12-Month Persistence and Multi-Domain Effectiveness of Guselkumab in Adults With Active Psoriatic Arthritis: Real-World Data From the PPD CorEvitas Psoriatic Arthritis/Spondyloarthritis Registry

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Key Takeaways

In this real-world population of pts with longstanding, active, and largely treatment-refractory PsA:

- **GUS on-label persisters demonstrated statistically significant improvements in clinical measures of joint and skin disease activity and patient-reported outcomes (PROs) at 12M**
- **50% of pts with moderate/high disease activity at baseline achieved LDA/REM at 12M with on-label, persistent GUS therapy**

Background

Guselkumab (GUS), a fully human, dual-acting interleukin (IL)-23p19 subunit inhibitor, has demonstrated significant efficacy in treating psoriatic arthritis (PsA) in Phase 3 clinical trials[1-3]

- GUS was approved by the United States Food and Drug Administration (US FDA) in July 2020 for adults with active PsA (dosing regimen: GUS 100 mg subcutaneous at Week [W]0, W4, then every 8 weeks [Q8W])[4]

Real-world data on GUS persistence and effectiveness are available from the prospective, multicenter, observational PPD™ CorEvitas™ PsA/Spondyloarthritis (SpA) Registry of adults with rheumatologist-diagnosed active PsA[5]

In a previous analysis of CorEvitas data, persistence through 6 months (6M) of on-label GUS therapy was associated with significant improvements in PsA signs and symptoms[5]

Objective

To assess real-world effectiveness and persistence of on-label GUS at 12M in participants (pts) with active PsA

Methods

CorEvitas PsA/SpA Registry

- Prospective, multicenter, observational registry of adults in the US with rheumatologist-diagnosed active PsA
- Collects data from healthcare providers and pts at the time of outpatient clinical rheumatology encounters
- This analysis included data from GUS initiators (October 12, 2017 – July 31, 2025)

Study Population

- **GUS On-Label Initiators**
  - CorEvitas registry pts with PsA who initiated GUS after FDA approval for active PsA (July 13, 2020) using the FDA-approved (on-label) dosing regimen (GUS 100 mg subcutaneously at W0, W4, then Q8W), either as monotherapy or in combination with a csDMARD
  - Had a valid baseline visit associated with GUS initiation and a 12M follow-up visit
- **GUS On-Label Persisters**
  - Pts who maintained on-label use of GUS through the 12M visit

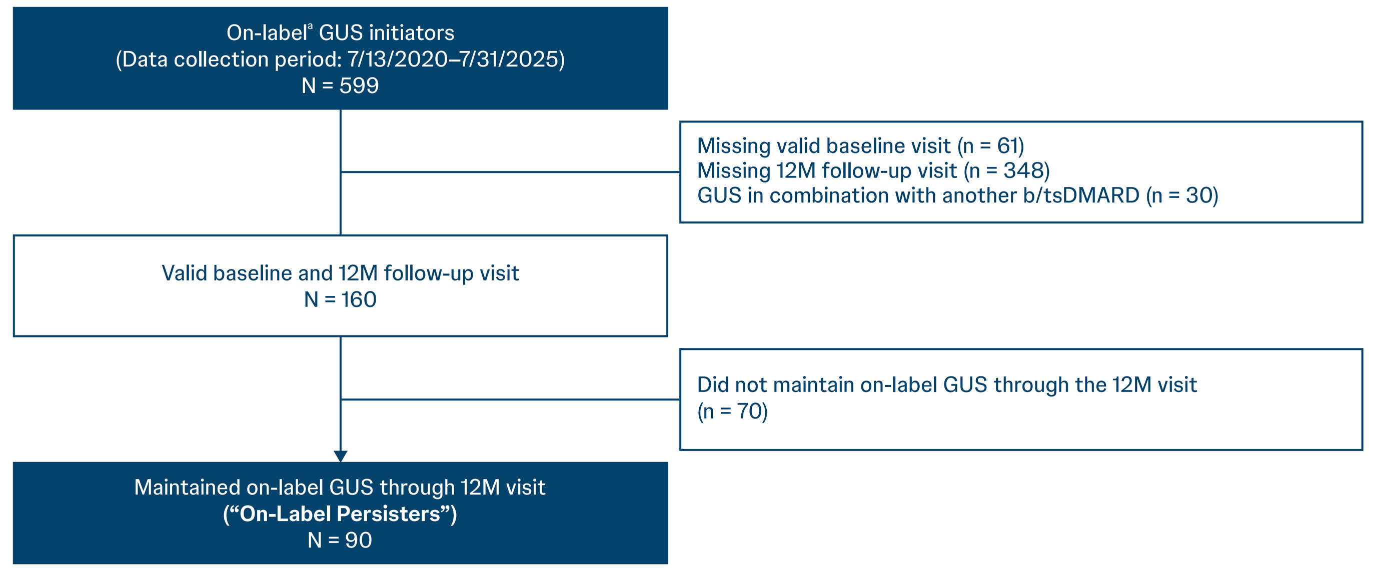
Effectiveness Endpoints Evaluated in GUS On-Label Persisters

