Real-world effectiveness of guselkumab in patients with psoriasis: Data from the Psoriasis Longitudinal Assessment and Registry (PSOLAR)

Luigi Naldi[1], Ahlem Azzabi[2], Steven Fakharzadeh[3], Wayne Gulliver[4*], Fowzia Ibrahim[5], Yerkebulan Kambarov[6], Kimberly Parnell Lafferty[3], Wayne Langholff[3], Yayoi Tada[7], Miriam Zimmermann[8], Bruce Strober[9,10]

[1]Dermatology Unit, San Bortolo Hospital, Vicenza; Centre of the Italian Group for Epidemiological Research in Dermatology (GISED), Bergamo, Italy; [2]Johnson & Johnson, Casablanca, Morocco; [3]Johnson & Johnson, Horsham, PA, USA; [4]Faculty of Medicine, Memorial University of Newfoundland, St. John's, NL, Canada; [5]Johnson & Johnson, High Wycombe, UK; [6]Johnson & Johnson, Beerse, Belgium; [7]Department of Dermatology, Teikyo University School of Medicine, Tokyo, Japan; [8]Johnson & Johnson, Zug, Switzerland; [9]Yale University, New Haven, CT, USA; [10]Central Connecticut Dermatology Research, Cromwell, CT, USA.

*Deceased. Dr. Gulliver contributed substantially to the conception of the study and the accepted abstract. He passed away during preparation of this poster.

Background

Psoriasis Longitudinal Assessment and Registry (PSOLAR; NCT00508547) is a large, international, prospective, disease-based registry including patients with psoriasis (PsO) who were receiving, or were candidates for, systemic therapy[1,2]

Multiple types of systemic therapy across drug classes are approved for PsO; PSOLAR aims to assess long-term safety and effectiveness and improve understanding of real-world biologic therapy use in patients with PsO[1,2]

PSOLAR was initiated in 2007 and was expanded in 2018 to include patients receiving the biologic guselkumab (GUS), a p19 subunit-targeted interleukin (IL)-23 inhibitor, or an IL-17 inhibitor (IL-17i)[1–6]

GUS is highly effective with a favorable safety profile, and is approved for adults with moderate-to-severe plaque PsO, for adults with active psoriatic arthritis in combination with methotrexate, and for adults with moderately to severely active ulcerative colitis or Crohn's disease[1–6]

Objective

This analysis of PSOLAR data explores the real-world effectiveness of GUS treatment in prevalent users with PsO

Methods

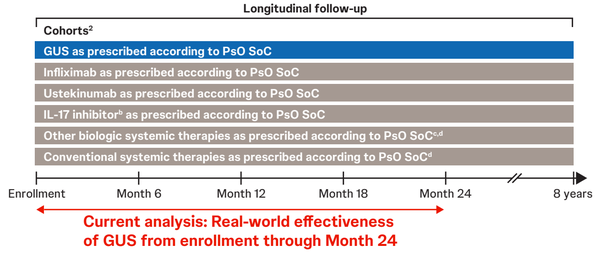
- Systemic therapies were prescribed by physicians according to standard clinical practice; this analysis focuses on participants who were treated with GUS[1,2]
- The **total population** of participants treated with GUS was divided into two subgroups
  - **Bio-naïve:** Had not received any prior biologic therapy
  - **Bio-experienced:** Had received prior biologic therapy
- Data were collected upon enrollment into the PSOLAR registry and approximately every 6 months thereafter; data reported here are through 2 years of follow-up (up to Month 24)

Key inclusion criteria[2]
- PsO diagnosis
- Incident or prevalent users[a] of GUS or an IL-17 inhibitor[b] at time of enrollment
- Ability to provide informed consent
- Willing to participate in regular follow-up visits
- No participation in clinical trials for investigational treatment

Endpoints[2]

Primary endpoint
- Safety

Key secondary endpoints
- Efficacy (PASI, BSA, PGA)
- QoL (DLQI, EuroQOL)
- Anxiety/depression (HADS)



[a]Incident users defined as participants starting treatment ≤30 days before or after enrollment visit; prevalent users defined as participants starting treatment >30 days prior to enrollment visit. [b]E.g. secukinumab, ixekizumab, brodalumab, bimekizumab. [c]Biologic therapies other than GUS, infliximab, ustekinumab, or IL-17 inhibitors. [d]Participants will not receive any intervention as a part of this study. ***BSA***=body surface area, ***DLQI***=Dermatology Life Quality Index, ***GUS***=guselkumab, ***HADS***=Hospital Anxiety and Depression Scale, ***IL***=interleukin, ***PASI***=Psoriasis Area and Severity Index, ***PGA***=Physician's Global Assessment, ***PsO***=psoriasis, ***QoL***=quality of life, ***SoC***=standard of care.

