Real-World On-Label Treatment Persistence Through 24 Months in Biologic-Naïve and Biologic-Experienced Patients With Psoriatic Arthritis: Comparison of Guselkumab versus Subcutaneous Tumor Necrosis Factor Inhibitors

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Key Takeaways

- **First real-world claims data analysis of on-label treatment persistence over 24 months in bio-naïve and bio-experienced pts with active PsA newly initiated on GUS vs initial SC TNFi**
- **Pts in the GUS cohort were significantly (~2x) more likely to remain persistent on treatment through 24 months in both the bio-naïve and bio-experienced cohorts**
- **Higher long-term on-label persistence may improve disease management outcomes in pts with active PsA initiating GUS[9], regardless of prior biologic treatment status**

Background

Guselkumab (GUS), a fully human interleukin (IL)-23 p19-subunit inhibitor, was approved by the US Food and Drug Administration (FDA) for the treatment of active psoriatic arthritis (PsA) in July 2020

- FDA-approved dosing regimen[1] (on-label): GUS 100 mg at week 0, week 4, then every 8 weeks

A previous claims-based analysis compared on-label persistence for patients (pts) with PsA initiating on-label treatment with GUS or their first subcutaneous (SC) tumor necrosis factor inhibitor (TNFi)[2,3]

- Pts receiving GUS were significantly (~2x) more likely to remain persistent through 24 months

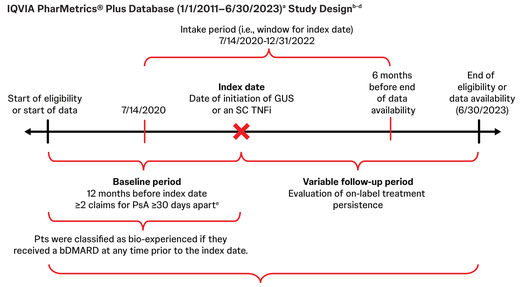
Real-world evidence is needed comparing on-label treatment persistence among biologic-naïve (bio-naïve) and biologic-experienced (bio-experienced) pts with active PsA initiating GUS versus SC TNFi

Objectives

This study utilized health plan claims data to compare treatment persistence through 24 months in bio-naïve and bio-experienced pts with active PsA either newly initiating the on-label GUS dosing regimen or starting an initial SC TNFi

Methods

IQVIA PharMetrics® Plus Database (1/1/2011–6/30/2023)[a] Study Design[b–d]



*[a]The IQVIA PharMetrics® Plus database is comprised of fully adjudicated claims for inpatient and outpatient services, and outpatient prescription drugs, offering a diverse representation of geographic zones, employers, payers, providers, and therapy areas. [b]A validated algorithm for identifying pts with PsA in US claims data was used: ≥2 claims with a PsA diagnosis (ICD-10-CM: L40.5x) ≥30 days apart and ≥1 prescription claim for a PsA-related medication (i.e., GUS or SC TNFi). [c]Pts could be bio-naïve or bio-experienced during baseline but were naïve to treatment with GUS or SC TNFi agents. [d]Pts in the SC TNFi cohort were newly initiated within the class. [e]Diagnoses for PsA include claims on the index date. **ICD-10-CM**-International Classification of Diseases, 10th revision, Clinical Modification.*

Patient Selection

- Index date: 1st[a] GUS or SC TNFi claim during intake period (7/14/2020-12/31/2022)[a]
- PsA pt identification: ≥2 PsA Dx (ICD-10-CM code L40.5x) ≥30 days apart within 12 months prior to the first study drug claim (baseline or on index date), and ≥1 claim for either GUS or SC TNFi[a]
- ≥12 months of continuous health insurance eligibility before index date
- ≥18 years of age
- No claims for other conditions for which GUS or TNFi are approved or other potentially confounding diseases[b]
- Pts were classified as bio-experienced if they had ≥1 claim for a PsA-indicated biologic disease-modifying antirheumatic drug (bDMARD) at any time prior to the index date, and bio-naïve otherwise

*[a]Pts could not have claims for >1 index agent on the index date. [b]Pts were excluded if they had a claim for ankylosing spondylitis, other inflammatory arthritis, other spondylopathies, rheumatoid arthritis, systemic connective tissue disorders, relapsing polychondritis, unclassified connective tissue disease, hidradenitis suppurativa, inflammatory bowel disease, or uveitis in the 12-month baseline period preceding the index date. **Dx**=Diagnoses.*

Censoring and Imputations

Censoring: On earliest of first off-label claim or last day of index agent supply preceding end of follow-up period if discontinuation was not observed

