Joint Disease Activity Trajectories in Participants with Active Psoriatic Arthritis Treated with Guselkumab: A Bayesian Analysis of Three Phase 3, Randomized, Controlled Studies

Iain B McInnes,[1] Mohamed Sharaf,[2] Xenofon Baraliakos,[3] Julio Ramírez,[4] Emmanouil Rampakakis,[5,6] Karissa Lozenski,[7] Carlo Selmi,[8,9] Laura C. Coates[10]

[1]College of Medical Veterinary and Life Sciences, University of Glasgow, Glasgow, UK; [2]Johnson & Johnson, Dubai, United Arab Emirates; [3]Ruhr-University Bochum, Rheumazentrum Ruhrgebiet, Herne, Germany; [4]Arthritis Unit, Rheumatology Department, Hospital Clinic, Barcelona, Spain; [5]Department of Pediatrics, McGill University, Montreal, Canada; [6]Scientific Affairs, JSS Medical Research, Inc, Montreal, Canada; [7]Johnson & Johnson, Horsham, PA, USA; [8]Department of Biomedical Sciences, Humanitas University, Milan, Italy; [9]Rheumatology and Clinical Immunology, IRCCS Humanitas Research Hospital, Rozzano, Milan, Italy; [10]Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences, University of Oxford, Botnar Research Centre, Oxford, UK.

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Key Takeaways

- **Distinct 1-year joint disease activity patterns were identified in a large, pooled cohort of GUS-treated participants with active PsA**
  - ✓ **Most participants (89%) showed early to continuous trajectories of response**
  - ✓ **cDAPSA improvement was observed as early as Week 4 across all trajectory groups**
  - ✓ **Early Sustained Joint Responders, characterized by shorter disease duration, achieved the highest cDAPSA LDA/REM rates and greatest PRO improvements**
  - ✓ **Despite marked SJC/TJC reductions, Continuous Joint Improvers showed more limited improvements in PROs, suggesting a contribution of non-inflammatory pain mechanisms**
- **Findings may inform expectation setting, response monitoring, and timely consideration of adjunct pain therapies**

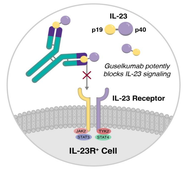
Background

Psoriatic arthritis (PsA) is chronic inflammatory disease affecting multiple domains, including peripheral and axial joints, enthesitis, dactylitis and psoriasis of the skin and nails[1]

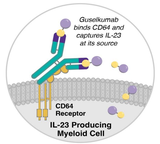
Guselkumab (GUS)

- Fully human, dual-acting monoclonal antibody that selectively inhibits interleukin (IL)-23 by targeting its p19 subunit and binding CD64 on IL-23-producing inflammatory monocytes[2]
- Approved for active PsA[3]
- Demonstrated efficacy across multiple PsA domains[4,5,6]

While randomized clinical trials (RCTs)-derived group-level data assess comparative efficacy, individual response trajectories have important implications for patient-centric, domain-specific PsA treatment



Dual-acting IL-23 Inhibitor



Objective

Identify participant-level joint response trajectory patterns from a pooled population of participants with active PsA treated with GUS over 1 year in RCTs

Methods

Analysis Cohort for Identification of cDAPSA Trajectory Groups

- Groups were identified using a **data-driven** GMM with Bayesian imputations

DISCOVER-1[a]	DISCOVER-2[b]	COSMOS[c]
SJC ≥3, TJC ≥3 CRP ≥0.3 mg/dL Bio-naïve or TNFi-experienced (31%)	SJC ≥5, TJC ≥5 CRP ≥0.6 mg/dL Bio-naïve	SJC ≥3, TJC ≥3 TNFi-IR
N=127 1:1:1 PBO:GUS Q4W:**GUS Q8W**	**N=248** 1:1:1 PBO:GUS Q4W:**GUS Q8W**	**N=189** 1:2 PBO:**GUS Q8W**