Key Takeaways

- **In the large real-world PSOLAR registry, all subgroups treated with GUS demonstrated substantial improvements in both PASI and BSA measures**
- **Improvements were observed at the first visit (Month 6) and maintained through 2 years of treatment, providing real-world evidence supporting the use of GUS as a highly effective long-term option for patients with PsO**
- **Bio-naïve patients experienced the greatest improvements, with 63% achieving and maintaining complete skin clearance (PASI=0) at 2 years, highlighting the benefit of effective intervention with GUS in this subgroup**

Results

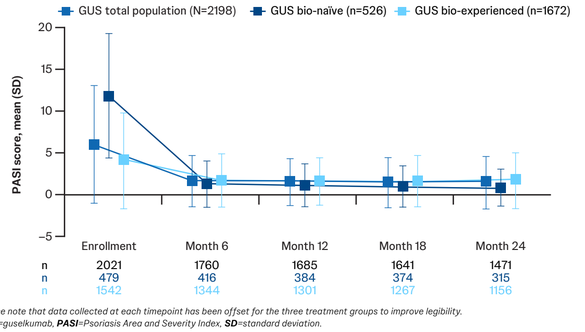
PSOLAR is a large registry including 2198 participants treated with GUS for PsO in real-world practice across global regions with long-term follow-up

- Mean follow-up for the total population receiving GUS at data cut-off (July 12, 2024) was 3.02 years (standard deviation [SD] 1.082)
- Most participants (88.9%) remained on GUS treatment at data cut-off

Baseline Characteristics	GUS total population (N=2198)[a]
Demographics	
Region, n (%)[b]	
North America	1184 (53.9%)
Europe	672 (30.6%)
Asia Pacific	342 (15.6%)
Subgroup, n (%)	
Bio-naïve	526 (23.9%)
Bio-experienced	1672 (76.1%)
Withdrawals	
Patients withdrawn, n (%)	244 (11.1%)
Reason for withdrawal, n (%)	**n=244**
Patient choice	96 (39.3%)
Inclusion/exclusion criteria not met	6 (2.5%)
Death	24 (9.8%)
Lost to follow-up	48 (19.7%)
Presumed lost to follow-up	32 (13.1%)
Site closed	12 (4.9%)
Other	26 (10.7%)
PsO Involvement	
PsO type, n (%)	
Plaque	2140 (97.4%)
Other	211 (9.6%)
BSA by palm method, %	**n=2114**
Mean (SD)	8.9% (12.72)
Median (IQR)	4.0% (0.5, 12.0)
BSA distribution, n (%)	**n=2114**
BSA <3%	920 (43.5%)
BSA 3–10%	612 (28.9%)
BSA >10%	582 (27.5%)
PASI score	**n=2021**
Mean (SD)	6.0 (7.02)
Median (IQR)	3.2 (0.5, 9.9)
PASI score distribution, n (%)	**n=2021**
PASI=0	427 (21.1%)
PASI<1	615 (30.4%)
PASI<3	974 (48.2%)
PASI<5	1205 (59.5%)

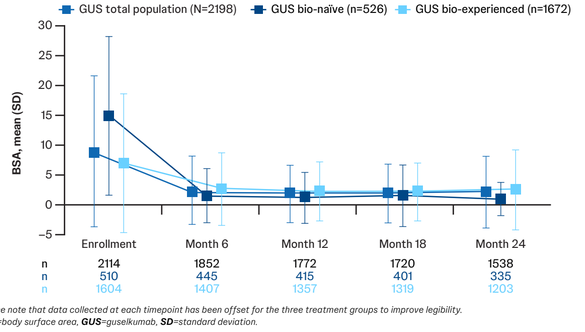
[a]Some patients received GUS ahead of registry enrollment. [b]Patients were enrolled from North America: Canada, USA; Europe: Austria, Belgium, Czech Republic, Greece, Israel, Italy, The Netherlands, Portugal, Slovakia, Spain, Sweden; Asia Pacific: Australia, Japan, South Korea, Taiwan. ***BSA***=body surface area, ***GUS***=guselkumab, ***IQR***=interquartile range, ***PASI***=Psoriasis Area and Severity Index, ***PsO***=psoriasis, ***SD***=standard deviation.

