Sponsor
Novartis Pharmaceuticals

Generic Drug Name
Secukinumab

Trial Indication(s)
Psoriasis

Protocol Number
CAIN457AUS28

Protocol Title
Characteristics, treatment patterns, and treatment satisfaction among psoriasis patients treated with Cosentyx (secukinumab)

Clinical Trial Phase
NA

Phase of Drug Development
NA

Study Start/End Dates
Study start date: 03/02/2021

Study Completion date: 31/03/2021

Reason for Termination

NA

Study Design/Methodology

This was a retrospective cohort study utilizing data from Modernizing Medicine Data Services' (MMDS) electronic medical records (EMR)-based dermatology database to evaluate secukinumab patient characteristics, treatment patterns, and outcomes. Psoriasis patients initiating secukinumab were identified and indexed to the first secukinumab use using the most recent data at study initiation (data period: March 1, 2018 to August 31, 2019) and with a subsequent data refresh (data period: March 1, 2017 – July 31, 2020).

Centers

Novartis Investigative Site

Objectives:

Primary objective(s)

- To assess improvement in patient-reported satisfaction with treatment effectiveness in PsO patients initiating secukinumab in overall and in the following subgroups:
    a. Bio-naive vs bio-experienced (pre-index) PsO patients initiating treatment with secukinumab
        i. Bio-naïve was defined as no observed treatment (i.e., injection, prescription or patient reported history) with any of the following biologic drugs of interest anytime pre-index: secukinumab, certolizumab, etanercept, adalimumab, infliximab, golimumab, ustekinumab, ixekizumab, brodalumab, abatacept, and guselkumab and risankizumab during all available history. Conversely, bio-experienced patients had pre-index use of one or more of the biologic drugs of interest during all available history
    b. Systemic-naive vs Systemic-experienced PsO patients initiating treatment with secukinumab
        i. Systemic-naïve was defined as no observed treatment (i.e., injection, prescription or patient reported history) with any of the biologic treatments listed above or with any of the following systemic (i.e., oral or injectable – no topical forms) drugs of interest pre-index: methotrexate, corticosteroids, acitretin or apremilast. Conversely, systemic-experienced patients had pre-index use of one or more of the systemic drugs of interest

c. Patients initiating secukinumab within 6 months after the PsO diagnosis vs more than 6 months after the PsO diagnosis

Secondary objective(s)

- To describe post-index (*6-month)* treatment patterns, clinical outcomes and patient report outcomes (PROs) including physician global assessment (PGA) and body surface area (BSA) in the overall sample and following subgroups:
  a. Bio-naive vs bio-experienced PsO patients initiating treatment with secukinumab
  b. Systemic-naive vs Systemic-experienced PsO patients initiating treatment with secukinumab
  c. Patients initiating secukinumab within 6 months after the PsO diagnosis vs more than 6 months after the PsO diagnosis

Test Product (s), Dose(s), and Mode(s) of Administration

NA

Statistical Methods

All analyses were performed by IQVIA. Measures including binary, categorical and continuous variables were reported using descriptive statistics. For continuous variables: mean, median, interquartile range, and standard deviation were generated as measures of central tendency and variance. For categorical variables, we used cross tabulation in count (frequency) and percentage to contrast such differences. 95% confidence intervals around mean changes in outcomes of interest (i.e., PGA, BSA, patient satisfaction at baseline vs. post treatment) were provided.

Multivariable logistic regression models were conducted to assess significant determinants of improved PsO outcomes (patient treatment satisfaction, PGA, BSA, PGA*BSA), respectively.

