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

Yayoi Tada,[1] Peter Foley,[2] April W. Armstrong,[3] Joseph F. Merola,[4] Jessie Chang,[5] Steven Fakharzadeh,[6] Emmanouil Rampakakis,[7,8] Yu-Huei Huang,[9] Luis Puig,[10] Richard G. Langley[11]

[1]Department of Dermatology, Teikyo University School of Medicine, Tokyo, Japan; [2]The University of Melbourne, St. Vincent's Hospital Melbourne and Probity Medical Research, Skin Health Institute, Carlton, VIC, Australia; [3]Department of Dermatology, University of California Los Angeles, Los Angeles, CA, USA; [4]Department of Dermatology, and Department of Medicine, Division of Rheumatology, UT Southwestern Medical Center and O'Donnell School of Public Health, Dallas, TX, USA; [5]Johnson & Johnson, Singapore, Singapore; [6]Johnson & Johnson, Horsham, PA, USA; [7]Department of Pediatrics, McGill University, Montreal, Quebec, Canada; [8]JSS Medical Research, Inc., Laval, Quebec, Canada; [9]Chang Gung Memorial Hospital and Chang Gung University, Taoyuan City, Taiwan; [10]Hospital de la Santa Creu i Sant Pau, Autonomous University of Barcelona, Barcelona, Spain; [11]Division of Dermatology, Department of Medicine, Dalhousie University, Halifax, Nova Scotia, Canada

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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 IL-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]

Objectives

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]	VOYAGE 2[b]
• ≥18 years of age • Plaque PsO for ≥6 months • IGA ≥3, PASI ≥12, BSA ≥10% • Candidate for systemic therapy or phototherapy	• ≥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. ***BSA***=body surface area; ***GUS***=guselkumab; ***IGA***=Investigator's Global Assessment; ***NPF***=National Psoriasis Foundation, ***PASI***=Psoriasis Area and Severity Index, ***pt***=participant, ***Q8W***=every 8 weeks, ***W***=week.

Results

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

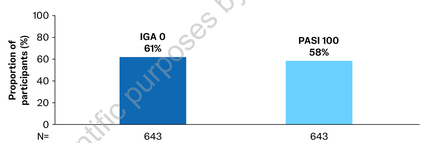
Baseline Characteristics		GUS Q8W (N=643)
Demographics		
	Age, yrs	44.2 (12.6)
	Male	71%
	Race, Asian/Black/White	16/2/80%
	BMI, kg/m²	29.9 (6.3)
Disease Characteristics		
	PsO disease duration, yrs	18.0 (12.2)
	% of BSA with PsO	28.2 (17.0)
	IGA score (0–4)	3.2 (0.4)
	Moderate (3)	77%
	Severe (4)	23%
	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.*

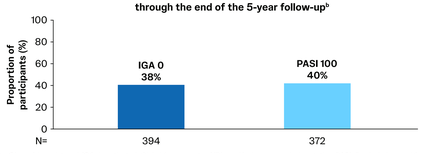
Among pts who achieved on-treatment remission, initial on-treatment remission status was maintained for a median of ~2 years; ~40% maintained on-treatment remission through 5 years

- 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]

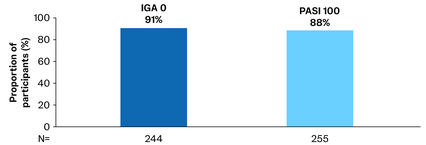


[a]*Time to event data were assessed using Kaplan-Meier survival analysis.*[b]*mNRI applied for missing data.* ***CI***=*confidence interval,* ***IGA***=*Investigator's Global Assessment,* ***mNRI***=*modified nonresponder imputation,* ***PASI***=*Psoriasis Area and Severity Index.*

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

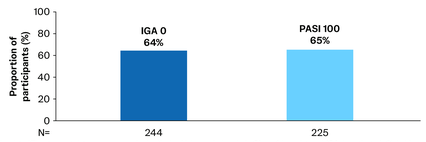
IGA 0	8.9 (8.1–9.1) weeks
PASI 100	9.0 (8.4–10.9) weeks

[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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