Pooled Cohort:
GUS Q8W[d]
N=564

cDAPSA
- Validated and simplified composite tool to assess PsA disease activity in clinical practice[7]
- Components: SJC66, TJC68, patient global assessment of arthritis (PtGA-Arthritis), and patient-reported pain (Pt Pain)

Assessments and Analyses

1. Differences Between Trajectory Groups in Baseline Characteristics
- One-way analysis of variance (ANOVA) for continuous variables
- Chi-square test for categorial variables

2. cDAPSA LDA/REM Response over 1 Year Within Each Trajectory Group
- Rates of response of cDAPSA≤13

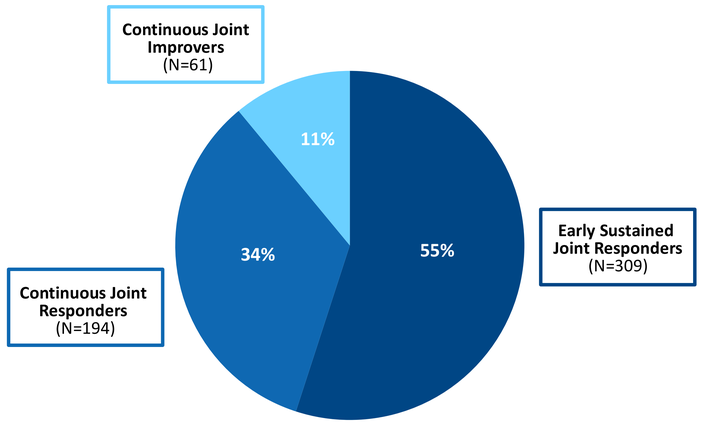
3. cDAPSA and its Components through 1 Year Within Each Trajectory Group
- Mixed models for repeated measures for:
  - Change from baseline through 1 year
- Percent improvement in means from baseline

*[a]NCT03162796. [b]NCT03158285. [c]NCT03796858. [d]Regimen common to 3 RCTs. **cDAPSA**=clinical Disease Activity Index for Psoriatic Arthritis, **CRP**=C-reactive protein, **GMM**=growth mixture model, **IR**=inadequate response, **LDA**=low disease activity, **PBO**=placebo, **Q4W**=every 4 weeks, **Q8W**=every 8 weeks, **REM**=remission, **SJC**=swollen joint count, **TJC**=tender joint count, **TNFi**=tumor necrosis factor inhibitor.*

Results

Three distinct trajectory groups were identified based on individual participant-level cDAPSA trajectories through 1 year of GUS

- Groups were **data-driven** and **not predefined**; they were identified from individual cDAPSA response patterns over 1 year, with **labels reflecting overall mean trajectories only**



Baseline disease duration and joint activity were lowest among Early Sustained Joint Responders and highest among Continuous Joint Improvers

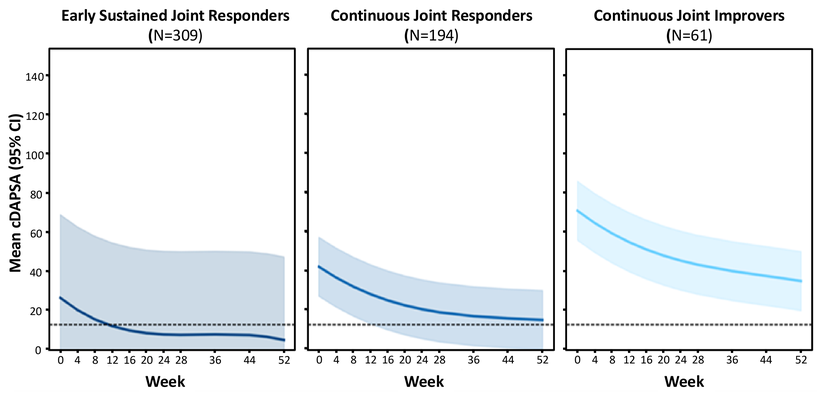
- Continuous Joint Responders exhibited baseline levels that were higher than, but generally closer to, those of Early Sustained Joint Responders