Study Population: Key Inclusion/Exclusion Criteria

Inclusion criteria

- ≥1 orders/administrations for secukinumab within the index window (March 1, 2018 to August 31,2019 for the base analysis; March 1, 2018 to January 31, 2020 for the refresh analysis). The date of the first order or administration was be the index date
- Patients in the MMDS database with a diagnosis of PsO on or prior to the 1st secukinumab order/administration

- ≥18 years of age as of the index date
- To ensure capturing continuous patient activities in the EMR dataset, patients must have at least one more visit (any visit regardless of diagnosis) in addition to the index visit within the first 6 months after secukinumab initiation
- Patients must have at least one visit (any visit regardless of diagnosis) within the 12 months pre-index period

Exclusion criteria

- Evidence of secukinumab use in the 12-month pre-index period
- Data quality issues (missing age, gender, prescription order information)

Participant Flow

A total of 17,743 patients meeting the inclusion and exclusion criteria were identified from the MMDS EMR database for the refreshed analysis, of which, 9,743 were biologic naïve, 7,991 were biological experienced, 7004 were systemic naïve and 10,730 were systemic experienced. In terms of treatment satisfaction score, 3,680 patients had ≥1 treatment satisfaction score at baseline or pre-index 12 month and 766 had at least 1 score at 6 month post index in additional to ≥ 1 score at baseline

Baseline Characteristics

Baseline characteristics are reported in the secondary outcomes section

Primary Outcome Result(s)

Treatment satisfaction at Baseline

Treatment satisfaction (n, %)	3,680	20.75%	1,571	16.12%	2,109	26.39%	861	12.29%	2,819	26.27%
1 = strongly agree	1,109	30.14%	396	25.21%	713	33.81%	243	28.22%	866	30.72%
2 = somewhat agree	1,056	28.70%	464	29.54%	592	28.07%	239	27.76%	817	28.98%
3 = Neither agree nor disagree	517	14.05%	264	16.80%	253	12.00%	146	16.96%	371	13.16%
4 = Somewhat disagree	518	14.08%	240	15.28%	278	13.18%	121	14.05%	397	14.08%
5 = Strongly disagree	480	13.04%	207	13.18%	273	12.94%	112	13.01%	368	13.05%

Mean (among those with available measure)	2.51		2.62		2.43		2.56		2.50	
SD	1.38		1.36		1.40		1.37		1.39	

Treatment satisfaction at 6 months post-index

	Overall cohort		**Biologic-naïve**		**Biologic-experienced**		**Systemic Naïve**		**Systemic experienced**	
	(N=766)		**(N= 331)**		**(N=435)**		**(N= 183)**		**(N=583)**	
Treatment satisfaction (n, %)	766	100.00%	331	100.00%	435	100.00%	183	100.00%	583	100.00%
1 = strongly agree	231	30.16%	85	25.68%	146	33.56%	55	30.05%	176	30.19%
2 = somewhat agree	218	28.46%	93	28.10%	125	28.74%	51	27.87%	167	28.64%
3 = Neither agree nor disagree	115	15.01%	63	19.03%	52	11.95%	32	17.49%	83	14.24%
4 = Somewhat disagree	111	14.49%	54	16.31%	57	13.10%	26	14.21%	85	14.58%
5 = Strongly disagree	91	11.88%	36	10.88%	55	12.64%	19	10.38%	72	12.35%
Mean (among those with available measure)	2.49		2.59		2.43		2.47		2.50	
SD	1.36		1.32		1.39		1.33		1.37	

Secondary Outcomes Result(s)

Baseline Demographics in the 12-Month Pre-Index Period

	Overall cohort		**Biologic-naïve**		**Biologic experienced**		**Systemic naïve**		**Systemic experienced**	
	(N=17,734)		**(N=9,743)**		**(N=7,991)**		**(N=7,004)**		**(N=10,730)**	
Characteristic	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Age Group (n, %)										
18-34 years	3,355	18.92%	1,893	19.43%	1,462	18.30%	1,436	20.50%	1,919	17.88%