Days of supply imputation rule	GUS	SC TNFi
Medical Claims[1,5-8]		
1st claim	28 days	28 days
2nd + claims	56 days	28 days
Pharmacy Claims		
1st claim	28 days	No imputation[b]
2nd + claims	Based on time to next claim[a]	No imputation[b]

[a]28 days if time to next claim <42 days; 56 days if time to next claim 42-70 days; 84 days if time to next claim >70 days; if there is no next claim, days of supply of the previous claim was carried forward or imputed as 56 days if the original value was missing or if this was the second claim; no imputation for claims with days supply 56-60 or >63. [b]Pharmacy claims for SC TNFi are typically consistent with approved labeling; therefore, reported days supply was used for SC TNFi and no imputation was performed.

Statistical Analyses

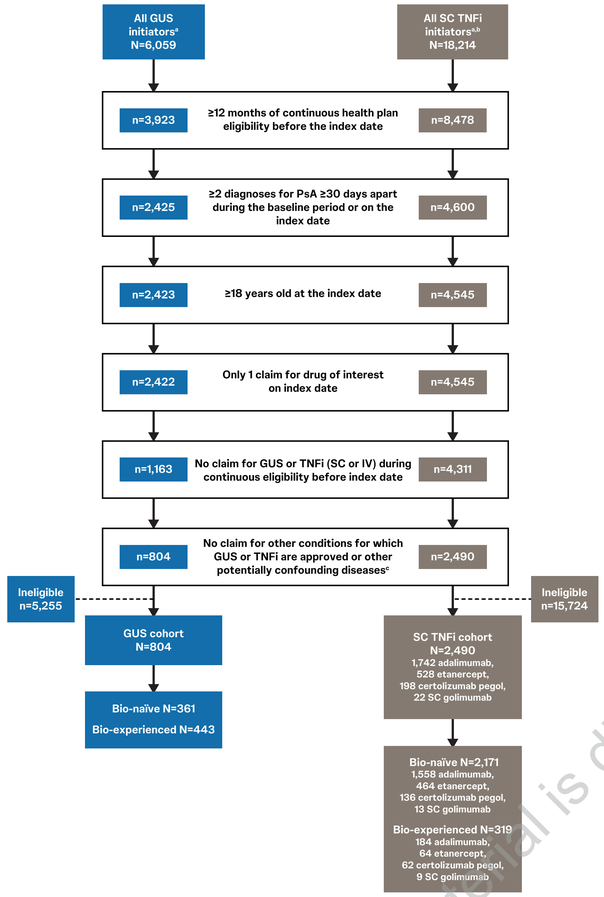
- **Baseline demographic and disease characteristics (12 months pre-index):**
  - Balanced between the GUS and SC TNFi cohorts separately for bio-naïve and bio-experienced pts ***using propensity score-weighting (overlap weights)***
- **On-label persistence up to 24 months post-index:**
  - No treatment discontinuation or dose modification relative to US FDA-approved labeling
  - Proportion of pts determined using ***weighted*** KM curves
  - GUS vs SC TNFi cohort comparison using ***weighted*** Cox proportional hazard models (further adjusted for csDMARD and tsDMARD use in bio-naive cohort only)

Days between administrations[a]	GUS	SC TNFi
Primary analysis		
2x[1,5-8]	112 days	56 days
Sensitivity analyses		
1x[1,5-8]	56 days	28 days
Fixed gap	112 days	112 days

*[a]Primary analysis was conducted based on 2x duration of time between administration per label. Sensitivity analyses were conducted based on 1x duration of time between administration per label as well as a fixed discontinuation gap of 112 days. **csDMARD**=conventional synthetic DMARD; **KM**=Kaplan-Meier; **tsDMARD**=targeted synthetic DMARD.*

Results

The GUS and SC TNFi cohorts, respectively, included 361 and 2,171 bio-naïve pts, and 443 and 319 bio-experienced pts



[a]1 GUS or SC TNFi claim during intake period (7/14/2020-12/31/2022). [b]The SC TNFi cohort is defined as pts with an index claim for an SC TNFi (i.e., adalimumab, certolizumab pegol, etanercept, or SC golimumab). [c]Assessed during the 12-month baseline period.

