Patient-Level Persistence of On-Treatment Remission With Guselkumab: Pooled Results From VOYAGE 1 and VOYAGE 2 Participants With Moderate-to-Severe Plaque Psoriasis

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Key Takeaways

In post-hoc analyses of pts with moderate-to-severe plaque PsO from VOYAGE 1 and 2, employing stringent mNRI for missing data:

- **GUS provided highly durable NPF-defined on-treatment remission of PsO**
 - **~60% of pts achieved on-treatment remission, with on-treatment remission status maintained for ~2 years**
 - **Of those who achieved on-treatment remission, ~40% maintained on-treatment remission through the end of the 5-year follow-up period**
- **Any loss of NPF-defined on-treatment remission status with GUS was largely transient**
 - **The majority (~90%) of pts who lost on-treatment remission regained IGA 0 or PASI 100 *response* within ~9 weeks (i.e., ~1 dosing interval) with continued GUS treatment**
 - **~65% of pts regained on-treatment *remission* status with continued GUS treatment**
- **Despite known differences in how IGA 0 and PASI 100 are scored and assessed, findings were generally consistent across these measures of complete skin clearance**
- **Real-world scenario analyses applying NPF on-treatment PsO remission criteria yielded outcomes comparable to or better than the primary definition**

Background

- Plaque psoriasis (PsO) is a chronic, immune-mediated disease, mainly affecting the skin but also causing systemic inflammation, frequently associated with comorbidities and substantial burden for patients and healthcare systems[1]
- Given the chronic nature and manifestations of PsO, achieving a sustained clinical response that translates to durable disease control remains a key therapeutic goal
- A recent Delphi consensus organized by the National Psoriasis Foundation (NPF) defined on-treatment remission for plaque PsO as achieving and maintaining PsO body surface area (BSA) of 0% or Investigator's Global Assessment (IGA) score of 0 for ≥6 months while on treatment[2]
- Guselkumab (GUS) is a fully human, dual-acting monoclonal antibody that selectively inhibits interleukin-23 by targeting its p19 subunit and binds CD64 expressed on IL-23-producing myeloid cells[3]
- GUS demonstrated high and durable population-level clinical response rates through up to 5 years in the phase 3 VOYAGE 1 and 2 studies in participants (pts) with moderate-to severe plaque PsO[4]

Objective

Post-hoc analyses of pooled VOYAGE 1 and 2 GUS-randomized pt data through 5 years evaluated:

- **Achievement and pt-level maintenance of NPF-defined on-treatment PsO remission**
- **Application of NPF on-treatment PsO remission criteria to approximate real-world scenarios**

Analysis Cohort

- Pooled from 2 RCTs of pts with moderate-to-severe plaque PsO who received continuous GUS Q8W treatment

VOYAGE 1[a]
- ≥18 years of age
- Plaque PsO for ≥6 months
- IGA ≥3, PASI ≥12, BSA ≥10%
- Candidate for systemic therapy or phototherapy

VOYAGE 2[b]
- ≥18 years of age
- Plaque PsO for ≥6 months
- IGA ≥3, PASI ≥12, BSA ≥10%
- Candidate for systemic therapy or phototherapy

N=837
2:1:2
GUS Q8W:PBO:ADA Q2W

N=992
2:1:1
GUS Q8W[c]:PBO:ADA Q2W

Continuous GUS Q8W N=643

[a]NCT02207231. [b]NCT02207244. [c]PASI 90 responders at W28 were rerandomized 1:1 to GUS 100 mg Q8W or PBO (withdrawn). Only pts with continuous GUS Q8W treatment were included. ***ADA****=adalimumab,* ***BSA****=body surface area,* ***GUS****=guselkumab,* ***IGA****=Investigator's Global Assessment,* ***PASI****=Psoriasis Area and Severity Index,* ***PBO****=placebo,* ***PsO****=psoriasis,* ***pts****=participants,* ***Q2W****=every 2 weeks,* ***Q8W****=every 8 weeks,* ***RCT****=randomized controlled trial,* ***W****=week.*

Assessments and Post Hoc Analyses

Rates and pt-level time to event through W252

Achievement of on-treatment remission

↓

Loss of initial on-treatment remission[a]

↓

Re-achievement of response (at any visit) after initial loss of on-treatment remission

↓

Re-achievement of on-treatment remission status after initial loss of on-treatment remission