35-44 years	3,310	18.66%	1,850	18.99%	1,460	18.27%	1,345	19.20%	1,965	18.31%
45-54 years	4,251	23.97%	2,288	23.48%	1,963	24.57%	1,649	23.54%	2,602	24.25%
55-64 years	4,012	22.62%	2,130	21.86%	1,882	23.55%	1,515	21.63%	2,497	23.27%
65-74 years	2,267	12.78%	1,274	13.08%	993	12.43%	856	12.22%	1,411	13.15%
75+ years	539	3.04%	308	3.16%	231	2.89%	203	2.90%	336	3.13%
Age (years)										
mean	49.7		49.6		49.9		49.1		50.2	
SD	14.7		14.9		14.4		14.9		14.6	
Gender (n, %)										
Male	8,646	48.75%	4,748	48.73%	3,898	48.78%	3,486	49.77%	5,160	48.09%
Female	9,088	51.25%	4,995	51.27%	4,093	51.22%	3,518	50.23%	5,570	51.91%
Region (n, %)										
Northeast	2,725	15.37%	1,411	14.48%	1,314	16.44%	998	14.25%	1,727	16.10%
Midwest	3,442	19.41%	1,895	19.45%	1,547	19.36%	1,327	18.95%	2,115	19.71%
South	8,064	45.47%	4,584	47.05%	3,480	43.55%	3,367	48.07%	4,697	43.77%
West	3,470	19.57%	1,833	18.81%	1,637	20.49%	1,295	18.49%	2,175	20.27%
Unknown	33	0.19%	20	0.21%	13	0.16%	17	0.24%	16	0.15%
Race (n, %)										
White	9,526	53.72%	4,960	50.91%	4,566	57.14%	3,444	49.17%	6,082	56.68%
Non-white/unknown	8,208	46.28%	4,783	49.09%	3,425	42.86%	3,560	50.83%	4,648	43.32%
Weight (kg)	2,931	16.53%	1,508	15.48%	1,423	17.81%	1,065	15.21%	1,866	17.39%
mean	92.5		91.5		93.6		91.9		92.9	
SD	23.8		23.2		24.4		23.3		24.1	
Index year (n, %)										
2018	6,463	36.44%	3,457	35.48%	3,006	37.62%	2,519	35.97%	3,944	36.76%
2019	10,176	57.38%	5,658	58.07%	4,518	56.54%	4,034	57.60%	6,142	57.24%
2020	1,095	6.17%	628	6.45%	467	5.84%	451	6.44%	644	6.00%

Baseline Demographics in the 12-Month Pre-Index Period among the subset with pre/post satisfaction scores at 6 months post-index

Characteristic	Overall cohort (N=766)		Biologic-naïve (N= 331)		Biologic experienced (N=435)		Systemic naïve (N= 183)		Systemic experienced (N=583)	
	n	%	n	%	n	%	n	%	n	%
Gender (n, %)										
Male	360	47.00%	160	48.34%	200	45.98%	86	46.99%	274	47.00%
Female	406	53.00%	171	51.66%	235	54.02%	97	53.01%	309	53.00%
Region (n, %)										
Northeast	81	10.57%	31	9.37%	50	11.49%	15	8.20%	66	11.32%
Midwest	161	21.02%	75	22.66%	86	19.77%	38	20.77%	123	21.10%
South	364	47.52%	155	46.83%	209	48.05%	89	48.63%	275	47.17%
West	160	20.89%	70	21.15%	90	20.69%	41	22.40%	119	20.41%
Race (n, %)										
White	437	57.05%	186	56.19%	251	57.70%	102	55.74%	335	57.46%
Non-white/unknown	329	42.95%	145	43.81%	184	42.30%	81	44.26%	248	42.54%
Weight (kg)	132	17.23%	55	16.62%	77	17.70%	31	16.94%	101	17.32%
mean	93.1		94.5		92.1		89.8		94.1	
SD	23.6		24.5		23.1		22.5		24.0	
Index year (n, %)										
2018	316	41.25%	124	37.46%	192	44.14%	71	38.80%	245	42.02%
2019	396	51.70%	182	54.98%	214	49.20%	100	54.64%	296	50.77%
2020	54	7.05%	25	7.55%	29	6.67%	12	6.56%	42	7.20%

Among the overall patients (N=17,734), 7,410 (41.78%), and 10,000 (56.39%) had PGA, and BSA assessment scores during the 12-month pre-index period (including index date).Mean (SD) PGA and BSA were 2.72 (1.13) and 19.65 (20.59), respectively. Almost half of patients

with an available PGA measure (43.77%) had moderate psoriasis severity based on physician global assessment (PGA), followed by severe psoriasis severity (25.30%), mild severity (14.75%), almost clear (9.91%) and clear (6.28%).

