Persistence, Effectiveness, Safety, and Patient Reported Impact of Guselkumab and IL-17 Inhibitors in Psoriatic Arthritis: Full Population Results of the PsABIOnd Global Observational Study Over 12 Months

Laure Gossec,[1] Mohamed Sharaf,[2] Frank Behrens,[3] Ennio Lubrano,[4] Mitsumasa Kishimoto,[5] Xenofon Baraliakos,[6] Ruben Queiro Silva,[7] Emmanouil Rampakakis,[8,9] László Köleséri,[10] Karissa Lozenski,[11] Enrique R. Soriano,[12] Proton Rahman,[13] Stefan Siebert[14]

[1]Sorbonne Université, Pitie-Salpetriere Hospital, Paris, France; [2]Johnson & Johnson, Dubai, United Arab Emirates; [3]Rheumatology and Fraunhofer IME - Translational Medicine and Pharmacology, Goethe University, Frankfurt, Germany; [4]Vincenzo Tiberio Department of Medicine and Health Sciences, University of Molise, Campobasso, Italy; [5]Department of Nephrology and Rheumatology, Kyorin University School of Medicine, Tokyo, Japan; [6]Ruhr-University Bochum, Rheumazentrum Ruhrgebiet, Herne, Germany; [7]Rheumatology Division & ISPA Translational Immunology Division, Hospital Universitario Central de Asturias, Oviedo University, Oviedo, Spain; [8]Department of Pediatrics, McGill University, Montreal, QC, Canada; [9]JSS Medical Research, Inc, Montreal, QC, Canada; [10]Data Sciences Staffing Solutions, IQVIA, Inc, Budapest, Hungary; [11]Johnson & Johnson, Horsham, PA, USA; [12]Rheumatology Section, Internal Medicine Service, Hospital Italiano de Buenos Aires and University Institute Hospital Italiano de Buenos Aire, Buenos Aires, Argentina; [13]Faculty of Medicine, Division of Rheumatology, Memorial University of Newfoundland, St. Johns, Canada; [14]School of Infection & Immunity, University of Glasgow, Glasgow, UK.

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Key Takeaways

- **At 12M, in the full PsABIOnd population of pts with PsA, GUS and IL-17i showed:**
  - ✓ **High treatment persistence**
  - ✓ **Similar effectiveness across key PsA domains**
  - ✓ **Comparable improvements in PROs**
  - ✓ **Generally similar safety profiles**
- **Both mechanisms of action appear to be effective for long-term PsA management in routine clinical practice, supporting findings from RCTs**

Background

Psoriatic arthritis (PsA) is chronic inflammatory disease affecting both joints and skin, with substantial impact on health-related quality of life[1,2]

Interleukin (IL)-23 inhibitors (i) and IL-17i have shown efficacy across clinical and patient-reported outcomes (PROs) in randomized controlled trials (RCTs), but evidence from real-world practice remains limited

PsABIOnd (NCT05049798)

- Global, ongoing observational study evaluating the treatment persistence, effectiveness and long-term safety of guselkumab (GUS) and IL-17i in routine participants (pts) with PsA[3]
- Previous 6-month (M) analysis showed similar persistence and effectiveness across various PsA domains with GUS and IL-17i[4]

Objective

Evaluate 12M treatment persistence, effectiveness, PROs, and safety in pts initiating GUS or IL-17i from the real-world PsABIOnd study

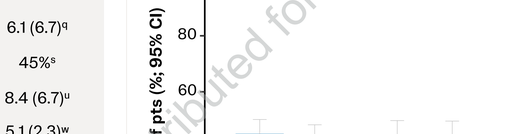
Methods

PsABIOnd Study Design

Participant Selection
- Adults diagnosed with PsA
- Initiating GUS or an IL-17i as a 1st-to-4th line of biologic therapy[a] per standard of care
- Enrollment completed in May 2024 with 1314 pts from 19 countries

Study Objectives
- Primary: 36M treatment persistence
- Secondary: 36M effectiveness via physician-completed assessments and ePROs, safety, predictors of response and persistence, patterns of treatment lines, etc

Current Analysis
- As of 08 August 2025, 1141 out of 1314 pts had analyzable 12M visit data



Assessments and Analyses

Persistence on treatment with GUS and IL-17i over 12M
- Kaplan-Meier analysis of treatment persistence (i.e., no stop or switch)[b]
- Propensity score (PS) analysis: HR of stopping/switching GUS vs IL-17i prior to the 12M visit, adjusting for baseline variable imbalances across cohorts

Safety with GUS and IL-17i through 12M

Outcome	Analyses
Adverse event	• No. (%) of pts experiencing ≥1 adverse event • Exposure-adjusted rate of events (events/100 PY)