- **Primary outcome:** Mean change (95% CI) in cDAPSA score from baseline to 12M visit
- **Secondary outcomes** (in order of multiplicity-controlled testing): Mean (95% CI) change from baseline to 12M visit in:
  - Physician Global Assessment of arthritis+PsO (0–100)
  - Patient-reported pain (Patient Pain; 0–100)
  - % BSA with PsO (0–100%)
- For primary and secondary outcomes, paired t-tests were used to determine statistical significance (α = 0.05)
  - To control for multiplicity, a fixed-sequence statistical strategy was used to test primary and secondary outcomes in a predefined order, all at the same significance level (α = 0.05)
- **Other outcomes** (not multiplicity-controlled) included:
  - Proportions of pts achieving cDAPSA LDA/REM among pts with moderate or high disease activity at baseline

BSA=body surface area, cDAPSA=clinical Disease Activity index for Psoriatic Arthritis, CI=confidence interval, csDMARD=conventional synthetic disease-modifying antirheumatic drug, FDA=Food and Drug Administration, GUS=guselkumab, LDA=low disease activity, M=month, PsA=psoriatic arthritis, PsO=psoriasis, pts=participants, Q8W=every 8 weeks, REM=remission, SpA=spondyloarthritis, US=United States.

Results

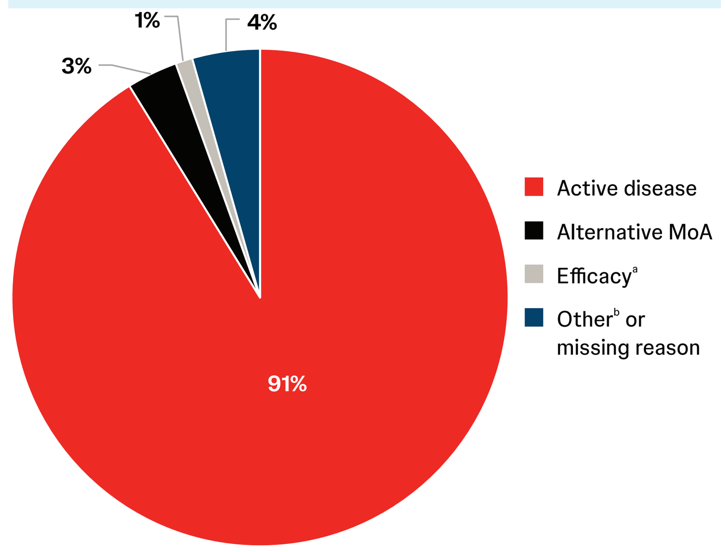
Of 160 on-label GUS initiators[a] with eligible baseline and 12M visits, 56% maintained on-label use through 12M