Baseline Patient Demographics and Disease Characteristics	Early Sustained Joint Responders (N=309)	Continuous Joint Responders (N=194)	Continuous Joint Improvers (N=61)	Total (N=564)
Demographics				
Age, years	46.9 (12.7)	47.2 (11.0)	48.8 (12.4)	47.2 (12.1)
Male*	55%	46%	41%	50%
BMI, kg/m^2	28.7 (6.0)	29.5 (6.3)	29.5 (6.4)	29.0 (6.2)
Disease characteristics				
PsA disease duration*, years	5.8 (6.1)	7.1 (6.9)	7.8 (7.5)	6.5 (6.6)
CRP*, mg/dL	1.4 (2.1)	1.9 (2.5)	2.0 (2.4)	1.7 (2.3)
PhGA** (VAS 0-10)	6.3 (1.7)	6.8 (1.4)	7.2 (1.5)	6.6 (1.6)
cDAPSA**	37.1 (17.1)	45.6 (12.9)	75.3 (22.0)	44.1 (20.0)
TJC**** (0-68)	15.9 (10.6)	21.0 (9.7)	40.1 (13.9)	20.3 (12.9)
SJC**** (0-66)	9.2 (6.1)	11.0 (5.2)	20.0 (12.1)	11.0 (7.4)
PtGA**** (VAS 0-10)	6.1 (1.9)	6.9 (1.7)	7.8 (1.4)	6.5 (1.9)
Pt Pain**** (VAS 0-10)	5.8 (2.1)	6.7 (1.7)	7.4 (1.6)	6.3 (2.0)
FACIT-Fatigue** (0-52)	31.7 (10.5)	26.3 (10.0)	26.6 (11.0)[a]	29.3 (10.7)[b]
SF-36 PCS** (0-100)	35.1 (7.7)	31.3 (6.3)	28.8 (7.2)[a]	33.1 (7.5)[b]
HAQ-DI** (0-3)	1.1 (0.6)	1.5 (0.5)	1.6 (0.5)[a]	1.3 (0.6)[b]
Prior treatments				
Anti-TNF	39%	42%	49%	41%
Non bDMARD	62%	71%	69%	66%
NSAID	58%	64%	64%	61%

*Nominal *p≤0.05, ***p≤0.0001 (see Methods). Data is presented as mean (SD) unless otherwise noted. [a]N=60. [b]N=563. **bDMARD**=biological disease-modifying antirheumatic drug, **BMI**=body mass index, **FACIT**=Functional Assessment of Chronic Illness Therapy, **HAQ-DI**=Health Assessment Questionnaire Disability Index, **NSAID**=nonsteroidal anti-inflammatory drugs, **PCS**=physical component score, **PhGA**=physician global assessment of arthritis, **SD**=standard deviation, **SF-36**=Short From-36, **TNF**=tumor-necrosis factor, **VAS**=visual analog scale.*

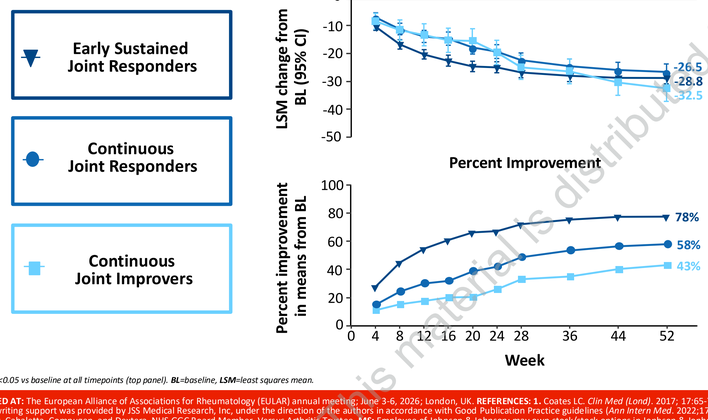
93% of Early Sustained Joint Responders achieved cDAPSA LDA/REM response with GUS over 1 year, with responses observed as early as Week 4

