Real-World On-Label Treatment Persistence Through 24 Months in Biologic-Naïve and Biologic-Experienced Patients With Psoriatic Arthritis: Comparison of Guselkumab versus Subcutaneous Interleukin-17A Inhibitors

Philip J. Mease[1,2], Jessica Walsh[3,4], Timothy P. Fitzgerald[5], Soumya D. Chakravarty[5,6], Elizabeth Adamson[5], Bruno Emond[7], Carmine Rossi[7], Samuel Schwartzbein[7], Kana Yokoji[7], Yuxi Wang[7], Patrick Lefebvre[7], Dominic Pilon[7], Shikha Singla[8], Joseph F. Merola[9]

[1]Rheumatology Research, Providence Swedish Medical Center, Seattle, WA, USA; [2]University of Washington School of Medicine, Seattle, WA, USA; [3]Salt Lake City Veterans Affairs Health, Salt Lake City, UT, USA; [4]University of Utah Health, Salt Lake City, UT, USA; [5]Johnson & Johnson, Horsham, PA, USA; [6]Drexel University College of Medicine, Philadelphia, PA, USA; [7]Analysis Group, Inc., Montreal, QC, Canada; [8]Medical College of Wisconsin, Milwaukee, WI, USA; [9]Department of Dermatology, and Department of Medicine, Division of Rheumatology, UT Southwestern Medical Center, Dallas, TX, USA

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 IL-17Ai per US FDA-approved labeling
- Pts in the GUS cohort were significantly more likely to remain persistent on treatment through 24 months in both the bio-naïve and bio-experienced populations
- Higher long-term on-label persistence may improve disease management outcomes in pts with active PsA initiating GUS[7], regardless of prior biologic treatment status