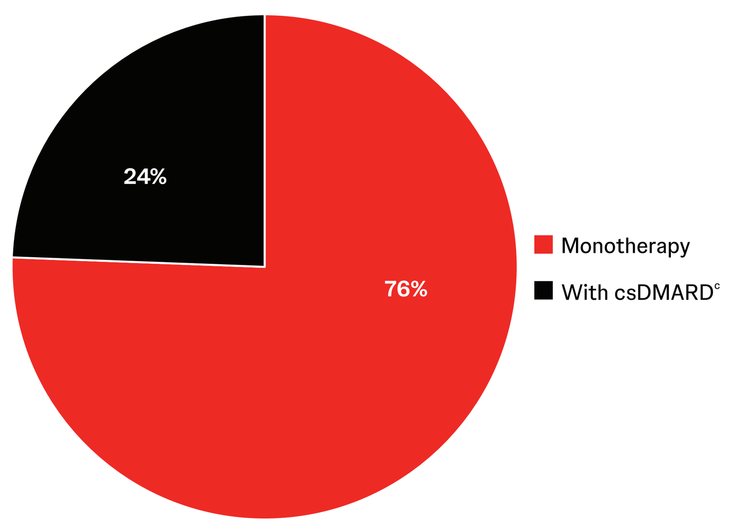
*[a]CorEvitas PsA/SpA Registry pts who initiated GUS after US FDA approval (7/13/2020) using the FDA-approved dosing regimen (100 mg at W0, W4 then Q8W). **bDMARD**=biologic disease-modifying antirheumatic drug, **FDA**=Food and Drug Administration, **GUS**=guselkumab, **M**=month, **PsA**=psoriatic arthritis, **pts**=participants, **SpA**=spondyloarthritis, **tsDMARD**=targeted synthetic disease-modifying antirheumatic drug, **US**=United States.*

The majority of GUS on-label persisters initiated GUS due to active disease and as monotherapy

91% initiated GUS due to active disease



76% initiated GUS as monotherapy



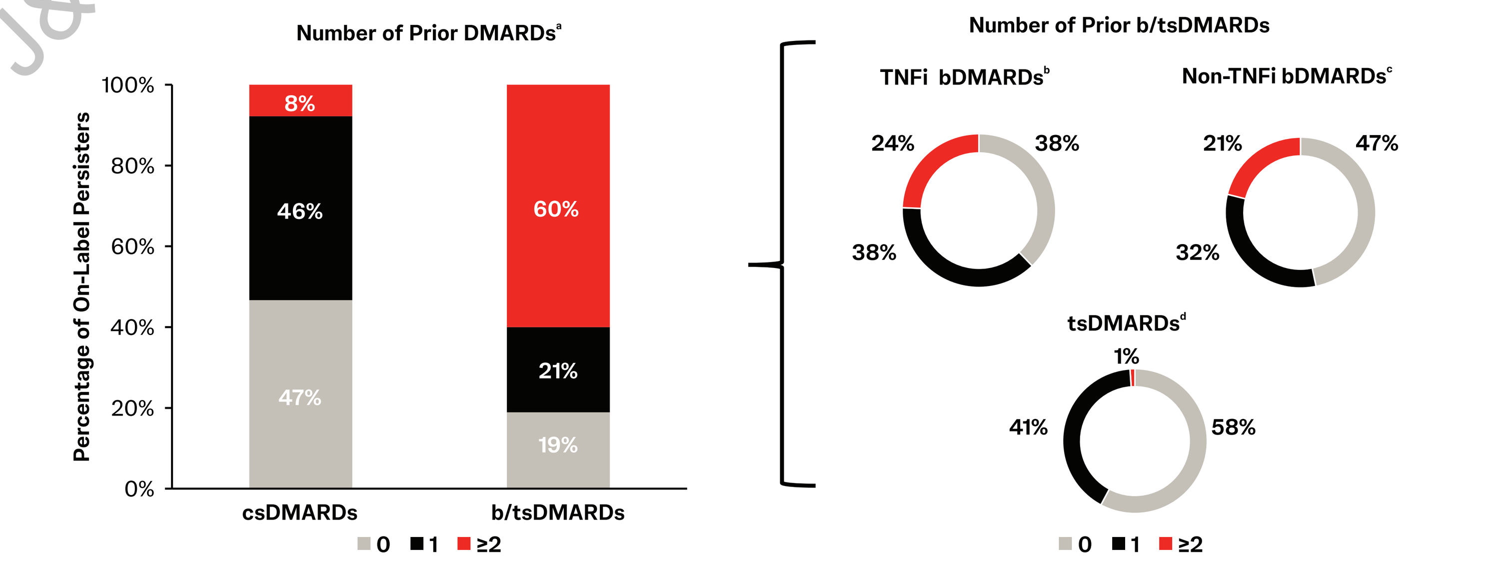
*Percentages may not add to 100% due to rounding. [a]Efficacy reasons defined as inadequate initial response or failure to maintain initial response. [b]Other reasons defined as fear of future side effect; temporary interruption; pt preference; to improve compliance; to improve tolerability; frequency of administration; route of administration; pt doing well. No pts cited safety/intolerability (serious side effect, minor side effect) or insurance (co pay/pt cost, denied by the insurance) as their reason for initiating GUS. The sum of all reason categories may total more than 100% given that pts could provide up to 3 reasons (3 pts provided multiple reasons). [b]Defined as any csDMARD confirmed to be initiated as of GUS baseline visit. Concomitant therapy may have started prior to or concurrently with GUS initiation. **csDMARDs**=conventional synthetic disease-modifying antirheumatic drugs, **GUS**=guselkumab, **MoA**=mechanism of action, **pts**=participants.*

