

Real-World On-Label Treatment Persistence Through 24 Months in Biologic-Naïve and Biologic-Experienced Patients With PsA: Guselkumab Versus tsDMARDs

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Background

Subcutaneous (SC) guselkumab (GUS; fully human, dual-acting selective interleukin (IL)-23p19-subunit inhibitor) and oral targeted synthetic disease-modifying antirheumatic drugs (tsDMARDs; apremilast, tofacitinib, upadacitinib) are approved for patients (pts) with active psoriatic arthritis (PsA)¹⁻⁴

- US Food and Drug Administration (FDA)-approved dosing regimen¹ (on-label): GUS 100 mg at Week 0, Week 4, then every 8 weeks¹

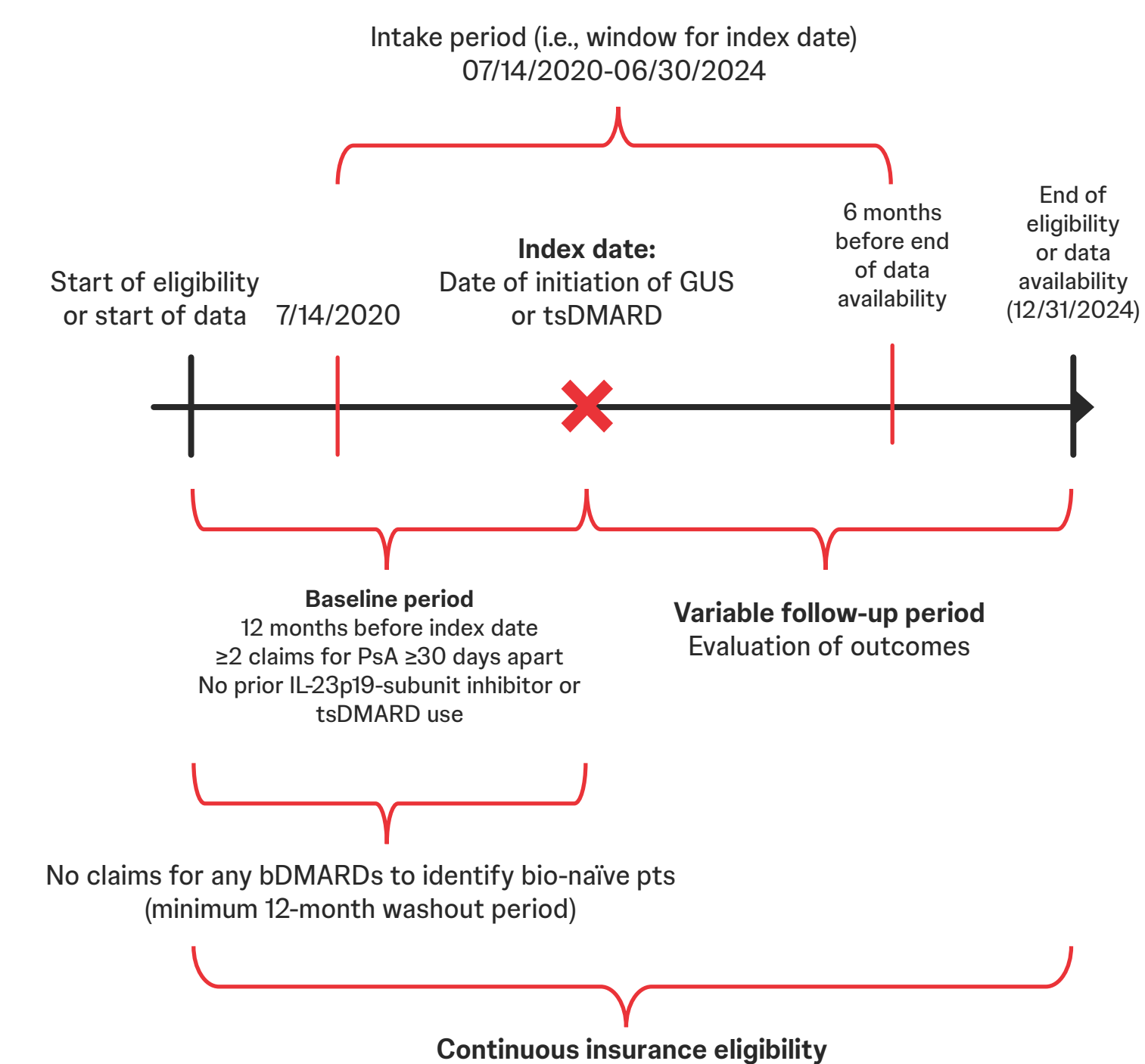
Persistence on therapy is key to maintaining long-term disease control in active PsA. However, real-world comparisons of long-term on-label persistence between pts receiving GUS and tsDMARDs are lacking