On-treatment remission analyses[4]

1. Primary NPF definition analysis

Complete skin clearance response for ≥6 months (i.e., at ≥4 consecutive Q8W GUS dosing visits) based on:
- IGA 0 (IGA score of 0)
- PASI 100 (100% improvement from baseline in PASI score)[b]

2. Real-world scenario analysis[c]

Response at the 1st and last Q8W GUS dosing visits within a 6-month interval (to approximate Q6-month real-world follow-up visits) based on:
- IGA 0
- PASI 100

- Time to event data were assessed using Kaplan-Meier survival analysis
 - Pts were censored at the time of study discontinuation
- Modified nonresponder imputation (mNRI) was applied for missing data within the 6-month interval post-achievement of response. Remission was considered:
 - "Achieved" if response achieved at the flanking Q8W dosing visits
 - "Not achieved" if lack of response at either or both flanking Q8W dosing visits
 - "Not achieved" if ≥2 consecutive missing Q8W dosing visits

[a]First Q8W visit after the achievement of on-treatment remission that no longer met the response criterion. [b]As BSA was not collected post-baseline in these studies, PASI was evaluated as a surrogate measure for skin clearance. [c]Based on typical timing of clinic follow-up visits. ***NPF****=National Psoriasis Foundation.*

Results

GUS-randomized pts pooled for analysis from 2 RCTs were predominantly male and had moderate-to-severe plaque PsO

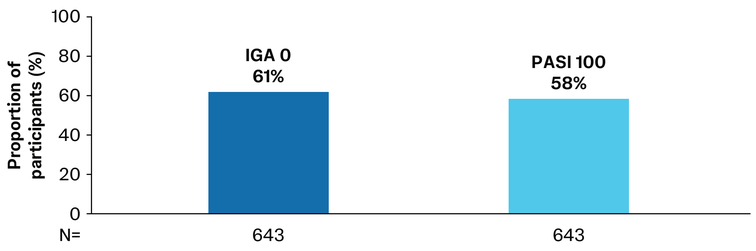
Baseline Characteristics		GUS Q8W (N=643)
Demographics		
	Age, years	44.2 (12.6)
	Male	71%
	Race, Asian/Black/White	16/2/80%
	BMI, kg/m^2	29.9 (6.3)
Disease Characteristics		
	PsO disease duration, years	18.0 (12.2)
	% of BSA with PsO	28.2 (17.0)
	IGA score (0–4)	3.2 (0.4)
	Moderate (3)	77%
	Severe (4)	23%
	PASI (0–72)	21.9 (9.2)
	DLQI (0–30)	14.3 (7.3)[a]
Prior treatment for PsO		
	Biologic agent	22%
	Conventional systemic agent	65%
	Topical agent	93%
	Phototherapy	59%

Data shown are mean (SD) unless otherwise noted. [a]N=635. ***BMI****=body mass index,* ***BSA****=body surface area,* ***DLQI****=Dermatology Life Quality Index,* ***GUS****=guselkumab,* ***IGA****=Investigator's Global Assessment,* ***PASI****=Psoriasis Area and Severity Index,* ***PsO****=psoriasis,* ***Q8W****=every 8 weeks,* ***SD****=standard deviation.*

Among GUS-randomized pts receiving continuous Q8W treatment, ~60% achieved on-treatment PsO remission

- In the real-world scenario analysis, 67% and 64% of GUS-randomized pts achieved on-treatment remission based on IGA 0 and PASI 100, respectively

Achievement of On-Treatment Remission[a]



Median[b] (95% CI) time to achievement of on-treatment remission[c]

IGA 0: 56.0 (40.0-64.0) weeks

PASI 100: 65.0 (56.3-88.3) weeks

[a]mNRI applied for missing data. [b]Time to event data were assessed using Kaplan-Meier survival analysis. [c]Includes the required 6 months of follow up after achievement of response per the on-treatment remission definition. ***CI****=confidence interval,* ***IGA****=Investigator's Global Assessment,* ***mNRI****=modified nonresponder imputation,* ***PASI****=Psoriasis Area and Severity Index.*

Among pts who achieved on-treatment remission, initial on-treatment remission status was maintained for a median of ~2 years; ~40% maintained on-treatment remission through 5 years

