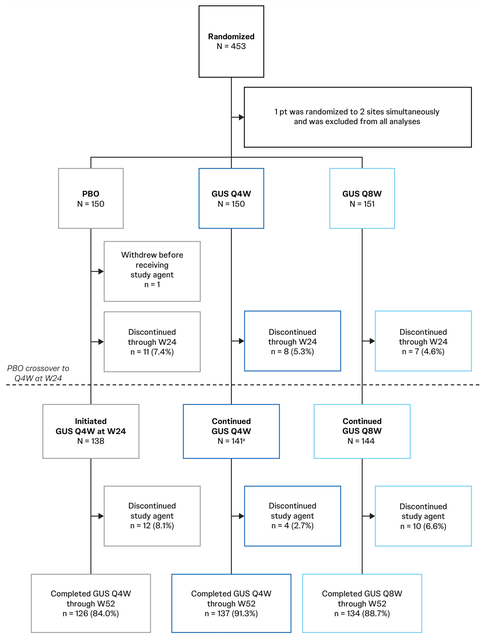
*Randomization was stratified by baseline use of csDMARDs. †Total number randomized=453, the full analysis set of 451 excludes 1 pt who was double randomized. ‡Crossover. §Final safety F/U at W112 is 12W after final study agent administration. **ACR20**=≥20% in American College of Rheumatology response criteria, **CASPAR**=ClASsification criteria for Psoriatic ARthritis, **CMH**=Cochran Mantel Haenszel, **CRP**=C-reactive protein, **csDMARDs**=conventional synthetic disease-modifying antirheumatic drugs, **DBL**=database lock, **EE**=early escape, **F/U**=follow-up, **IGA**=Investigator's Global Assessment of PsO, **MD**=major disruption: involving Ukraine and neighboring countries/territories beginning 24 February 2022, **MDA**=Minimal Disease Activity, **MI**=multiple imputation, **ND**=natural disaster, site closure, site access restrictions, or lockdowns due to the COVID-19 pandemic, **NRI**=nonresponder imputation, **PASI 90**=≥90% improvement in Psoriasis Area and Severity, **PE**=primary endpoint, **R**=randomization, **SC**=subcutaneous, **SJC**=Swollen joint count, **TJC**=Tender joint count.

Key Takeaways

- **In the SOLSTICE TNFi-IR PsA population, response rate for achieving improvements in joint (ACR20/50/70) and skin (IGA 0/1; PASI 90) outcomes were sustained or numerically increased from W24-52 among GUS-randomized pts**
- **MDA response rates numerically increased from W24-W52 in GUS-randomized pts**
- **Similar efficacy observed for both GUS Q4W and Q8W**
- **The GUS safety profile from W24-52 was consistent with that during the PBO-controlled period; no new safety signals were identified**

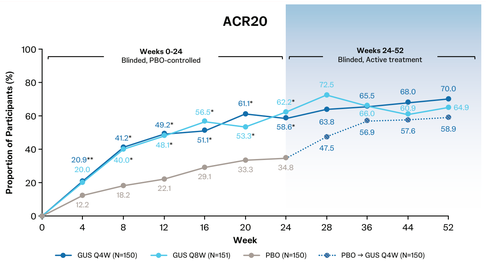
Results

Of 451 analyzed pts, 88.0% completed treatment through W52



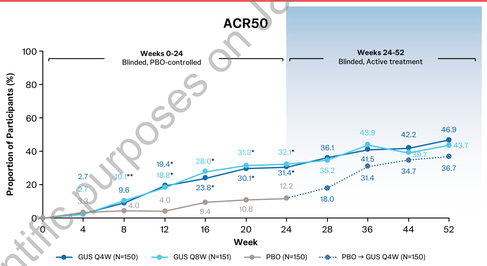
*One additional pt discontinued study agent after receiving their W24 dose.

ACR20/50/70 response rates increased numerically from W24-W52 in GUS-randomized pts



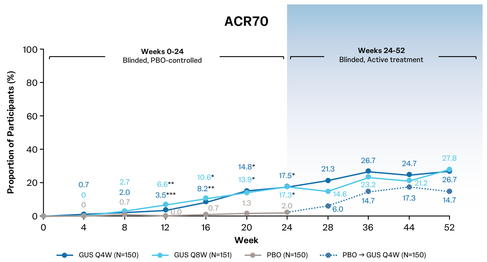
*p<0.001, **p=0.042 vs PBO

ACR20 was weekly controlled at W16 and multiplicity-controlled at W24; all other p values are nominal. Post hoc analysis (W4, W8, W12, W20, W28–W52) used methods consistent with primary and major secondary endpoint analysis.



*p<0.001, **p=0.039 vs PBO

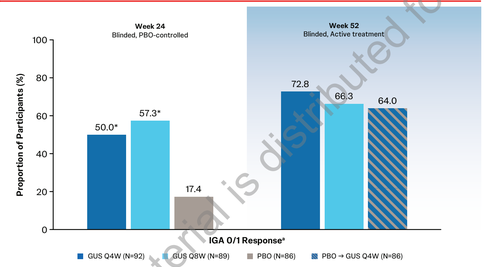
ACR50 was weekly controlled at W16 and W24; all other p values are nominal. Post hoc analysis (W4, W8, W12, W20, W28-W52) used methods consistent with primary and major secondary endpoint analysis.