Background

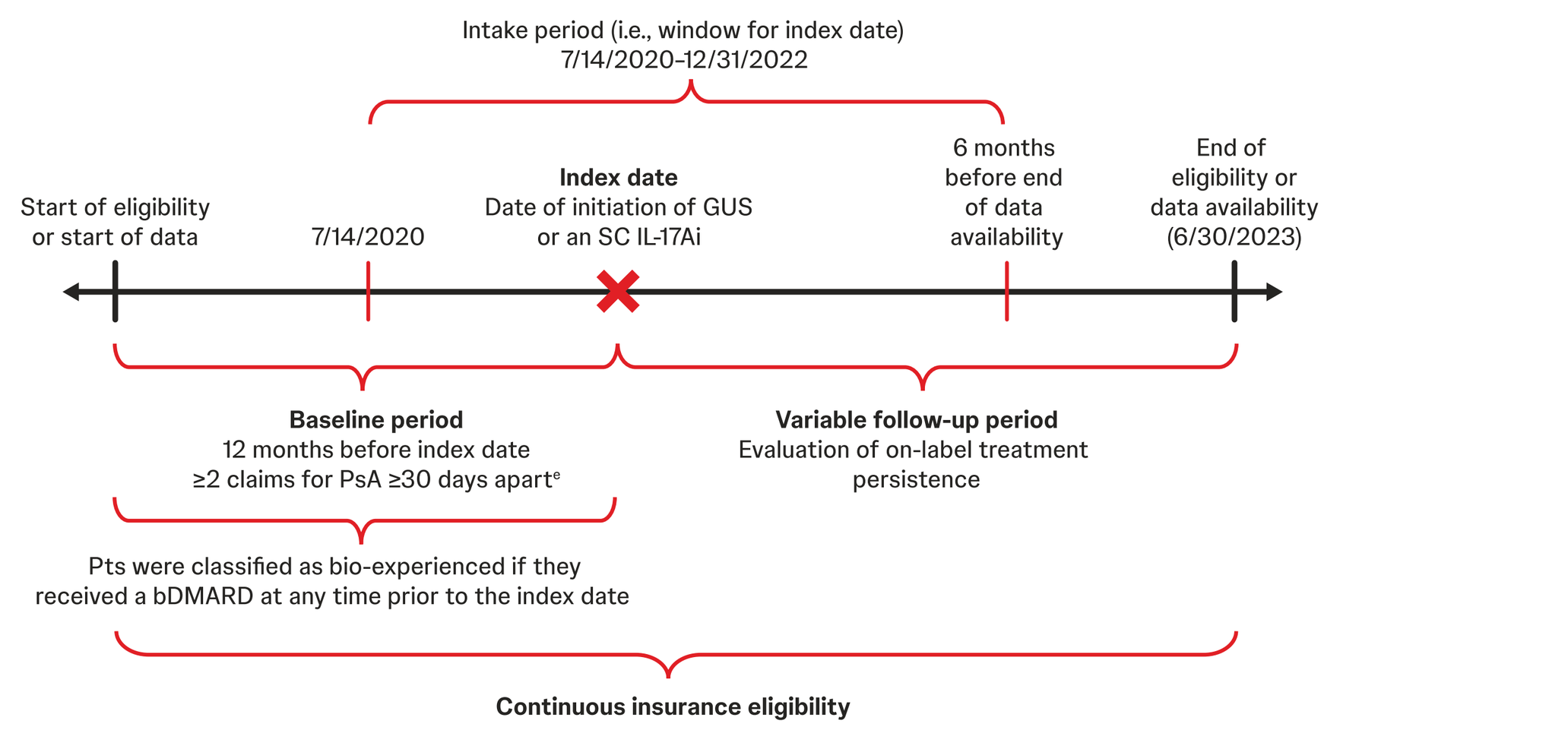
- Guselkumab (GUS), a fully human interleukin (IL)-23 p19-subunit inhibitor, was approved by the US Food and Drug Administration (FDA) for the treatment of active psoriatic arthritis (PsA) in July 2020
  - FDA-approved dosing regimen[1] (on-label): GUS 100 mg at week 0, week 4, then every 8 weeks
- A previous claims-based analysis compared on-label persistence for patients (pts) with PsA initiating on-label treatment with GUS or their first subcutaneous (SC) IL-17A inhibitor (IL-17Ai)[2,3]
  - Pts receiving GUS were significantly (~1.5x) more likely to remain persistent through 24 months
- However, real-world evidence comparing long-term on-label persistence between biologic-naïve (bio-naïve) and biologic-experienced (bio-experienced) populations with active PsA receiving GUS or SC IL-17Ai is still lacking

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 newly initiating on-label therapy with either GUS or an initial SC IL-17Ai

Methods

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


Intake period (i.e., window for index date)
7/14/2020-12/31/2022
Start of eligibility or start of data
7/14/2020
Index date
Date of initiation of GUS or an SC IL-17Ai
6 months before end of data availability
End of eligibility or data availability (6/30/2023)
Baseline period
12 months before index date
≥2 claims for PsA ≥30 days apart[e]
Variable follow-up period
Evaluation of on-label treatment persistence
Pts were classified as bio-experienced if they received a bDMARD at any time prior to the index date
Continuous insurance eligibility

[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 IL-17Ai). [c]Pts could be bio-naïve or bio-experienced during baseline but were naïve to treatment with GUS or SC IL-17Ai agents. [d]Pts in the SC IL-17Ai cohort were newly initiated within the class. [e]Diagnoses for PsA include claims on the index date. **bDMARD**=biological disease-modifying antirheumatic drug, **GUS**=guselkumab; **ICD-10-CM**=International Classification of Disease, 10th revision, Clinical Modification, **IL-17Ai**=interleukin-17A inhibitor, **PsA**=psoriatic arthritis, **Pts**=patients, **SC**=subcutaneous, **US**=United States.