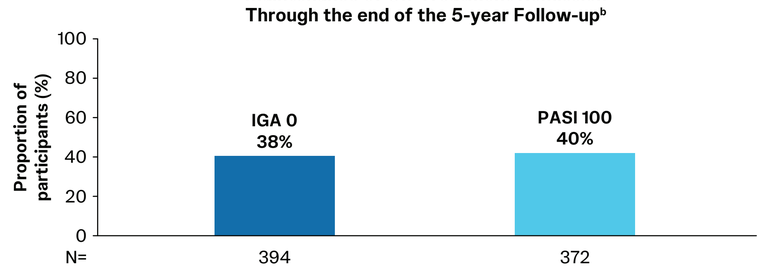
- In the real-world scenario analysis, the median duration of on-treatment remission status was ~1.5 years

Median[a] (95% CI) durability of initial on-treatment remission

IGA 0: 104.0 (88.0–128.0) weeks

PASI 100: 97.0 (81.7–121.1) weeks

Maintenance of On-Treatment Remission Through the end of the 5-year Follow-up[b]

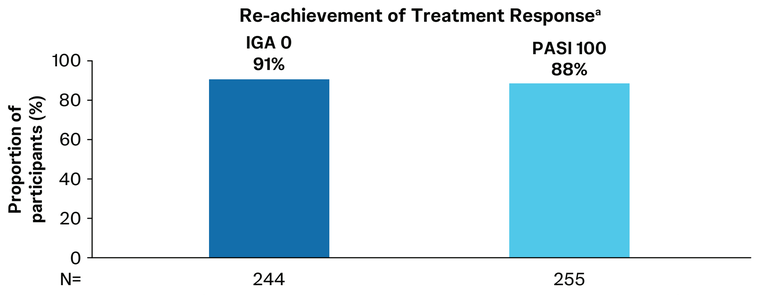


[a]Time to event data were assessed using Kaplan-Meier survival analysis. [b]mNRI applied for missing data. ***CI****=confidence interval,* ***IGA****=Investigator's Global Assessment,* ***mNRI****=modified nonresponder imputation,* ***PASI****=Psoriasis Area and Severity Index.*

Among pts who lost initial on-treatment remission status, ~90% regained IGA 0 or PASI 100 response, generally within ~1 dosing interval

- In the real-world scenario analysis, ~90% of pts who lost on-treatment remission status subsequently regained treatment response, with a median time to re-achievement of response of ~9 weeks

Re-achievement of Treatment Response[a]



Median[b] (95% CI) time to re-achievement of treatment response

IGA 0: 8.9 (8.1–9.1) weeks

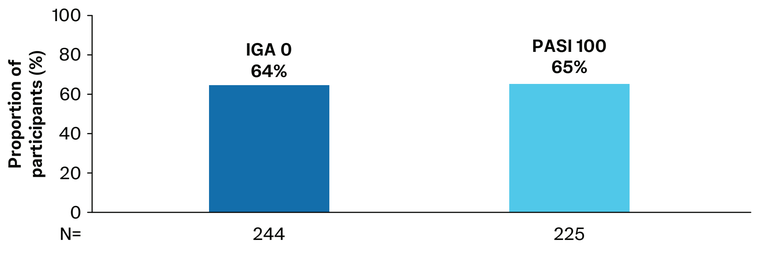
PASI 100: 9.0 (8.4–10.9) weeks

[a]mNRI applied for missing data. [b]Time to event data were assessed using Kaplan-Meier survival analysis. ***CI****=confidence interval,* ***IGA****=Investigator's Global Assessment,* ***mNRI****=modified nonresponder imputation,* ***PASI****=Psoriasis Area and Severity Index.*

Among pts who lost initial on-treatment remission status, ~65% regained on-treatment remission

- In the real-world scenario analysis, 75% and 73% of pts who lost on-treatment remission status subsequently regained on-treatment remission based on IGA 0 and PASI 100, respectively

Re-achievement of On-Treatment Remission[a]



Median[b] (95% CI) time to re-achievement of on-treatment remission

IGA 0: 39.3 (24.9–57.0) weeks

PASI 100: 32.0 (24.0–56.0) weeks

[a]mNRI applied for missing data. [b]Time to event data were assessed using Kaplan-Meier survival analysis. ***CI****=confidence interval,* ***IGA****=Investigator's Global Assessment,* ***mNRI****=modified nonresponder imputation,* ***PASI****=Psoriasis Area and Severity Index.*

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