

# 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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# 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.<sup>1</sup>



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  $\geq 6$  months while on treatment<sup>2</sup>



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<sup>3</sup>



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<sup>4</sup>

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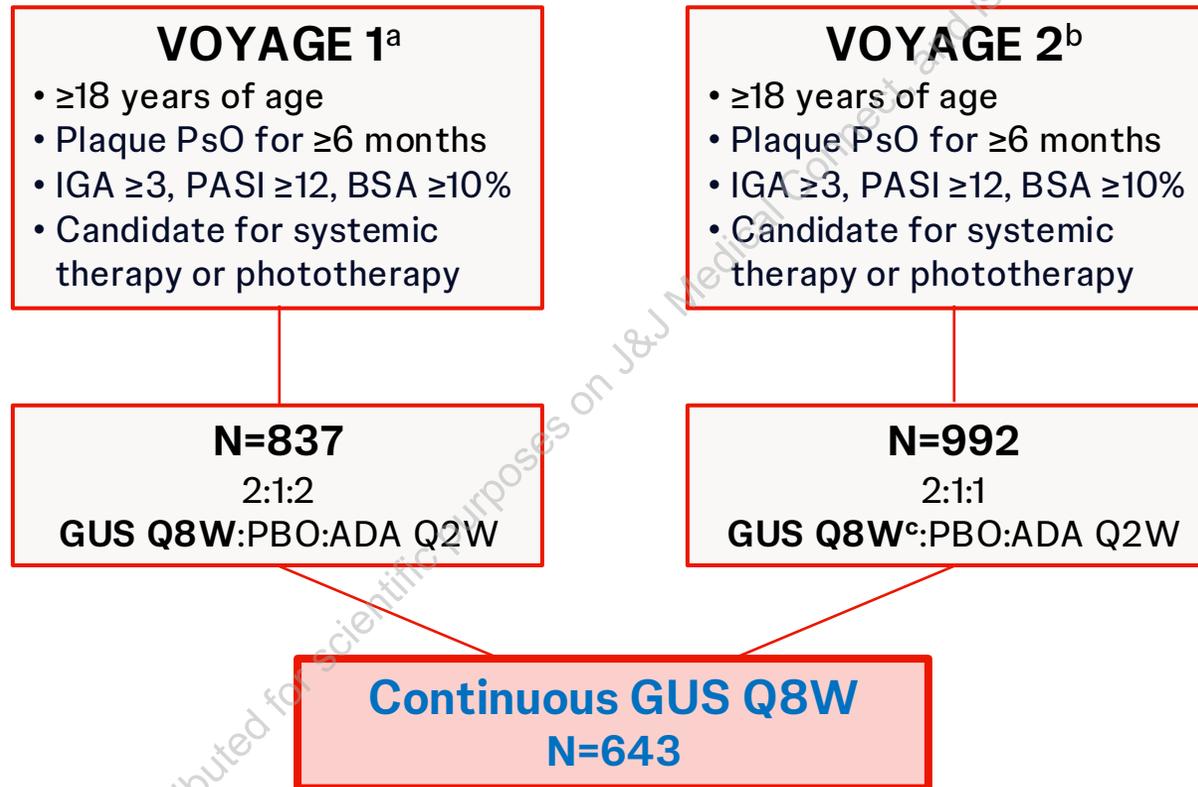
# Objective



**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**

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



<sup>a</sup>NCT02207231. <sup>b</sup>NCT02207244. <sup>c</sup>PASI 90 responders at W28 were rerandomized 1:1 to GUS 100 mg Q8W or PBO (withdrawn).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, PASI=Psoriasis Area and Severity Index, PBO=placebo, RCT=randomized controlled trial, Q2W=every 2 weeks, Q8W=every 8 weeks, W=week.