Objective

This study used health plan claims data to compare on-label treatment persistence in pts with PsA newly initiating GUS or a tsDMARD (apremilast; Janus kinase inhibitors [JAKi; tofacitinib, upadacitinib]), including biologic-naïve (bio-naïve) and biologic-experienced (bio-experienced), through 24 months

Methods

IQVIA PharMetrics® Plus database (07/14/2019 - 12/31/2024) Study Design



GUS=guselkumab, IL-23p19=interleukin-23 p19 subunit, PsA=psoriatic arthritis, tsDMARD=targeted synthetic disease-modifying antirheumatic drug.

Statistical Analyses				
Baseline demographic and disease characteristics (12 months pre-index): Balanced between the GUS and tsDMARDs separately for the overall, bio-naïve, and bio-experienced populations using propensity score-weighting (overlap weights)				
	On-label persistence up to 24 months post-index: - No treatment discontinuation or dose modification relative to FDA-approved labeling - Proportion of pts determined using weighted KM curves - GUS vs tsDMARDs comparison using weighted Cox proportional hazard models			
	Subgroups: Balancing and on-label persistence analyses for overall population replicated for GUS vs tsDMARD subgroups (i.e., apremilast, JAKi)			
Days between administration or refill ¹	GUS	Apremilast	Upadacitinib	Tofacitinib
Primary analysis				
2x ¹⁻⁴	112 days	60 days	60 days	60 days
Sensitivity analyses				
1x ¹⁻⁴	56 days	30 days	30 days	30 days
Fixed gap	112 days	112 days	112 days	112 days