Patient Selection

- Index date: 1st GUS or SC IL-17Ai claim during intake period (7/14/2020-12/31/2022)[a]
- PsA pt identification: ≥2 PsA diagnoses (International Classification of Disease, 10th revision, Clinical Modification [ICD-10-CM] code L40.5x) ≥30 days apart within 12 months prior to or on the index date, and ≥1 claim for either GUS or first SC IL-17Ai[4]
- ≥12 months of continuous health insurance eligibility before index date
- ≥18 years of age
- No claims for other conditions for which GUS or IL-17Ai 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]Patients could not have claims for >1 index agent on the index date. [b]Patients 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.

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 IL-17Ai
Medical claims[1,5,6]		
1st claim	28 days	N/A[b]
2nd + claims	56 days	N/A[b]
Pharmacy claims		
1st claim	28 days	No imputation[c]
2nd + claims	Based on time to next claim[a]	No imputation[c]

[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 >60. [b]There is no Healthcare Common Procedure Coding System code for SC IL-17Ai in medical claims. [c]Pharmacy claims for SC IL-17Ai are typically consistent with approved labeling; therefore, reported days supply was used for SC IL-17Ai and no imputation was performed. **GUS**=guselkumab, **IL-17Ai**=interleukin-17A inhibitor, **N/A**=not applicable, **SC**=subcutaneous.

Statistical Analyses

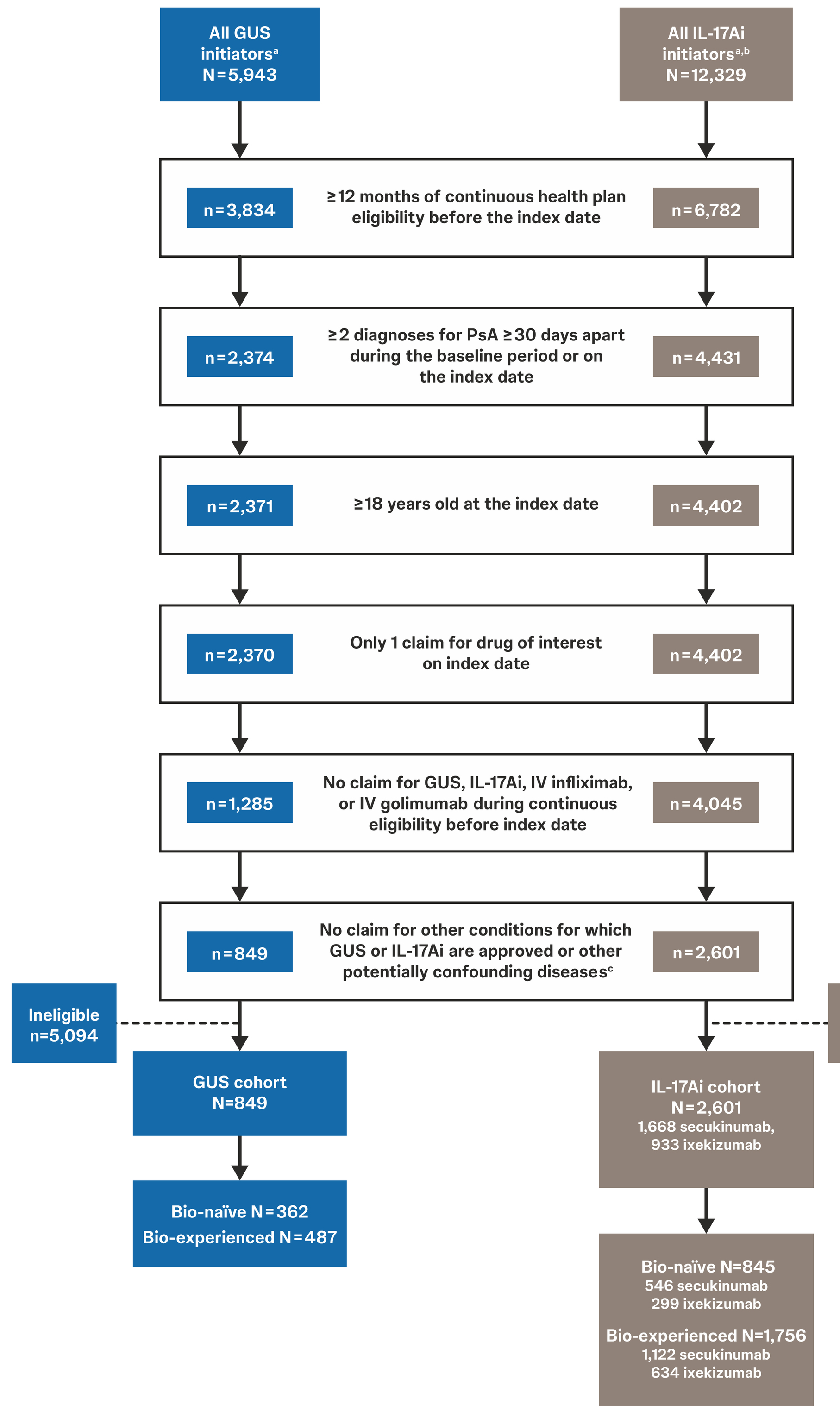
- **Baseline demographic and disease characteristics (12 months pre-index):**
  - Balanced between the GUS and SC IL-17Ai cohorts separately for bio-naïve and bio-experienced pts ***using propensity score weighting (overlap weights)***
- **On-label persistence up to 24 months post-index:**
  - No treatment discontinuation or dose modification relative to US FDA-approved labeling
  - Proportion of pts determined using ***weighted*** Kaplan-Meier curves
  - GUS vs SC IL-17Ai cohorts compared using ***weighted*** Cox proportional hazard models

