Guselkumab for Treatment of Juvenile Psoriatic Arthritis: Data Extrapolation from Studies in Adjacent Adult and Pediatric Populations

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Background

- Psoriatic arthritis (PsA) and juvenile PsA (jPsA) are chronic inflammatory diseases affecting the skin and joints that differ by age of onset, but have similar manifestation, progression, and clinical characteristics
- PsA and psoriasis (PsO) share similar pathogenic mechanisms (with interleukin [IL]-23 as a key mediator) and clinical features across all ages, yet no currently approved pediatric treatment selectively targets the IL-23 pathway. Thus, jPsA has unmet clinical needs[1]
- Guselkumab (GUS) is a fully human, dual-acting, IL-23p19-subunit inhibitor shown to be safe and effective in adult PsO and PsA patients in the phase 3 VOYAGE 1 and 2 and DISCOVER-1 and -2 trials, respectively[2-6], with consistent clinical benefits and safety in pediatric PsO participants in the Phase 3 PROTOSTAR trial[7]
- As jPsA is rare, a previously employed extrapolation approach[8], for which the FDA provided guidance[9], was used to establish GUS effectiveness and safety in jPsA

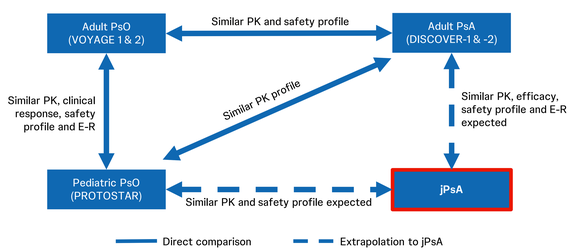
Objectives

Demonstrate similarity of:

- **Serum GUS concentrations among children and adults with PsO, adults with PsO and adults with PsA, and children with PsO and adults with PsA**
- **Clinical response with GUS among children and adults with PsO, and children with PsO, and adults with PsA**
- **GUS safety profile among children and adults in randomized controlled trials**

Methods

Extrapolation approach using data from GUS Phase 3 trials in related populations



E-R=exposure-response; PK=pharmacokinetics.

GUS Phase 3 trials in related populations contributing data to extrapolation analyses

Moderate-to-severe Pediatric PsO (+/- jPsA)		Moderate-to-severe Adult PsO	Active Adult PsA
≥6 to <18 years		≥18 years	≥18 years
PROTOSTAR		VOYAGE 1 & 2	DISCOVER-1 & -2
N=92 (3 of whom had jPsA)[a]		N=1221	N=375
<70kg: GUS 1.3 mg/kg at W0, W4, then Q8W[b]	≥70 kg: GUS 100 mg at W0, W4, then Q8W[b]	GUS at W0, W4, then Q8W	GUS at W0, W4, then Q8W

- Serum GUS levels were compared across all studies and between pediatric PsO participants with or without jPsA
- Skin response rates were assessed[c]:
  - IGA of cleared (0) or minimal (1) (IGA 0/1)
  - PASI 75/90/100
- GUS safety profiles were summarized across studies

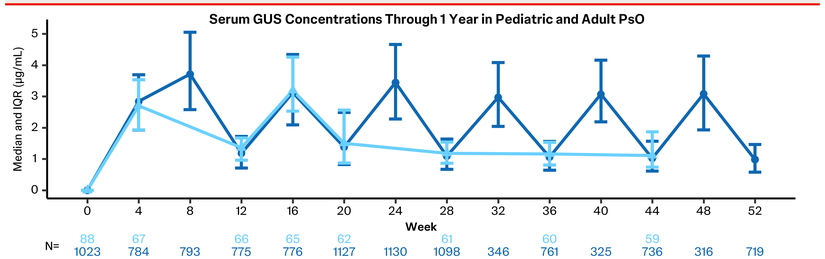
[a]Includes participants randomized to PBO who crossed over to GUS at W16 (n=23), 1 of whom had jPsA, and all participants randomized to receive GUS at W0. [b]Part 1 participants who were PASI 90 responders at W16 did not receive additional doses of GUS until they lost ≥50% of this response, at which time they received 1 dose of GUS, followed by a dose 4W later, then Q8W through W52. Part 2 participants received continuous open-label GUS treatment through W52. [c]Non-responder imputation was used for treatment failure, rescue medication (PROTOSTAR only) and missing data. For IGA 0/1 and PASI responses among adults with PsA, only participants with baseline BSA ≥3% and IGA score ≥3 were included. **IGA**=Investigator's Global Assessment; **PASI**=Psoriasis Area and Severity Index; **PBO**=placebo; **Q8W**=every 8 weeks; **W**=week.