# Assessments & Post hoc Analyses

## Rates and pt-level time to event through W252

Achievement of **on-treatment remission**



Loss of initial **on-treatment remission**<sup>a</sup>



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 definition<sup>4</sup>

### 1. Primary NPF definition analysis

Complete skin clearance response for  $\geq 6$  months (i.e., at  $\geq 4$  consecutive Q8W GUS dosing visits) based on:

- IGA 0 (IGA score of 0)
- PASI 100 (100% improvement from baseline in PASI score)<sup>b</sup>

### 2. Real-world scenario analysis<sup>c</sup>

Response at 1<sup>st</sup> 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
  - Participants were right 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  $\geq 2$  consecutive missing Q8W dosing visits

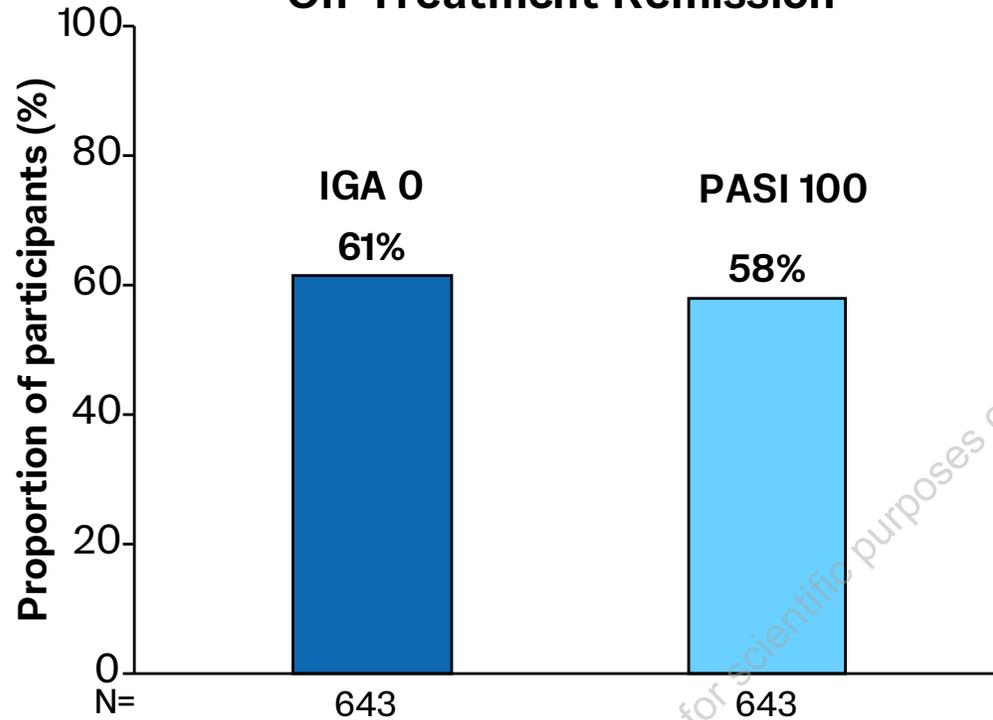
<sup>a</sup>First Q8W visit after on-treatment remission that no longer met the response criteria. <sup>b</sup>BSA was not collected post-baseline in these studies, PASI was evaluated as a surrogate measure for skin clearance. <sup>c</sup>Based on typical timing of clinic follow-up visits. Q=every.

# 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)
<b>Demographics</b>		
	Age, yrs	44.2 (12.6)
	Male	71%
	Race, Asian/Black/White	16%/2%/80%
	BMI, kg/m <sup>2</sup>	29.9 (6.3)
<b>Disease Characteristics</b>		
	PsO disease duration, yrs	18.0 (12.2)
	% of BSA with PsO	28.2 (17.0)
	IGA score	3.2 (0.4)
	Moderate (3)	77%
	Severe (4)	23%
	PASI (0-72)	21.9 (9.2)
DLQI (0-30)	14.3 (7.3) <sup>a</sup>	
<b>Prior PsO treatments</b>		
	Biologic agent	22%
	Conventional systemic agent	65%
	Topical agent	93%
	Phototherapy	59%