Baseline characteristics of GUS on-label persisters

Baseline Characteristics	GUS On-Label Persisters (N = 90)
Demographics	
Age, yrs	51.3 (13.5)
Female	58%
Race, White	86%
Ethnicity, non-Hispanic	85%
BMI,[a] kg/m^2	32.1 (6.9)
Normal/underweight, <25 kg/m^2	11%
Overweight, ≥25 to <30 kg/m^2	29%
Obese, ≥30 kg/m^2	60%
Related Conditions[b]	
IBD[c]	7%
Crohn's disease	0%
Ulcerative Colitis	1%
Uveitis	1%
PsA Characteristics	
Yrs since PsA diagnosis	7.0 (7.6)
Median (IQR)	4.0 (1.0, 11.0)
History of PsO[d]	97%
% BSA, 0–100[e,f]	7.1 (12.0)
Median (IQR)	2.0 (1.0, 8.0)
Axial PsA[g]	44%
Disease Activity	
Tender joint count, 0–68[h]	7.4 (12.2)
Swollen joint count, 0–66[h]	3.0 (6.9)
Physician Global Assessment of arthritis+PsO, VAS 0–100[e,i]	38.4 (23.8)
Physician Global Assessment of arthritis, VAS 0–100[j]	32.5 (23.2)
Investigator's Global Assessment of PsO[e,k]	
Clear / Almost Clear	14% / 12%
Mild / Moderate / Severe	40% / 25% / 8%
cDAPSA[k]	21.5 (18.2)
REM, ≤4	5%
LDA, >4 to ≤13	25%
Moderate, >13 to ≤27	51%
High, >27	19%
MDA[l]	15%
VLDA[a]	2%
PRO Measures	
Patient Pain, VAS 0–100[a]	55.7 (23.8)
Patient Global Assessment of arthritis+PsO, VAS 0–100[e,l]	50.8 (23.6)
HAQ-DI, 0–3[a]	0.9 (0.6)