Key Takeaways

- **Phase 3 GUS studies in adults with PsO, adults with PsA, and children with PsO (3 of whom also had jPsA) showed comparable GUS:**
  - ✓ **Serum PK concentrations**
  - ✓ **Clinical responses**
  - ✓ **Safety profile**
- **Findings corroborate extrapolation of efficacy and safety data from adults with PsO and PsA and children with PsO to children with jPsA**
- **Findings support the use of GUS in children with jPsA**

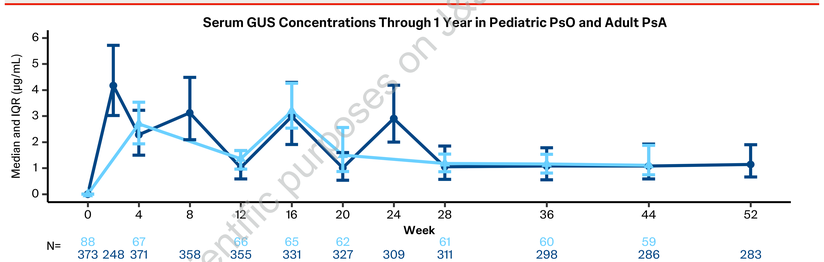
Results

Serum GUS concentrations were consistent between children and adults with moderate-to-severe PsO



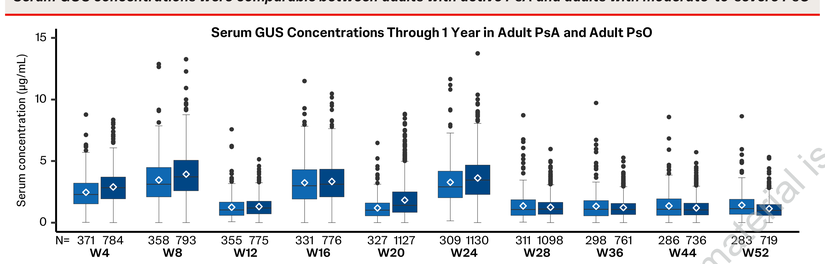
*VOYAGE 2 participants who were randomized to GUS but withdrew, due to being a PASI 90 responder at W28 and rerandomization to PBO, were excluded after withdrawal from GUS (n=182). Pediatric participants randomized to GUS who withdrew, due to being a PASI 90 responder at W16, were excluded after withdrawal from GUS (n=23). For all studies, participants randomized to PBO at W0 who later crossed over to GUS were only included at visits where serum concentrations were available after receiving their first dose of GUS (n=20). **IQR**=interquartile range; **Ped**=pediatric.*

Serum GUS concentrations were similar between children with moderate-to-severe PsO and adults with active PsA