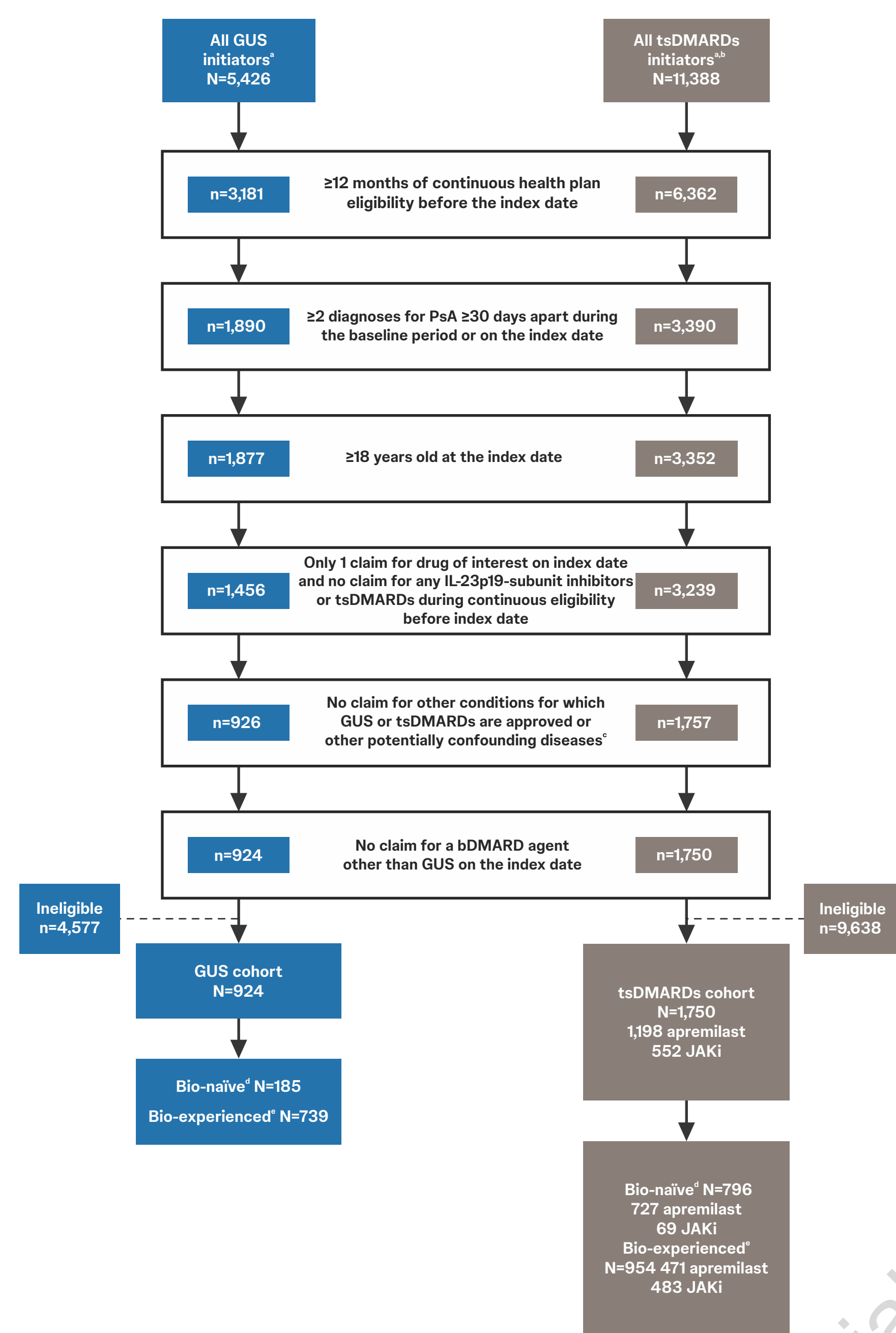
¹Primary analysis was conducted based on 2x duration of time between administration per label. Sensitivity analyses were conducted based on 1x duration of time between administration per label as well as a fixed discontinuation gap of 112 days. GUS=guselkumab, JAKi=Janus kinase inhibitor, KM=Kaplan-Meier, tsDMARD=targeted synthetic disease-modifying antirheumatic drug.

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	Apremilast	Upadacitinib	Tofacitinib
Medical Claims ¹⁻⁴				
1st claim	28 days	Not found in medical claims ⁵	Not found in medical claims ⁵	Not found in medical claims ⁵
2nd + claims	56 days	Not found in medical claims ⁵	Not found in medical claims ⁵	Not found in medical claims ⁵
Pharmacy Claims				
1st claim	28 days	28 days	28 or 30 days ⁵	30 or 90 days ⁵
2nd + claims	Based on time to next claim ⁶	30 or 90 days ⁵	28 or 30 days ⁵	30 or 90 days ⁵

¹28 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. ²If the original value was missing or if this was the second claim, no imputation for claims with days of supply 56-60 or >60. ³As there are no procedure codes for apremilast, upadacitinib, and tofacitinib, there are no medical claims and no imputations were made. ⁴If the second or later claim was a pharmacy claim with days of supply <90 days, days of supply were imputed to 30 days. If the second or later claim was a pharmacy claim with days of supply ≥90 days, days of supply were imputed to 90 days. ⁵For pharmacy claims, if days of supply were equal to 28 days, no imputation was applied and the value was retained as 28 days; if days of supply were not equal to 28 days, days of supply were imputed to 30 days. GUS=guselkumab.