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

## Achievement of On-Treatment Remission<sup>a</sup>



## Median<sup>b</sup> (95% CI) time to achievement of on-treatment remission<sup>c</sup>

**IGA 0**  
56.0 (40.0-64.0) weeks

**PASI 100**  
65.0 (56.3-88.3) weeks

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

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 status through 5 years

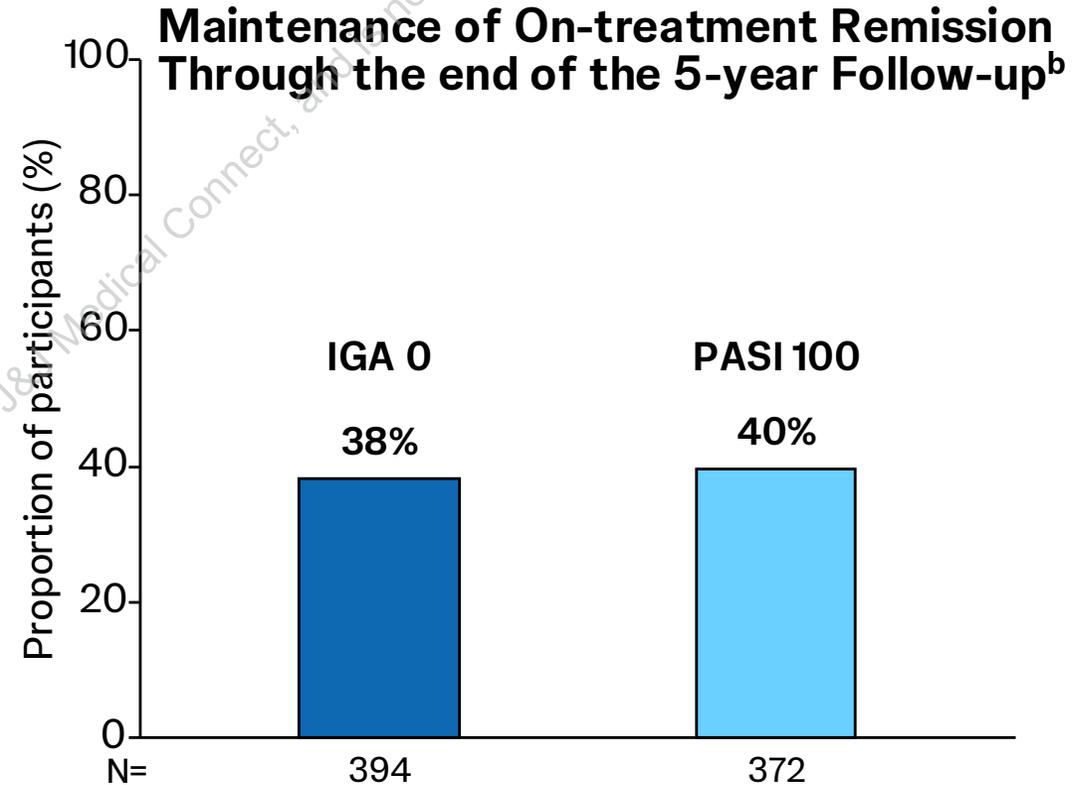
**Median<sup>a</sup> (95% CI) durability of initial on-treatment remission**