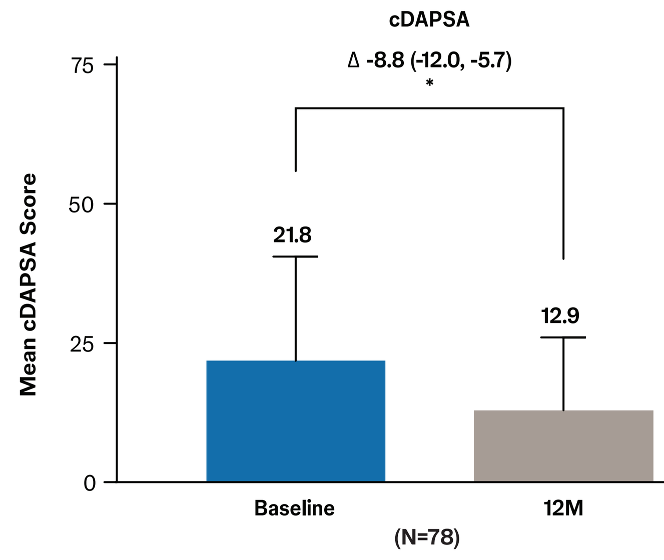
*Data shown are mean (SD) unless otherwise noted. Percentages may not add to 100% due to rounding. [a]N=89. [b]Related conditions are considered at all points up to and including the baseline visit and therefore represent any past or current presence of these conditions. [c]Includes Crohn's disease, ulcerative colitis, possible IBD, and other IBD. [d]Evidence of current PsO or a personal history of PsO; does not include family history of PsO. [e]Limited to pts with history of PsO. [f]N=82. [g]Axial involvement defined by physician-reported PsA diagnosis and either (1) diagnosis of axial SpA or ankylosing spondylitis, (2) physician indicated spinal involvement or completed any of the mobility measurements (includes occiput-to-wall distance, lateral lumbar flexion and lumbar flexion [Schöber]), or (3) any of the following criteria for diagnosing axial sPA: inflammatory back pain; ≥3 months back pain (age of onset <45 years); low back pain and stiffness for >3 months which improves with exercise and is not relieved by rest; limitation of motion of the lumbar spine in both the sagittal and frontal planes; active (acute) inflammation on MRI highly suggestive of sacroiliitis associated with SpA; and sacroiliitis grade ≥2 bilaterally or grade 3–4 unilaterally by radiograph. [h]N=85. [i]N=84. [j]N=87. [k]N=83. [l]N=86. **BMI**=body mass index, **BSA**=body surface area, **cDAPSA**=clinical Disease Activity index for Psoriatic Arthritis, **GUS**=guselkumab, **HAQ-DI**=Health Assessment Questionnaire-Disability Index, **IBD**=inflammatory bowel disease, **IQR**=interquartile range, **LDA**=low disease activity, **MDA**=minimal disease activity, **MRI**=magnetic resonance imaging, **N**=total number of participants, **PRO**=patient-reported outcome, **PsA**=psoriatic arthritis, **PsO**=psoriasis, **pts**=participants, **REM**=remission, **SD**=standard deviation, **SpA**=spondyloarthritis, **VAS**=visual analogue scale, **VLDA**=very low disease activity, **Yrs**=year.*

The majority of GUS on-label persisters were b/tsDMARD-experienced, and 60% had received ≥2 prior b/tsDMARDs



*Percentages may not add to 100% due to rounding. Counts do not include pt's current therapy. [a]Pts could have received prior csDMARDs and/or b/tsDMARDs. [b]TNFi bDMARDs: adalimumab, certolizumab pegol, etanercept, etanercept-szzs, golimumab, infliximab, infliximab-dyyb. [c]Non-TNFi bDMARDs: abatacept, anakinra, ixekizumab, rituximab, secukinumab, tocilizumab, ustekinumab, risankizumab-rzaa. [d]tsDMARDs: apremilast, tofacitinib, upadacitinib. **bDMARDs**=biologic disease-modifying antirheumatic drugs, **csDMARDs**=conventional synthetic disease-modifying antirheumatic drugs, **GUS**=guselkumab, **TNFi**=tumor necrosis factor inhibitor, **pts**=participants, **tsDMARDs**=targeted synthetic disease-modifying antirheumatic drugs.*