Results

The GUS and tsDMARD cohorts, respectively, included 924 and 1,750 pts overall, 185 and 796 bio-naïve pts, and 739 and 954 bio-experienced pts



Weighted baseline demographic and clinical characteristics were similar between the GUS and tsDMARD cohorts

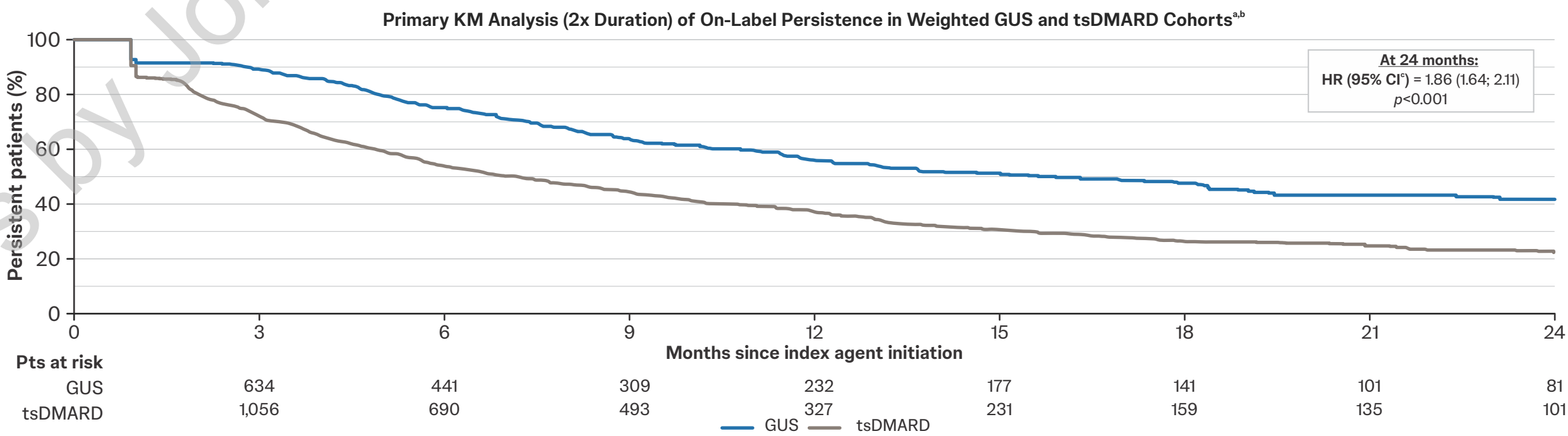
- Balancing was achieved for all comparisons (i.e., GUS vs tsDMARD in bio-naïve, GUS vs tsDMARD in bio-experienced, GUS vs apremilast, and GUS vs JAKi)

Weighted Baseline Demographics and Clinical Characteristics ^a	GUS (N=924)	tsDMARD (N=1,750)
Demographics		
Age at index date (years), Mean ± SD [median]	50.3 ± 12.0 [50.7]	50.3 ± 12.0 [50.6]
Female	59.1	59.1
Insurance type at index date		
Preferred provider organization	45.8	45.8
Health maintenance organization	39.0	39.3
Other ^b	15.2	14.9
Year of index date		
2020	6.4	6.4
2021	25.8	25.8
2022	28.8	28.8
2023	26.4	26.4
2024	12.6	12.6
Characteristics		
Months between latest observed PsA diagnosis and index date, Mean ± SD [median]	1.1 ± 1.5 [0.5]	1.1 ± 1.6 [0.5]
Quan-CCL, Mean ± SD [median]	0.8 ± 1.4 [0.0]	0.8 ± 1.5 [0.0]
Comorbidities		
Hyperlipidemia	41.6	41.6
Osteoarthritis	34.0	34.0
Diabetes	20.9	18.2
Peripheral vascular disease	4.0	4.2
Psoriasis	80.6	80.6
Smoking	16.2	13.9
Medication Use ^c		
tsDMARDs ^d	64.3	64.3
csDMARDs ^d	34.3	34.3
Corticosteroids	70.5	72.0