Weighted baseline demographic and clinical characteristics were similar between GUS and SC TNFi cohorts, except for prior csDMARD and tsDMARD use among bio-naïve pts

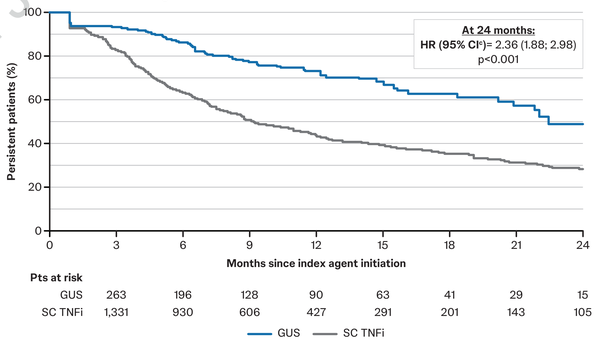
Weighted Baseline Demographics and Clinical Characteristics[a]	Bio-naïve		Bio-experienced	
	GUS (N=361)	SC TNFi (N=2,171)	GUS (N=443)	SC TNFi (N=319)
Demographics				
Age at index date (years), Mean ± SD [median]	48.8 ± 11.6 [50.1]	49.0 ± 11.6 [50.6]	49.5 ± 10.9 [50.2]	49.5 ± 10.6 [50.8]
Female	60.2	60.2	62.3	62.3
Insurance type at index date				
Preferred provider organization	77.5	77.7	72.7	72.7
Health maintenance organization	10.0	10.0	16.2	16.4
Other[b]	12.4	12.4	11.1	10.9
Year of index date				
2020	11.1	11.1	14.0	14.0
2021	39.9	39.9	45.4	45.4
2022	49.0	49.0	40.6	40.6
Characteristics				
Months between latest observed PsA diagnosis and index date, Mean ± SD [median]	1.3 ± 1.5 [0.8]	1.3 ± 1.7 [0.7]	1.1 ± 1.4 [0.7]	1.1 ± 1.5 [0.6]
Quan-CCI, Mean ± SD [median]	0.6 ± 1.3 [0.0]	0.5 ± 1.2 [0.0]	0.6 ± 1.2 [0.0]	0.6 ± 1.2 [0.0]
Comorbidities				
Hyperlipidemia	35.0	35.0	33.2	33.2
Osteoarthritis	29.4	29.4	29.0	29.2
Diabetes	14.6	16.1	15.8	16.6
Peripheral vascular disease	2.1	2.0	0.9	1.5
Psoriasis	89.3	89.3	83.0	83.0
Smoking	12.1	10.0	10.5	11.5
Medication Use[c]				
bDMARDs[d]	0	0	87.4	87.4
0	0	0	12.6	12.6
1	0	0	76.9	78.3
≥2	0	0	10.5	9.1
csDMARDs[e]	25.5	35.1	27.0	27.0
tsDMARDs[f]	31.7	22.6	15.4	15.4
Corticosteroids	72.5	68.2	66.3	70.1

*Data are % unless otherwise noted. [a]Propensity score using overlap weighting. [b]Includes point-of-service, consumer directed health care, indemnity/traditional, and unknown plan type. [c]During 12 months before index date. [d]Includes anti-IL-17A (i.e., secukinumab and ixekizumab), anti-IL-12/23 (i.e., ustekinumab), anti-CTLA-4 (i.e., abatacept), and anti-IL-23 (i.e., risankizumab). [e]Includes methotrexate, leflunomide, cyclosporine, mycophenolate, and azathioprine. [f]Includes apremilast, deucravacitinib, and Janus kinase inhibitors (i.e., upadacitinib, baricitinib, and tofacitinib). **Quan-CCI**=Quan-Charlson Comorbidity Index; **SD**=standard deviation.*

Bio-naïve and bio-experienced pts treated with GUS were significantly more likely to remain persistent with on-label treatment through 24 months vs. pts treated with TNFs

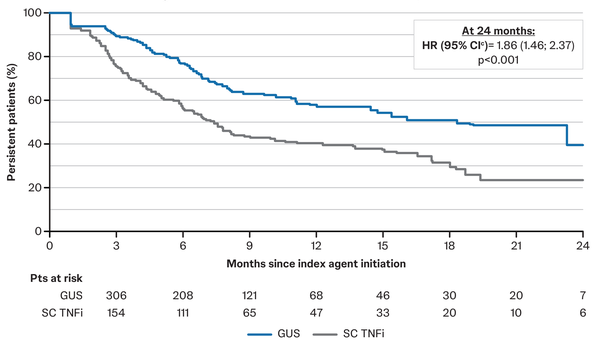
- **Bio-naïve pts:**
  - **On-label persistence at 24 months:** 48.9% with GUS vs 28.4% with SC TNFi
  - Sensitivity analyses for bio-naive pts demonstrated similar trends
  - **Median time to discontinuation:** 22.4 months with GUS vs 9.2 months with SC TNFi