Improvements in mean Psoriasis Area and Severity Index (PASI) scores were observed at the first visit (Month 6) and remained low through 2 years across the total population and both subgroups



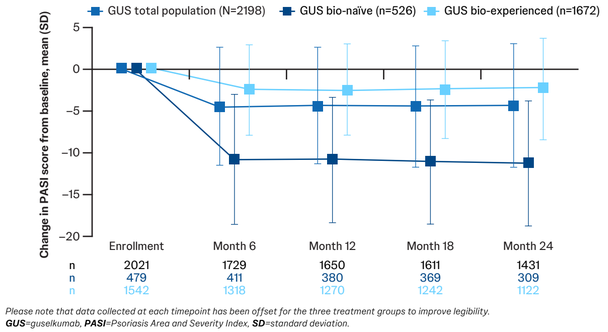
Please note that data collected at each timepoint has been offset for the three treatment groups to improve legibility.
GUS=guselkumab, ***PASI***=Psoriasis Area and Severity Index, ***SD***=standard deviation.

Reductions in mean BSA were observed at the first visit (Month 6) and maintained through 2 years across the total population and both subgroups



Please note that data collected at each timepoint has been offset for the three treatment groups to improve legibility.
BSA=body surface area, ***GUS***=guselkumab, ***SD***=standard deviation.

Long-term improvements in mean PASI score from baseline were maintained through 2 years for GUS-treated patients, with greater improvements in bio-naïve patients



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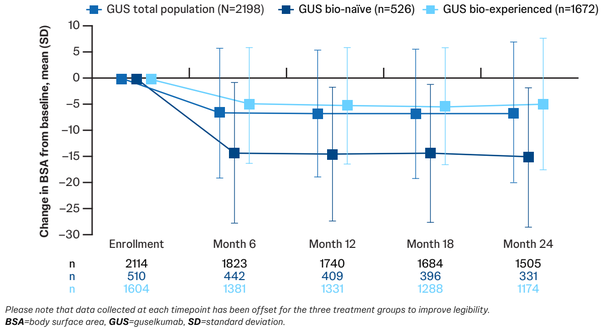
GUS=guselkumab, ***PASI***=Psoriasis Area and Severity Index, ***SD***=standard deviation.

Long-term reductions in mean BSA from baseline were maintained through 2 years in GUS-treated patients, with greater reductions in bio-naïve patients



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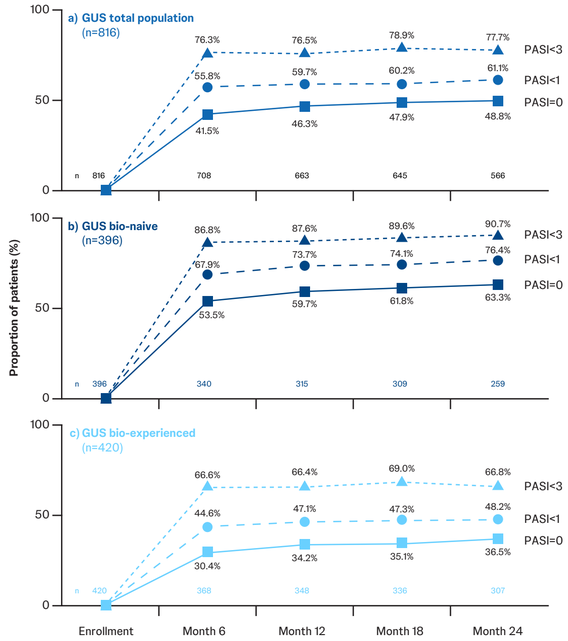
Of GUS-treated patients with PASI≥5 at baseline, 61% achieved and maintained PASI<1 through 2 years; 63% of bio-naïve patients achieved PASI=0 (at 2 years)

Proportions of patients with PASI=0, <1, or <3 among patients with PASI≥5 at enrollment



GUS=guselkumab, ***PASI***=Psoriasis Area and Severity Index.

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