Days between administrations[a]	GUS	SC IL-17Ai
Primary analysis		
2x[1,5,6]	112 days	56 days
Sensitivity analyses		
1x[1,5,6]	56 days	28 days
Fixed gap	112 days	112 days

[a]Primary analysis was conducted based on 2x the FDA maintenance interval between administration per label after induction. Sensitivity analyses were conducted based on 1x the FDA maintenance interval between administration per label after induction as well as a fixed discontinuation gap of 112 days. **GUS**=guselkumab, **IL-17Ai**=interleukin-17A inhibitor, **SC**=subcutaneous.

Results

The GUS and SC IL-17Ai cohorts, respectively, included 362 and 845 bio-naïve pts and 487 and 1,756 bio-experienced pts


All GUS initiators[a] N=5,943
All IL-17Ai initiators[a,b] N=12,329
n=3,834
≥12 months of continuous health plan eligibility before the index date
n=6,782
n=2,374
≥2 diagnoses for PsA ≥30 days apart during the baseline period or on the index date
n=4,431
n=2,371
≥18 years old at the index date
n=4,402
n=2,370
Only 1 claim for drug of interest on index date
n=4,402
n=1,285
No claim for GUS, IL-17Ai, IV infliximab, or IV golimumab during continuous eligibility before index date
n=4,045
n=849
No claim for other conditions for which GUS or IL-17Ai are approved or other potentially confounding diseases[c]
n=2,601
Ineligible n=5,094
Ineligible n=9,728
GUS cohort N=849
IL-17Ai cohort N=2,601
1,668 secukinumab, 933 ixekizumab
Bio-naïve N=362
Bio-experienced N=487
Bio-naïve N=845
546 secukinumab
299 ixekizumab
Bio-experienced N=1,756
1,122 secukinumab
634 ixekizumab

[a]1st GUS or SC IL-17Ai claim during intake period (7/14/2020-12/31/2022). [b]The SC IL-17Ai cohort is defined as pts with an index claim for an SC IL-17Ai (ie, ixekinumab or secukinumab). [c]Assessed during the 12-month baseline period. **GUS**=guselkumab, **IL-17Ai**=interleukin-17A inhibitor, **IV**=intravenous, **PsA**=psoriatic arthritis, **Pts**=patients, **SC**=subcutaneous.