Psoriasis-related therapy measured in the12 months pre-index period (not including index date): the majority (64.90%) used topical therapy, followed by biologics (30.82%), Apremilast (PDE 4 inhibitor) (8.40%), methotrexate (7.37%), corticosteroids (6.29%), phototherapy and Psoralen plus ultraviolet A photochemotherapy (PUVA) (2.50%), Other systemic plaque psoriasis therapy (Acitretin) (1.08%), and NSAID/Salicylates (0.38%).

Clinical Characteristics in the 12-Month Pre-Index Period

	Overall cohort		**Biologic-naïve**		**Biologic experienced**		**Systemic Naïve**		**Systemic experienced**	
	(N=17,734)		**(N=9,743)**		**(N=7,991)**		**(N=7,004)**		**(N=10,730)**	
Characteristic	n	%	n	%	n	%	n	%	n	%
Psoriasis subtype, not mutually exclusive (n, %)										
ACRODERMATITIS CONTINUA	-	-	-	-	-	-	-	-	-	-
DERMATITIS REPENS	-	-	-	-	-	-	-	-	-	-
ERYTHRODERMIC PSORIASIS	16	0.09%	12	0.12%	-	-	-	-	10	0.09%
GENERALIZED PLAQUE PSORIASIS	2,571	14.50%	1,405	14.42%	1,166	14.59%	1,026	14.65%	1,545	14.40%
GUTTATE PSORIASIS	262	1.48%	185	1.90%	77	0.96%	133	1.90%	129	1.20%
INVERSE PSORIASIS	262	1.48%	172	1.77%	90	1.13%	128	1.83%	134	1.25%
LOCALIZED PLAQUE PSORIASIS	337	1.90%	195	2.00%	142	1.78%	135	1.93%	202	1.88%
LOCALIZED SCALP PSORIASIS	270	1.52%	172	1.77%	98	1.23%	132	1.88%	138	1.29%
NAIL PSORIASIS	185	1.04%	109	1.12%	76	0.95%	79	1.13%	106	0.99%
OSTRACEOUS PSORIASIS	-	-	-	0.00%	-	-	-	-	-	-
PALMOPLANTAR PSORIASIS	280	1.58%	176	1.81%	104	1.30%	97	1.38%	183	1.71%
PALMOPLANTAR PUSTULOSIS	15	0.08%	-	-	-	-	-	-	-	-
PSORIASIFORM DERMATITIS	38	0.21%	28	0.29%	10	0.13%	19	0.27%	19	0.18%
PSORIASIS VULGARIS	1,214	6.85%	675	6.93%	539	6.75%	528	7.54%	686	6.39%