*p<0.001, **p=0.002, ***p=0.021 vs PBO

ACR70 was weekly controlled at W24; all other p values are nominal. Post hoc analysis (W4, W8, W12, W20, W28-W52) used methods consistent with primary and major secondary endpoint analysis.

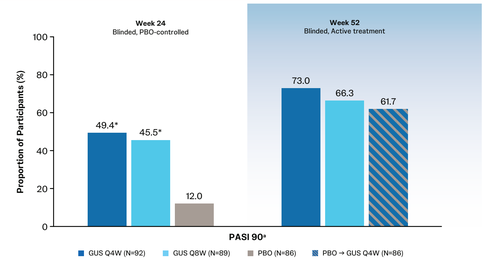
Response rates for achieving almost clear or clear skin numerically increased from W24-W52 in GUS-randomized pts



*p<0.001 vs PBO

*Among pts with baseline BSA ≥3% and IGA ≥2 (mild). Post hoc analysis used methods consistent with primary and major secondary endpoint analysis. **BSA**=body surface area.

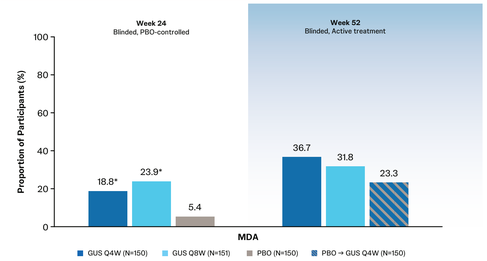
In the Q4W and Q8W groups, PASI 90 response rates indicated improvements in psoriatic skin disease from W24-W52



*p<0.001 vs PBO

*Among pts with baseline BSA ≥3% and IGA ≥2 (mild). Post hoc analysis used methods consistent with primary and major secondary endpoint analysis.

MDA response rates numerically increased from W24-W52 in GUS-randomized pts



*p<0.001 vs PBO

Post hoc analysis used methods consistent with primary and major secondary endpoint analysis.

Frequencies of AEs and SAEs were similar across treatment groups

	GUS Q4W W0-24	GUS Q8W W0-24	PBO W0-24	GUS Q4W W0-52	GUS Q8W W0-52	PBO → GUS Q4W W24-52[b]
Safety Analysis Set, N[a]	150	151	149	150	151	138
Mean weeks of follow-up	24.0	23.7	23.6	50.7	50.2	27.4
Mean number of GUS administrations	5.7	3.8	0	12.1	6.6	6.7
Pts with ≥1 of the following:						
AE	70 (46.7)	81 (53.6)	72 (48.3)	97 (64.7)	101 (66.9)	64 (46.4)
Events/100 PYs	178.1	212.2	207.0	170.1	200.4	181.0
SAE	2 (1.3)	4 (2.6)	6 (4.0)	5 (3.3)	10 (6.6)	2 (1.4)
Events/100 PYs	2.9	7.2	8.8	3.4	9.6	2.8
AE leading to discontinuation of study agent	1 (0.7)	2 (1.3)	3 (2.0)	1 (0.7)	2 (1.3)	2 (1.4)
Events/100 PYs	1.4	1.4	4.4	0.7	1.4	2.8
Infections	35 (23.3)	43 (28.5)	44 (29.5)	50 (33.3)	63 (41.7)	39 (28.3)
Events/100 PYs	55.6	78.0	74.9	47.3	73.7	70.4
Opportunistic infections	0	0	0	0	0	0
Events/100 PYs	0	0	0	0	0	0
Injection site reactions	1 (0.7)	2 (1.3)	1 (0.7)	6 (4.0)	3 (2.0)	1 (0.7)
Events/100 PYs	2.8	2.9	1.5	7.5	2.8	5.5

Safety events of interest W0-W24:

- 2 x serious infections (pyelonephritis, laryngitis)
- 1 x malignancy (basal cell carcinoma)
- 1 x MACE
- 2 x VTEs (DVT and PE in same pt)
- 1 x Death (MACE pt)

Safety events of interest W24–W52:

- 1 x serious infections (cellulitis)
- 2 x malignancy (gastric cancer, colon cancer [fatal]
- 1 x death (colon cancer)

*Data reported as n (%) unless otherwise noted. Includes all pts who received ≥1 study agent administration. [a]Pts are counted only once for any given event, regardless of the number of times they actually experienced the event. [b]Includes only pts who received GUS Q4W following crossover at W24. AEs are coded using Medical Dictionary for Regulatory Activities Version 27.0. **AE**=Adverse event; **MACE**=Major adverse cardiovascular event (cardiovascular death, nonfatal myocardial infarction, and nonfatal stroke); **PY**=patient-year; **SAE**=Serious adverse event; **VTE**=Venous thromboembolism events.*

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