Weighted baseline demographic and clinical characteristics were similar between the GUS and SC IL-17Ai cohorts among bio-naïve and bio-experienced pts

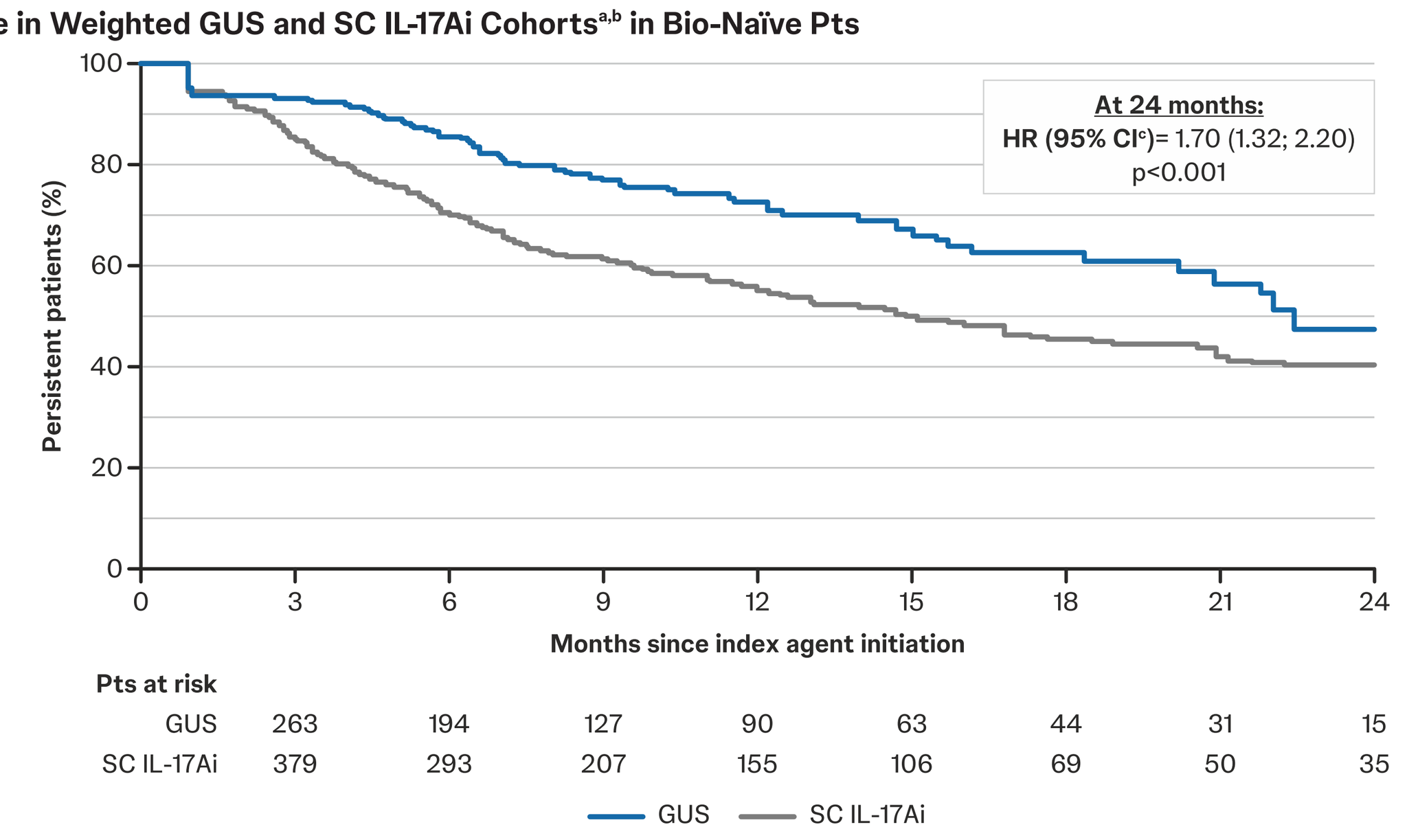
Weighted Baseline Demographics and Clinical Characteristics[a]	Bio-naïve GUS (N=362)	Bio-naïve SC IL-17Ai (N=845)	Bio-experienced GUS (N=487)	Bio-experienced SC IL-17Ai (N=1,756)
Demographics				
Age at index date (years), Mean ± SD [median]	49.5 ± 11.6 [50.8]	49.6 ± 11.9 [51.3]	49.7 ± 10.6 [50.7]	49.4 ± 11.0 [50.5]
Female	58.6	58.6	60.3	60.3
Insurance type at index date				
Preferred provider organization	77.7	77.7	78.5	78.5
Health maintenance organization	10.7	10.7	11.4	11.4
Other[b]	11.6	11.6	10.1	10.1
Year of index date				
2020	12.2	12.2	11.0	11.0
2021	40.2	40.2	39.2	39.2
2022	47.7	47.7	49.8	49.8
Characteristics				
Months between latest observed PsA diagnosis and index date, Mean ± SD [median]	1.4 ± 1.7 [0.8]	1.4 ± 1.6 [0.9]	1.2 ± 1.5 [0.7]	1.2 ± 1.3 [0.8]
Quan-CCI, Mean ± SD [median]	0.6 ± 1.2 [0.0]	0.6 ± 1.2 [0.0]	0.5 ± 1.2 [0.0]	0.6 ± 1.3 [0.0]
Comorbidities				
Hyperlipidemia	37.8	37.5	33.6	33.6
Osteoarthritis	27.8	29.2	29.9	29.9
Diabetes	15.7	14.3	13.6	14.6
Peripheral vascular disease	2.0	2.3	2.4	2.4
Psoriasis	89.2	89.2	81.3	81.3
Smoking	12.1	12.7	9.0	9.0
Medication Use[c]				
bDMARDs[d]	0	0	85.0	85.1
0	0	0	15.0	14.9
1	0	0	74.3	73.9
≥2	0	0	10.7	11.2
csDMARDs[e]	24.2	24.2	27.4	27.0
tsDMARDs[f]	29.4	29.2	16.7	16.3
Corticosteroids	71.6	68.5	72.4	74.0