**IGA 0**

**104.0 (88.0–128.0) weeks**

**PASI 100**

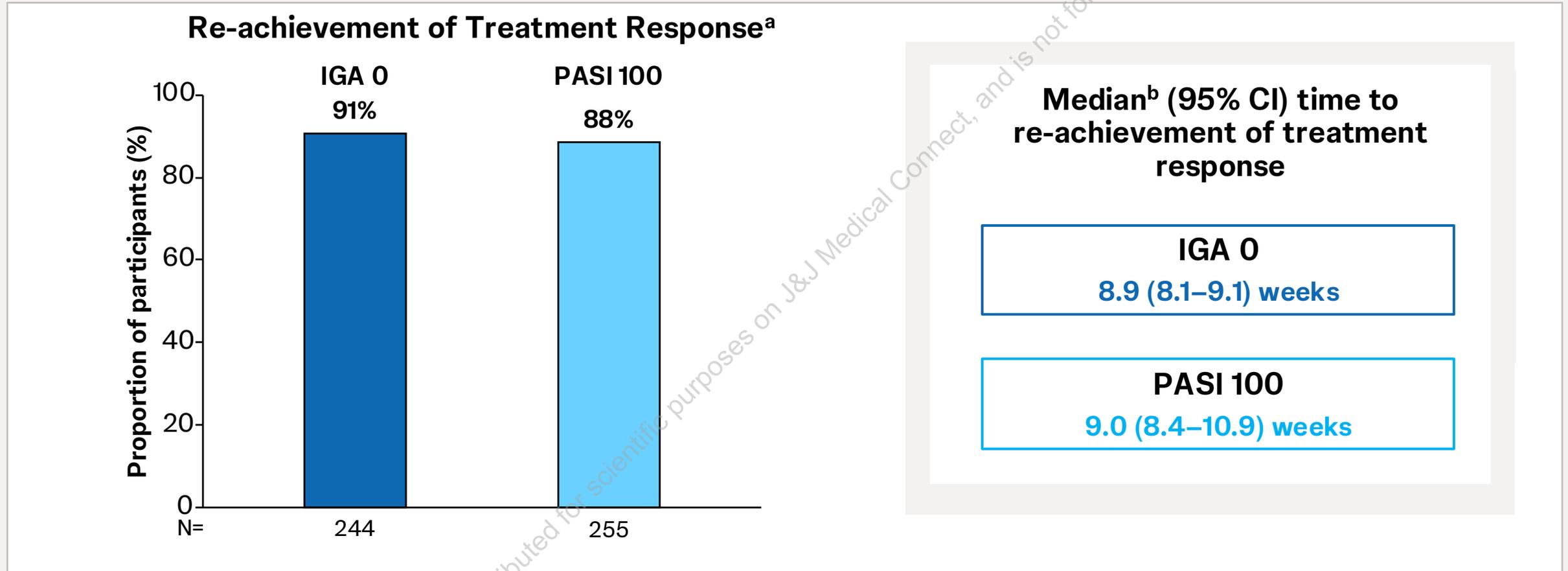
**97.0 (81.7–121.1) weeks**



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

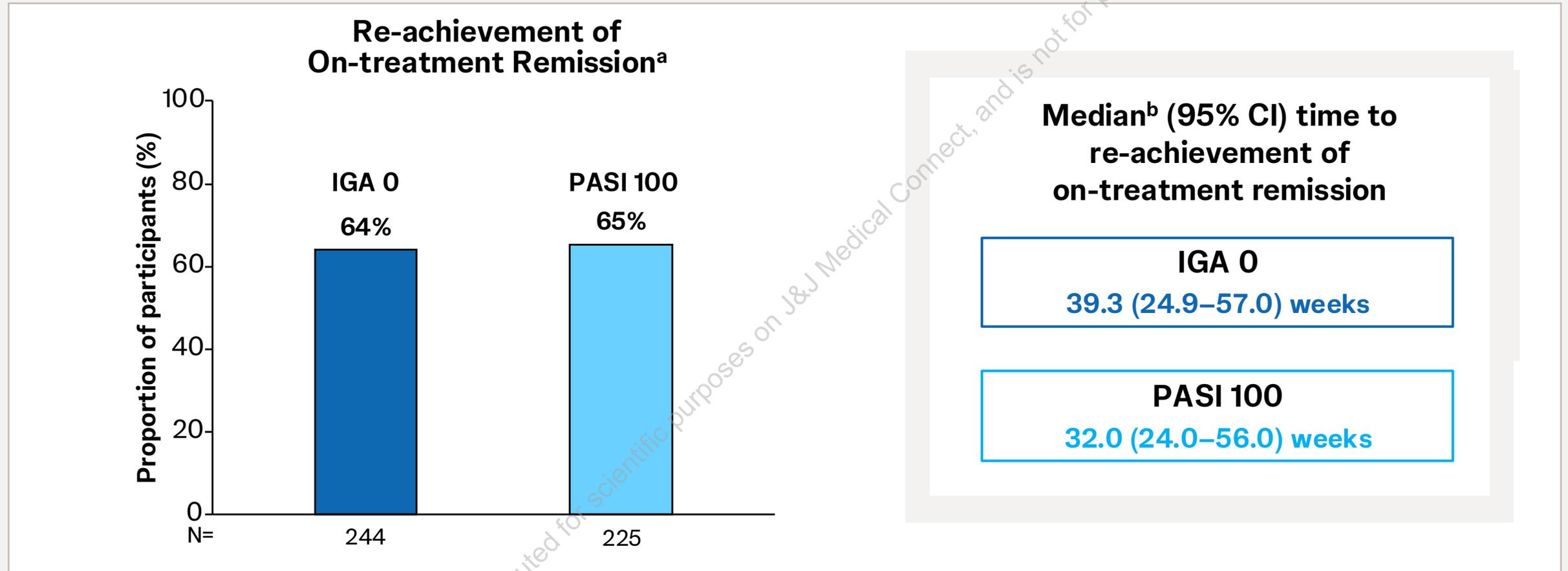
<sup>a</sup>Time to event data were assessed using Kaplan-Meier survival analysis. <sup>b</sup>mNRI applied for missing data.

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, ~90% of pts who lose on-treatment remissions status subsequently regained treatment response, with a median time to re-achievement of response of ~9 weeks

# 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

# 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**

# References

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