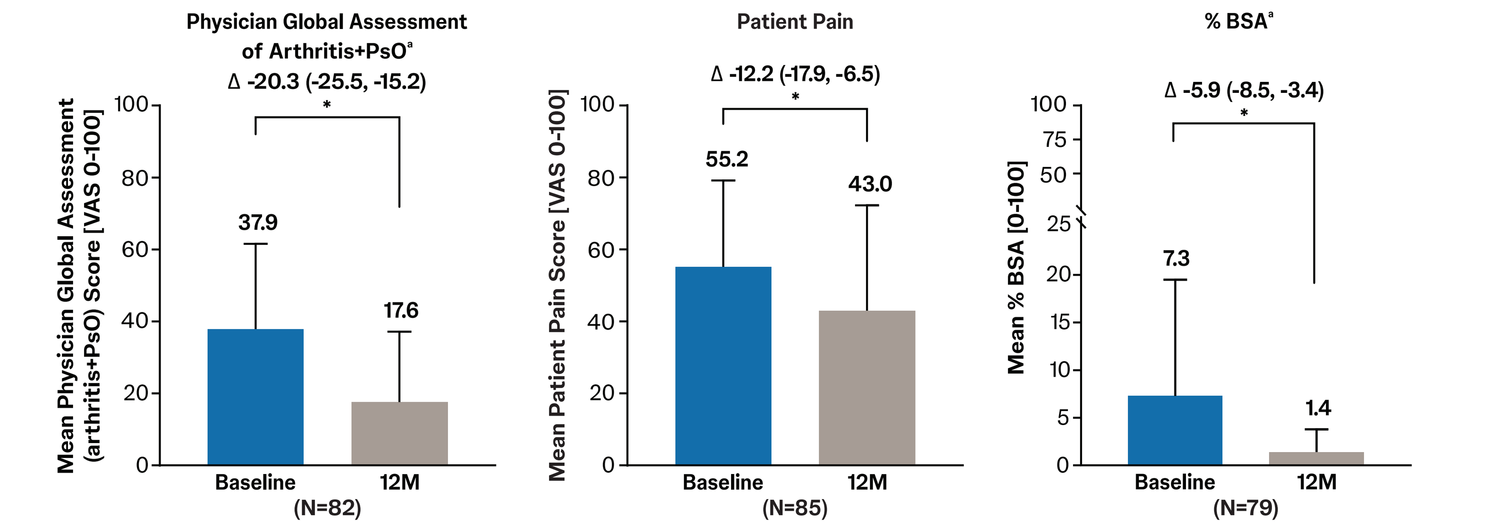
Among GUS on-label persisters, significant mean improvements from baseline to 12M were observed in the primary endpoint: cDAPSA



***p*<0.001, based on paired t-tests.**

*Δ represents mean change (95% CI) measured as 12M minus baseline. Error bars represent SDs. **cDAPSA**=clinical Disease Activity index for Psoriatic Arthritis, **CI**=confidence interval, **GUS**=guselkumab, **M**=month, **N**=total number of participants, **SD**=standard deviation.*

Among GUS on-label persisters, significant mean improvements from baseline to 12M were observed in all major secondary endpoints: Physician Global Assessment, Patient Pain, and % BSA



***p*<0.001, based on paired t-tests.**

*Δ represents mean change (95% CI) measured as 12M minus baseline. Error bars represent SDs. [a]Evaluated in pts with history of PsO. **BSA**=body surface area, **CI**=confidence interval, **GUS**=guselkumab, **M**=month, **N**=total number of participants, **PsO**=psoriasis, **pts**=participants, **SD**=standard deviation, **VAS**=visual analog scale.*

Half of GUS on-label persisters with moderate/high disease activity at baseline achieved LDA/REM at 12M

cDAPSA at GUS initiation[a]	cDAPSA LDA/REM at 12M[a]
Moderate/High (n=54)	**27/54 (50%)**
Moderate (n=38)	21/38 (55%)
High (n=16)	6/16 (38%)

*[a]REM: cDAPSA ≤4; LDA: cDAPSA >4 to ≤13; moderate: cDAPSA >13 to ≤27; high: cDAPSA >27. **cDAPSA**=clinical Disease Activity index for Psoriatic Arthritis, **GUS**=guselkumab, **LDA**=low disease activity, **M**=month, **n**=number of participants in each subgroup, **REM**=remission.*

Strengths and Limitations

Strengths

- Observational design of the CorEvitas PsA/SpA Registry captures real-world practice patterns and data on pts seen in routine clinical practice across several regions of the US
- More representative of the US PsA patient population than clinical trial populations
- Standardized data collection instruments and methods across all sites
- Primary and major secondary endpoints were controlled for multiplicity

Limitations

- Modest sample size
- May not be generalizable to regions outside the US
- Pt selection based on a 12M follow-up period requirement and further restricting to those who persist at follow-up may introduce time and selection biases

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REFERENCES: 1. Deodhar A. *Lancet.* 2020;395:1115–1125. **2.** Mease PJ. *Lancet.* 2020;395:1126–1136. **3.** Mease PJ. *Ann Rheum Dis.* 2025;84:1983–1994. **4.** Tremfya: Package insert. Horsham, PA: Janssen Biotech, Inc.; 2025. **5.** Mease PJ. *Rheumatol Ther.* 2023;10:1479–501.
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