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 the 12 months before index date. [d]Includes SC TNFi (i.e., adalimumab, etanercept, certolizumab pegol, and SC golimumab), 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). **bDMARD**=biological disease-modifying antirheumatic drug, **csDMARD**=conventional synthetic DMARD, **CTLA-4**=cytotoxic T-lymphocyte-associated protein 4, **GUS**=guselkumab, **IL-12**=interleukin-12, **IL-17Ai**=interleukin-17A inhibitor, **IL-23**=interleukin-23, **PsA**=psoriatic arthritis, **Quan-CCI**=Quan-Charlson Comorbidity Index, **SC**=subcutaneous, **SD**=standard deviation, **TNFi**=tumor necrosis factor inhibitor, **tsDMARD**=targeted synthetic DMARD.

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 SC IL-17Ai

- Bio-naïve pts:
  - **On-label persistence at 24 months:** 47.5% with GUS vs 40.3% with SC IL-17Ai
  - Sensitivity analyses for bio-naïve pts demonstrated similar trends
  - **Median time to discontinuation:** 22.4 months with GUS vs 14.9 months with SC IL-17Ai

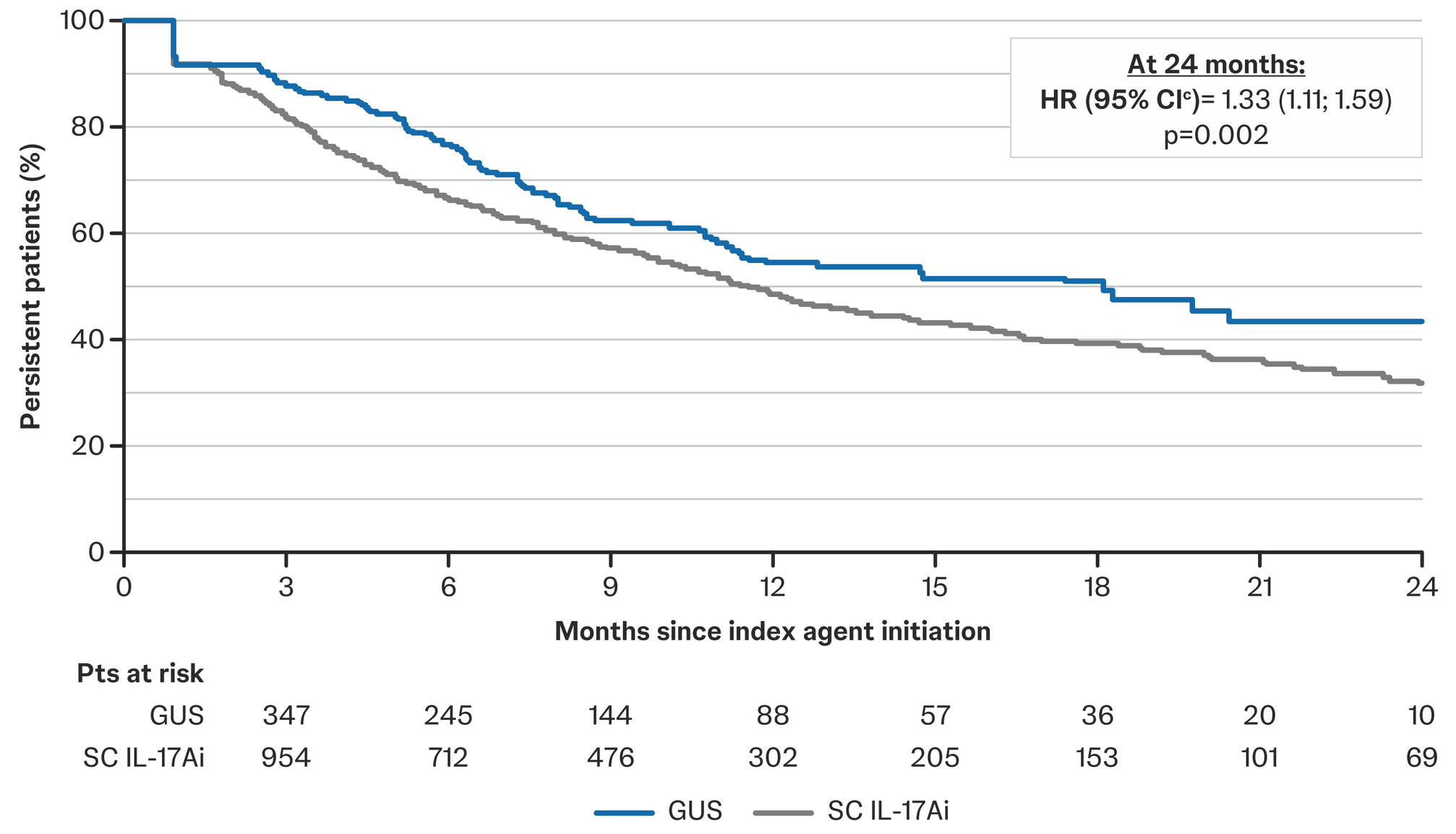
On-Label Persistence in Weighted GUS and SC IL-17Ai Cohorts[a,b] in Bio-Naïve Pts



Pts at risk	0	3	6	9	12	15	18	21	24
GUS		263	194	127	90	63	44	31	15
SC IL-17Ai		379	293	207	155	106	69	50	35

- Bio-experienced pts
  - **On-label persistence at 24 months:** 43.3% with GUS vs 32.0% with SC IL-17Ai
  - Sensitivity analyses for bio-experienced pts demonstrated similar trends
  - **Median time to discontinuation:** 18.1 months with GUS vs 11.6 months with SC IL-17Ai

On-Label Persistence in Weighted GUS and SC IL-17Ai Cohorts[a,b] in Bio-Experienced Pts



Pts at risk	0	3	6	9	12	15	18	21	24
GUS		347	245	144	88	57	36	20	10
SC IL-17Ai		954	712	476	302	205	153	101	69

[a]Primary analysis: discontinuation was defined as having a gap in treatment of more than 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 IL-17Ai). [b]Pts with dose changes inconsistent with FDA-approved dosing were censored as of the first dose change. [c]A weighted Cox proportional hazards model was used to compare on-label persistence between cohorts. **CI**=confidence interval, **GUS**=guselkumab, **HR**=hazard ratio, **IL-17Ai**=interleukin-17A inhibitor, **Pts**=patients, **SC**=subcutaneous.