Data are % unless otherwise noted. ^aPropensity score using overlap weighting. ^bIncludes point-of-service, consumer directed health care, indemnity/traditional, and unknown plan type. ^cDuring 12 months before index date. ^dIncludes tumor necrosis factor inhibitors (i.e., adalimumab, etanercept, certolizumab pegol), intravenous (IV) golimumab, SC golimumab, infliximab, adalimumab (biosimilars), etanercept (biosimilars), and infliximab (biosimilars), anti-IL-23/23 (i.e., ustekinumab), anti-cytotoxic T lymphocyte antigen-4 (i.e., abatacept), and anti-IL-17 (i.e., SC secukinumab, ixekizumab, and IV secukinumab). ^eIncludes methotrexate, sulfasalazine, infliximab, hydroxychloroquine, azathioprine, cyclosporine, and mycophenolate. ^ftsDMARD=biologic disease-modifying antirheumatic drug. ^gCI=confidence interval. ^htsDMARD=conventional synthetic disease-modifying antirheumatic drug. ⁱGUS=guselkumab. ^jJAKi=Janus kinase inhibitor. ^kKM=Kaplan-Meier. ^lQuan-CCL=Quan Charlon Comorbidity Index. ^mSC=subcutaneous. ⁿSD=standard deviation. ^otsDMARD=targeted synthetic disease-modifying antirheumatic drug.

Pts treated with GUS vs tsDMARDs were significantly (1.86x) more likely to remain persistent with on-label treatment through 24 months

- Proportion of pts with on-label persistence at 24 months: GUS (41.6%) vs tsDMARD (22.7%)
- Median time to discontinuation: GUS (15.9 months) vs tsDMARD (7.2 months)
- Trends were consistent in other comparisons: GUS vs tsDMARD in bio-naïve, GUS vs tsDMARD in bio-experienced, GUS vs apremilast, GUS vs JAKi, and sensitivity analyses



¹Primary 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 tsDMARD). ²Pts with dose changes inconsistent with the FDA-approved dosing were censored as of the first dose change. ³A weighted Cox proportional hazards model was used to compare on-label persistence between cohorts. ⁴CI=confidence interval. ⁵FDA=Food and Drug Administration. ⁶GUS=guselkumab. ⁷HR=hazard ratio. ⁸JAKi=Janus kinase inhibitor. ⁹KM=Kaplan-Meier. ¹⁰pts=patients. ¹¹tsDMARDs=targeted synthetic disease-modifying antirheumatic drugs.

GUS was associated with significantly higher on-label persistence than tsDMARDs at all assessed time points (3, 12, 18, and 24 months), overall and in both biologic-naïve and biologic-experienced pts

On-label persistence through 24 months in weighted GUS and tsDMARD cohorts^{a,b,c} – Primary analysis (2x duration)

	3 months	12 months	18 months	24 months
GUS vs tsDMARDs – Overall KM Persistence, % (95% CI)				
GUS (N=924)	89.2 (83.5; 93.0)	56.1 (49.7; 62.0)	47.8 (40.5; 54.8)	41.6 (32.9; 50.1)
tsDMARD (N=1,750)	72.6 (68.8; 76.1)	37.3 (32.2; 42.3)	26.4 (20.4; 32.8)	22.7 (16.0; 30.2)
HR (95% CI) ^d	2.65 (2.10; 3.35)*	1.88 (1.64; 2.16)*	1.90 (1.67; 2.17)*	1.86 (1.64; 2.11)*
GUS vs tsDMARDs – Bio-naïve KM Persistence, % (95% CI)				
GUS (N=185)	91.0 (73.5; 97.2)	65.6 (51.5; 76.5)	53.9 (38.0; 67.4)	43.1 (22.1; 62.6)
tsDMARD (N=796)	73.8 (67.4; 79.1)	43.6 (35.5; 51.4)	28.5 (18.9; 38.8)	25.5 (15.5; 36.8)
HR (95% CI) ^d	3.08 (1.81; 5.25)*	2.21 (1.61; 3.03)*	2.18 (1.63; 2.92)*	2.04 (1.54; 2.69)*
GUS vs tsDMARDs – Bio-experienced KM Persistence, % (95% CI)				
GUS (N=739)	88.8 (82.4; 93.0)	53.5 (46.2; 60.2)	46.7 (38.5; 54.4)	41.6 (32.2; 50.7)
tsDMARD (N=954)	71.7 (66.6; 76.3)	34.7 (28.3; 41.2)	24.6 (16.5; 33.5)	20.8 (11.6; 31.9)
HR (95% CI) ^d	2.64 (2.02; 3.45)*	1.87 (1.59; 2.19)*	1.91 (1.64; 2.22)*	1.89 (1.63; 2.19)*