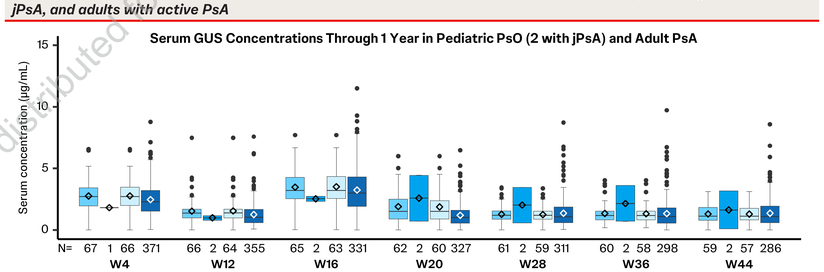
Pediatric participants randomized to PBO at W0 who later received GUS were only included at visits where serum concentrations were available after receiving their first dose of GUS at W16 (n=20). Pediatric participants randomized to GUS who withdrew, due to being a PASI 90 responder at W16, were excluded after withdrawal from GUS (n=23).

Serum GUS concentrations were comparable between adults with active PsA and adults with moderate-to-severe PsO



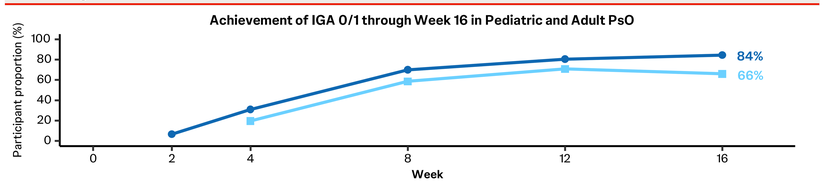
Diamonds denote means. Dots represent outliers (outside +/-1.5 times the interquartile range). For all studies, participants randomized to PBO at W0 who later received GUS were only included at visits where serum concentrations were available after receiving their first dose of GUS (n=389). VOYAGE 2 participants who were randomized to GUS but withdrew, due to being a PASI 90 responder at W28 and rerandomization to PBO, were excluded after withdrawal from GUS (n=182).

Serum GUS concentrations were comparable between children with moderate-to-severe PsO, including those with jPsA, and adults with active PsA



Diamonds denote means. Dots represent outliers (outside +/-1.5 times the interquartile range). Pediatric participants randomized to PBO at W0 who later received GUS were only included at visits where serum concentrations were available after they received their first dose of GUS at W16 (n=20). Pediatric participants randomized to GUS who withdrew, due to being a PASI 90 responder at W16, were excluded after withdrawal from GUS (n=13).

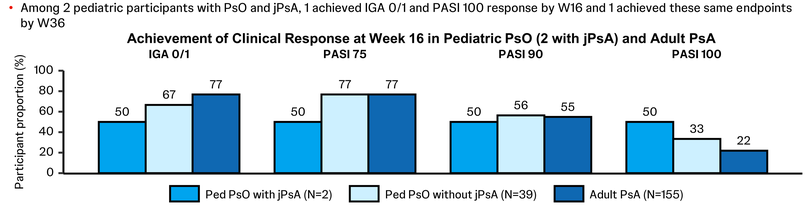
IGA 0/1 response rates were comparable between GUS-treated children and adults with moderate-to-severe PsO through W16



Data from VOYAGE 1, VOYAGE 2, and PROTOSTAR part 1 were included.

IGA 0/1 and PASI 75/90/100 response rates were similar between GUS-treated children with moderate-to-severe PsO (2 with jPsA) and adults with active PsA through W16

- Among 2 pediatric participants with PsO and jPsA, 1 achieved IGA 0/1 and PASI 100 response by W16 and 1 achieved these same endpoints by W36



Data from DISCOVER-1, DISCOVER-2, and PROTOSTAR part 1 were included.

GUS safety profile was generally consistent between pediatric PsO participants with and without jPsA through 1 year

- No new safety signals were identified compared with established GUS safety profile in adults[10]

	PsO with jPsA (N=3)	PsO without jPsA (N=89)
Discontinued treatment	0 (0%)	2 (2.2%)
Adverse event	2 (67%)	70 (79%)
Serious adverse event	1 (33%)	2 (2.2%)
Any infection	2 (67%)	50 (56%)
Serious infection	0 (0%)	0 (0%)
Injection-site reaction	0 (0%)	4 (4%)

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