- Approximately half (44%) of Continuous Joint Responders achieved cDAPSA LDA/REM response through 1 year of GUS
- Continuous Joint Improvers showed substantial improvements in cDAPSA through 1 year of GUS; none achieved LDA/REM



*Mean (bold line) and 95% CI (shaded area) for parameter values of the best fit lines from each group are shown. cDAPSA LDA/REM threshold of 13 is presented as a horizontal dashed line. **CI**=confidence interval.*

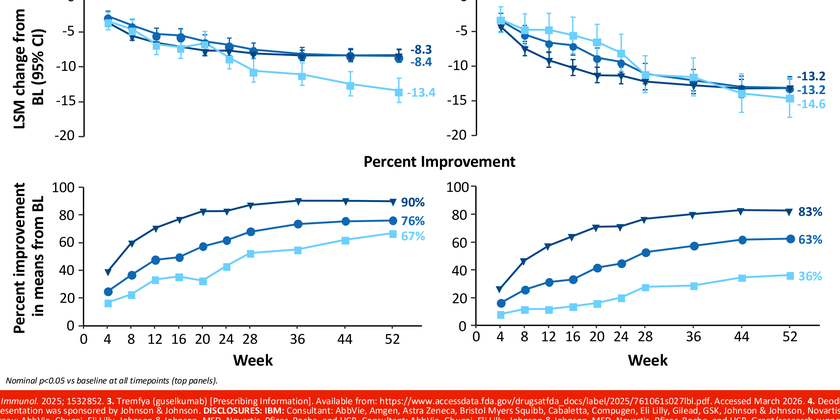
GUS significantly reduced cDAPSA as early as Week 4, with continuous improvement through 1 year across all three trajectory groups



*Nominal p<0.05 vs baseline at all timepoints (top panel). **BL**=baseline, **LSM**=least squares mean.*

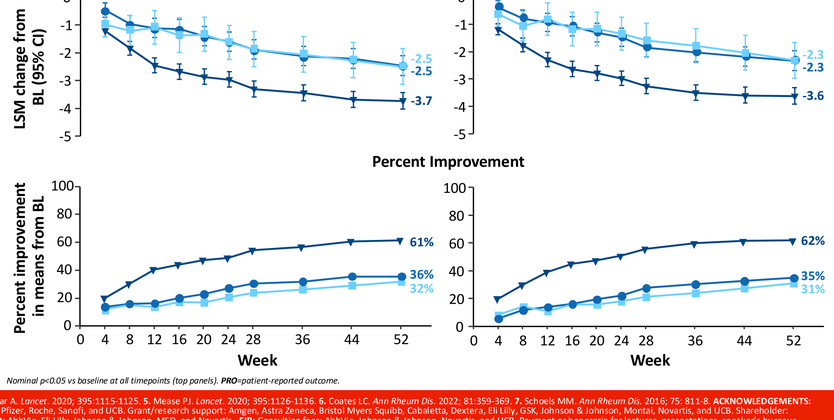
Early Sustained Joint Responders exhibited a 90% and 83% mean improvement in SJC and TJC, respectively, through 1 year of GUS

- Continuous Joint Improvers exhibited the greatest absolute reduction in SJC and TJC, representing mean improvements of 67% and 36%, respectively



Nominal p<0.05 vs baseline at all timepoints (top panels).

Early Sustained Joint Responders reported the greatest absolute reductions in PROs, representing improvements of 60% through 1 year of GUS



*Nominal p<0.05 vs baseline at all timepoints (top panels). **PRO**=patient-reported outcome.*

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