¹p<0.001 based on the chi-square test. ²Primary 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 tsDMARD). ³Pts with dose changes inconsistent with the FDA-approved dosing were censored as of the first dose change. ⁴Overlap 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. ⁵A weighted Cox proportional hazards model was used to compare on-label persistence between cohorts. ⁶CI=confidence interval. ⁷FDA=Food and Drug Administration. ⁸GUS=guselkumab. ⁹HR=hazard ratio. ¹⁰KM=Kaplan-Meier. ¹¹pts=patients. ¹²tsDMARDs=targeted synthetic disease-modifying antirheumatic drugs.

Key Takeaways

✓ **First real-world claims analysis comparing on-label persistence over 24 months in pts with active PsA initiating GUS vs tsDMARDs, including bio-naïve and bio-experienced pts**

✓ **Pts initiating GUS demonstrated significantly higher short-term and long-term on-label persistence than those initiating tsDMARDs in the overall, bio-naïve, and bio-experienced groups**

- Findings were consistent for subgroup comparisons (GUS vs apremilast and vs JAKi) and sensitivity analyses

GUS was associated with significantly higher on-label persistence vs apremilast and vs JAKi at each assessed time point (3, 12, 18, and 24 months)

On-label persistence through 24 months in weighted GUS and tsDMARD subgroups^{a,b,c} – Primary analysis (2x duration)

	3 months	12 months	18 months	24 months
GUS vs Apremilast – Overall KM Persistence, % (95% CI)				
GUS (N=924)	88.7 (82.9; 92.6)	55.0 (48.1; 61.4)	46.0 (38.0; 53.7)	39.4 (29.6; 48.9)
Apremilast (N=1,198)	70.3 (65.5; 74.6)	35.6 (29.5; 41.7)	24.4 (17.4; 32.1)	21.3 (13.7; 30.0)
HR (95% CI) ^d	2.83 (2.23; 3.60)*	1.99 (1.72; 2.30)*	1.99 (1.74; 2.29)*	1.94 (1.69; 2.22)*
GUS vs JAKi – Overall KM Persistence, % (95% CI)				
GUS (N=924)	88.5 (82.7; 92.4)	54.1 (46.8; 60.8)	47.7 (39.4; 55.5)	41.9 (32.0; 51.5)
JAKi (N=552)	75.2 (68.4; 80.7)	41.0 (33.3; 48.5)	30.6 (21.2; 40.6)	25.2 (14.2; 37.8)
HR (95% CI) ^d	2.09 (1.59; 2.75)*	1.52 (1.28; 1.81)*	1.58 (1.34; 1.86)*	1.57 (1.34; 1.85)*

¹p<0.001 based on the chi-square test. ²Primary 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 tsDMARD). ³Pts with dose changes inconsistent with the FDA-approved dosing were censored as of the first dose change. ⁴Overlap 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. ⁵A weighted Cox proportional hazards model was used to compare on-label persistence between cohorts. ⁶CI=confidence interval. ⁷FDA=Food and Drug Administration. ⁸GUS=guselkumab. ⁹HR=hazard ratio. ¹⁰JAKi=Janus kinase inhibitor. ¹¹KM=Kaplan-Meier. ¹²tsDMARD=targeted synthetic disease-modifying antirheumatic drug.

Strengths and limitations

- Strengths**
 - PsA pts were identified using a case finding algorithm validated in US claims data⁵
 - A long follow-up window allowed robust assessment of both short-term and long-term persistence outcomes
 - Baseline characteristics for the GUS and tsDMARD cohorts were balanced across all comparisons
- Limitations**
 - Claims data do not ensure treatments are taken as prescribed
 - Differences in route of administration may limit the direct comparability of treatment persistence across cohorts
 - Treatment effectiveness and reasons for discontinuation could not be assessed using claims data