PsA clinical outcomes and PROs with GUS and IL-17i at the 12M visit

Outcome	Analyses
cDAPSA LDA/REM	Achievement of cDAPSA score ≤13[c]
DAPSA LDA/REM	Achievement of DAPSA score ≤14[c]
MDA	Achievement of 5 out of 7 criteria[d,e]
Mild psoriasis BSA	Achievement of BSA <3%[f]
LEI	Mean change from baseline to 12M
No. of digits affected by dactylitis	
No. of nails affected by PsO	
PsAID-12 MCII	PsAID-12 decrease ≥1.4[5]
PsAID-12 item scores	Mean at baseline and 12M
DLQI 0/1	Achievement of DLQI 0 or 1[f]

- Descriptive unadjusted data were analyzed
- LOCF was used for imputation of missing data in pts with no 12M visit
- Pts were analyzed by initial treatment line[g]
- Treatment comparison was based on 95% CI

*[a]Monotherapy or in combination with other agents. [b]Defined as the time from the date of the first treatment administration to the date of the last treatment dose of the initial treatment line administration plus 1 dosing interval or until start of subsequent treatment. [c]Among pts with baseline score >cutoff. [d]Criteria include tender joint count ≤1, swollen joint count ≤1, BSA <3%, patient pain ≤15mm, PtGA ≤20mm, HAQ-DI ≤0.5, and total pain/tenderness enthesitis score ≤1 (or no enthesitis). [e]Among non-MDA achievers at baseline. [f]Among pts with BSA ≥3. [g]Only pts receiving ≥1 dose of the index drug were included. **BSA**=body surface area, **cDAPSA**=Clinical Disease Activity Index for PsA, **CI**=confidence interval, **DLQI**=Dermatology Life Quality Index, **ePRO**=electronic patient-reported outcome, **HAQ-DI**=health assessment questionnaire-disability index, **HR**=hazard ratio, **HRQoL**=health-related quality of life, **LDA**=low disease activity, **LEI**=Leeds Enthesitis Index, **LOCF**=last observation carried forward, **MCII**=minimal clinically important improvement, **MDA**=minimal disease activity, **PsAID-12**=PsA impact of disease-12, **PsO**=psoriasis, **PtGA**=patient global disease activity, **PY**=pt year, **REM**=remission.*

Results

Baseline characteristics were generally well-balanced between treatment cohorts

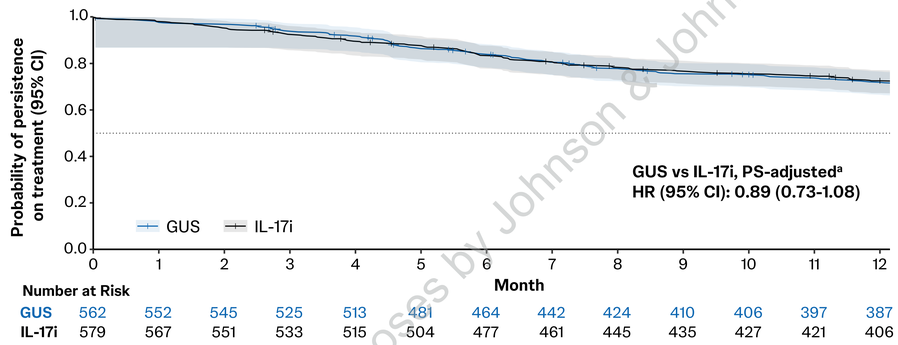
- A higher proportion of GUS pts were initiating their 4th treatment line

Baseline characteristics of PsABIOnd study pts	GUS (N=562)	IL-17i (N=579)
Demographics		
Age, years	53.1 (12.8)	53.4 (12.0)
Male	40%	41%
BMI, kg/m^2	30.0 (6.5)[a]	29.4 (6.3)[b]
Disease Characteristics		
PsA disease duration, years	8.0 (7.9)[c]	7.4 (9.0)[d]
cDAPSA (0-154)	24.6 (14.6)[e]	27.6 (17.3)[f]
DAPSA	25.8 (15.3)[g]	28.4 (16.8)[h]
Enthesitis	47%[i]	50%[j]
LEI (1-6)	2.4 (1.4)[k]	2.6 (1.5)[l]
Dactylitis	16%[i]	19%[j]
No. affected digits (0-20)	2.5 (2.2)[m]	2.4 (2.4)[n]
Psoriatic BSA		
3-10%	36%[o]	31%[p]
>10%	12%[o]	9%[p]
DLQI (0-30)	7.3 (7.2)[b]	6.1 (6.7)[q]
Any PsO nail lesions	46%[r]	45%[s]
No. of affected nails (0-20)	8.6 (6.3)[t]	8.4 (6.7)[u]
PsAID-12 total score (0-10)	5.1 (2.2)[v]	5.1 (2.3)[w]
Initial bDMARD treatment line		
1st	36%	37%
2nd	27%	36%
3rd	22%	19%
4th	15%	8%