In bio-naïve and bio-experienced pts, GUS was associated with significantly higher on-label persistence vs SC IL-17Ai at each time point assessed (6/12/18/24 months)

On-label persistence through 24 months in weighted GUS and SC IL-17Ai bio-naïve an 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=362)	194 (53.6)	90 (25.0)	44 (12.1)	15 (4.3)
SC IL-17Ai (N=845)	293 (34.7)	155 (18.3)	69 (8.2)	35 (4.2)
Hazard ratios (95% CI)	2.18 (1.54; 3.09)	1.92 (1.44; 2.55)	1.83 (1.40; 2.38)	1.70 (1.32; 2.20)
Chi-square p-value	<0.001	<0.001	<0.001	<0.001
KM Persistence, % (95% CI)				
GUS	85.7 (76.1; 91.6)	72.6 (62.8; 80.3)	62.6 (50.1; 72.8)	47.5 (22.7; 68.7)
SC IL-17Ai	70.6 (63.2; 76.8)	55.2 (46.0; 63.4)	45.2 (33.6; 56.1)	40.3 (26.2; 54.0)
Log-rank test p-value	<0.001	<0.001	<0.001	<0.001
Bio-experienced cohorts				
Pts at risk, n (%)[c]				
GUS (N=487)	245 (50.2)	88 (18.1)	36 (7.5)	10 (2.1)
SC IL-17Ai (N=1,756)	712 (40.6)	302 (17.2)	153 (8.7)	69 (3.9)
Hazard ratios (95% CI)	1.52 (1.21; 1.90)	1.28 (1.07; 1.54)	1.34 (1.12; 1.61)	1.33 (1.11; 1.59)
Chi-square p-value	<0.001	0.007	0.001	0.002
KM Persistence, % (95% CI)				
GUS	76.7 (69.3; 82.6)	54.4 (45.2; 62.7)	51.0 (40.6; 60.5)	43.3 (26.1; 59.3)
SC IL-17Ai	67.1 (62.5; 71.3)	48.6 (42.6; 54.3)	39.3 (31.9; 46.6)	32.0 (22.1; 42.3)
Log-rank test p-value	<0.001	0.010	0.002	0.002

[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 IL-17Ai cohorts. [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. **CI**=confidence interval, **GUS**=guselkumab, **IL-17Ai**=interleukin-17A inhibitor, **KM**=Kaplan-Meier, **Pts**=patients, **SC**=subcutaneous.

Strengths and Limitations

- Strengths:
  - A case-finding algorithm validated in US claims data was used to identify pts with active PsA[4]
  - Baseline demographic and disease characteristics between the GUS and SC IL-17Ai cohorts were balanced
- Limitations:
  - Claims data do not ensure treatments are taken as prescribed
  - Claims data do not provide treatment effectiveness nor reasons for discontinuation

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REFERENCES: 1. Tremfya: Package insert. Janssen Biotech, Inc.; 2022. **2.** Mease et al., *Adv Ther* 2024; submitted. **3.** Mease et al. Presented at: CCR-West, San Diego, CA September 26–29, 2024. **4.** Lee H. *Pharmacoepidemiol Drug Saf.* 2020;29:404–8. **5.** Cosentyx: Package insert. Novartis.; 2023. **6.** Taltz: Package insert. Eli Lilly.; 2022. **7.** Fitzgerald T. *Dermatol Ther.* 2023;13:1053–68.
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