On-Label Persistence in Weighted GUS and SC TNFi Cohorts[a,b] in Bio-Naïve Pts



- **Bio-experienced pts**
  - **On-label persistence at 24 months:** 39.5% with GUS vs 23.3% with SC TNFi
  - Sensitivity analyses for bio-experienced pts demonstrated similar trends
  - **Median time to discontinuation:** 18.4 months with GUS vs 7.4 months with SC TNFi

On-Label Persistence in Weighted GUS and SC TNFi Cohorts[a,b] in Bio-Experienced Pts



*[a]Primary analysis; discontinuation was defined as a gap in treatment of > twice the duration of days of supply for a claim (i.e., 2 x 56 = 112 days for GUS or 2 x 28 = 56 days for SC TNFi). [b]Pts with dose changes inconsistent with the FDA-approved dosing were censored as of the first dose change. [c]A weighted Cox proportional hazards model, further adjusted for baseline tsDMARD and csDMARD use (among bio-naïve pts), was used to compare on-label persistence between cohorts. **CI**=confidence interval; **HR**=hazard ratio.*

In bio-naïve and bio-experienced pts, GUS was associated with ~2x higher on-label persistence vs SC TNFi at each time point assessed (6/12/18/24 months)

On-label persistence through 24 months in weighted GUS and SC TNFi bio-naïve and bio-experienced cohorts[a]
Primary analysis (2x duration)

Cox proportional hazards model[b]	6 months	12 months	18 months	24 months
Bio-naïve cohorts				
Pts at risk, n (%)[c]				
GUS (N=361)	196 (54.3)	90 (25.0)	41 (11.4)	15 (4.2)
SC TNFi (N=2,171)	930 (42.8)	427 (19.7)	201 (9.3)	105 (4.8)
Hazard ratios (95% CI)	2.92 (2.12; 4.04)	2.66 (2.05; 3.44)	2.49 (1.96; 3.16)	2.36 (1.88; 2.98)
Chi-square p-value	<0.001	<0.001	<0.001	<0.001
KM Persistence, % (95% CI)				
GUS	86.2 (76.6; 92.1)	73.1 (63.2; 80.7)	62.9 (50.2; 73.1)	48.9 (24.9; 69.3)
SC TNFi	63.8 (59.3; 68.0)	43.8 (38.0; 49.4)	35.3 (28.4; 42.3)	28.4 (19.6; 37.9)
Log-rank test p-value	<0.001	<0.001	<0.001	<0.001
Bio-experienced cohorts				
Pts at risk, n (%)[c]				
GUS (N=443)	208 (46.9)	68 (15.3)	30 (6.8)	7 (1.5)
SC TNFi (N=319)	111 (34.8)	47 (14.7)	20 (6.2)	6 (1.8)
Hazard ratios (95% CI)	2.12 (1.56; 2.87)	1.85 (1.44; 2.39)	1.84 (1.44; 2.36)	1.86 (1.46; 2.37)
Chi-square p-value	<0.001	<0.001	<0.001	<0.001
KM Persistence, % (95% CI)				
GUS	76.9 (68.3; 83.4)	57.7 (47.1; 67.0)	50.6 (36.3; 63.2)	39.5 (3.6; 63.0)
SC TNFi	58.1 (47.0; 67.6)	40.3 (27.7; 52.4)	31.1 (15.3; 48.5)	23.3 (5.2; 48.2)
Log-rank test p-value	<0.001	<0.001	<0.001	<0.001

[a]Propensity score weights were used to obtain a balanced sample. Weights were estimated using a multivariable logistic regression model. Baseline covariates included several demographic and clinical characteristics. [b]Weighted Cox proportional hazard models were used to compare risk of discontinuation between the GUS and SC TNFi cohorts. Models further adjusted for baseline use of tsDMARDs and csDMARDs in bio-naive cohort only. [c]Pts at risk of having the event are pts who have not had the event and have not been lost to follow-up at that point in time.

Strengths and Limitations

- Strengths:
  - PsA pts were identified using a case finding algorithm validated in US claims data[4]
  - The GUS and SC TNFi cohorts were balanced for baseline demographic and disease characteristics, with further adjustment for prior tsDMARD and csDMARD use for bio-naïve pts
- Limitations:
  - Claims data do not ensure treatments are taken as prescribed
  - Treatment effectiveness and reasons for discontinuation could not be assessed using claims data

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