*Data is presented as mean (SD) unless otherwise noted. [a]N=528. [b]N=523. [c]N=555. [d]N=578. [e]N=484. [f]N=489. [g]N=417. [h]N=996. [i]N=534. [j]N=537. [k]N=249. [l]N=271. [m]N=88. [n]N=101. [o]N=504. [p]N=510. [q]N=524. [r]N=502. [s]N=507. [t]N=229. [u]N=227. [v]N=514. [w]N=522. **BMI**=body mass index, **bDMARD**=biological disease-modifying antirheumatic drug, **SD**=standard deviation.*

Treatment persistence was high with both GUS and IL-17i at 12M

- At 12M, 76% of GUS and 77% of IL-17i pts remained on initial treatment line; lower than at 6M (95%/93%)
- Discontinuation reasons were similar (GUS/IL-17i: primary failure: 11.7%/9.8%; adverse events: 7.3%/9.2%)



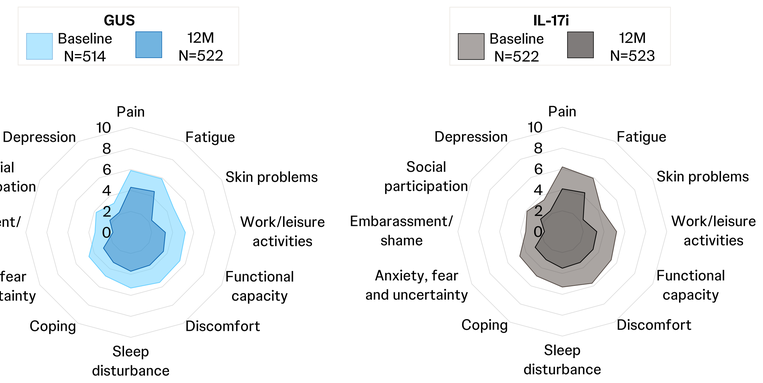
Number at risk shows pts remaining under observation and switch/stop event-free at each time point; patients were right censored at their last observation or at study termination and were removed from these counts after their censoring time. [a]Adjusted for potential confounders at baseline including initial bDMARD treatment line, among others.

Treatment effectiveness was similar with GUS and IL-17i across PsA outcomes and PROs at 12M

- GUS/IL-17i: LEI (-1.3/-1.5); number of digits affected by dactylitis (-1.9/-2.1); number nails affected by PsO (-5.4/-4.9)

Last observation carried forward was imputed for pts with no 12M visit. [a]Achievement of DLQI 0/1 among pts with % BSA >3 at baseline.

PsAID-12 item scores were comparable between treatment cohorts at 12M



Last observation carried forward was imputed for pts with no 12M visit.

Exposure-adjusted adverse event rates were generally comparable with GUS and IL-17i through 12M

- Rates of gastrointestinal adverse events were lower with GUS
- No cases of active tuberculosis occurred in either cohort

Overall summary of adverse events through 12M	GUS (N=604)	IL-17i (N=641)
≥1 Adverse event	322 (53%)	368 (57%)
Event/100 PY (95% CI)	116.6 (108.1, 125.5)	156.0 (146.6, 165.9)
Common adverse events (>5%)		
COVID-19	45 (7%)	36 (6%)
Nasopharyngitis	32 (5%)	35 (5%)
≥1 Serious adverse event	41 (7%)	44 (7%)
Event/100 PY (95% CI)	9.4 (7.1, 12.2)	8.4 (6.3, 10.9)
Adverse event leading to study discontinuation	21 (3%)	21 (3%)
Event/100 PY (95% CI)	4.0 (2.5, 5.9)	4.4 (3.0, 6.3)
Gastrointestinal-related adverse event[a]	41 (7%)	72 (11%)
Event/100 PY (95% CI)	7.8 (5.7, 10.3)	15.5 (12.7, 18.8)
Malignancy	4 (0.7%)	3 (0.5%)
Event/100 PY (95% CI)	0.7 (0.2, 1.7)	0.5 (0.1, 1.3)
Death	0 (0%)	2 (0.3%)
Event/100 PY (95% CI)	0.0 (0.0, 0.0)	0.5 (0.1, 1.3)

Data is presented as n (%) unless otherwise noted. Rates of special interest adverse events in GUS/IL-17i pts: Candida infection/candidiasis (<1%/2%), fungal infection (including candidiasis) (1%/4%), other fungal infection (unspecified) (<1%/2%), uveitis (<1%/<1%). [a]Includes all events with System Organ Class of 'Gastrointestinal Disorders'.

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