PUSTULAR PSORIASIS	64	0.36%	35	0.36%	29	0.36%	21	0.30%	43	0.40%
PSORIASIS	12,826	72.32%	6,947	71.30%	5,879	73.57%	4,979	71.09%	7,847	73.13%
Plaque psoriasis with unknown subtype during 12 months pre-index (including index date)	91	0.51%	41	0.42%	50	0.63%	30	0.43%	61	0.57%
Plaque location, not mutually exclusive (n, %)										
Hand (includes hand, finger, wrist)	1,466	8.27%	785	8.06%	681	8.52%	512	7.31%	954	8.89%
Arm	4,799	27.06%	2,556	26.23%	2,243	28.07%	1,737	24.80%	3,062	28.54%
Leg (includes feet, toe)	5,096	28.74%	2,710	27.81%	2,386	29.86%	1,835	26.20%	3,261	30.39%
Trunk	4,901	27.64%	2,644	27.14%	2,257	28.24%	1,833	26.17%	3,068	28.59%
Scalp	2,444	13.78%	1,376	14.12%	1,068	13.37%	949	13.55%	1,495	13.93%
Head and neck (includes face, ear, eyelid, nose, lip)	1,679	9.47%	949	9.74%	730	9.14%	633	9.04%	1,046	9.75%
Axillae	52	0.29%	35	0.36%	17	0.21%	23	0.33%	29	0.27%
Nail	125	0.70%	74	0.76%	51	0.64%	52	0.74%	73	0.68%
Genitalia	113	0.64%	74	0.76%	39	0.49%	53	0.76%	60	0.56%
Others†	130	0.73%	73	0.75%	57	0.71%	57	0.81%	73	0.68%
Unknown	9,065	51.12%	5,034	51.67%	4,031	50.44%	3,715	53.04%	5,350	49.86%
Psoriasis severity§										
Physician global assessment (PGA) (n, %)	7,410	41.78%	3,783	38.83%	3,627	45.39%	2,527	36.08%	4,883	45.51%
0 = clear	465	6.28%	198	5.23%	267	7.36%	155	6.13%	310	6.35%
1 = almost clear	734	9.91%	287	7.59%	447	12.32%	198	7.84%	536	10.98%
2 = mild	1,093	14.75%	451	11.92%	642	17.70%	275	10.88%	818	16.75%
3 = moderate	3,243	43.77%	1,746	46.15%	1,497	41.27%	1,129	44.68%	2,114	43.29%
4 = severe	1,875	25.30%	1,101	29.10%	774	21.34%	770	30.47%	1,105	22.63%
Mean (among those with available measure)	2.72		2.86		2.57		2.86		2.65	
SD	1.13		1.08		1.17		1.12		1.13	
Patient-reported global assessment (n, %)	4,273	24.09%	1,920	19.71%	2,353	29.45%	1,093	15.61%	3,180	29.64%
0 = clear	248	5.80%	72	3.75%	176	7.48%	50	4.57%	198	6.23%
1 = almost clear	818	19.14%	295	15.36%	523	22.23%	164	15.00%	654	20.57%

2 = mild	972	22.75%	442	23.02%	530	22.52%	251	22.96%	721	22.67%
3 = moderate	1,653	38.68%	832	43.33%	821	34.89%	480	43.92%	1,173	36.89%
4 = severe	582	13.62%	279	14.53%	303	12.88%	148	13.54%	434	13.65%
Mean (among those with available measure)	2.35		2.50		2.23		2.47		2.31	
SD	1.11		1.04		1.15		1.05		1.13	
Total body surface area (TBSA) (n, %)	10,000	56.39%	5,281	54.20%	4,719	59.05%	3,627	51.78%	6,373	59.39%
<3% (mild)	1,246	12.46%	493	9.34%	753	15.96%	353	9.73%	893	14.01%
3–10% (moderate)	3,627	36.27%	1,818	34.43%	1,809	38.33%	1,232	33.97%	2,395	37.58%
>10% (severe)	5,127	51.27%	2,970	56.24%	2,157	45.71%	2,042	56.30%	3,085	48.41%
Mean, % (among those with available measure)	19.65		21.48		17.61		21.57		18.56	
SD	20.59		21.36		19.48		21.34		20.07	
Median	12.00		15.00		10.00		15.00		10.00	
PGA x TBSA^ (n, %)	5,518	31.12%	2,922	29.99%	2,596	32.49%	1,991	28.43%	3,527	32.87%
Mean (among those with available measures on the *same* visit)	62.43		69.66		54.30		69.84		58.25	
SD	75.07		78.24		70.46		77.38		73.41	
Comorbidities of interest in the entire study period (n, %)										
Anxiety	3,250	18.33%	1,753	17.99%	1,497	18.73%	1,262	18.02%	1,988	18.53%
Cerebrovascular disease (including hemorrhagic stroke and transient ischemic attack [TIA])	269	1.52%	147	1.51%	122	1.53%	99	1.41%	170	1.58%
Coronary heart disease	448	2.53%	257	2.64%	191	2.39%	169	2.41%	279	2.60%
Ankylosing spondylitis	-	-	-	-	-	-	-	-	-	-
Crohn's disease or Ulcerative colitis	-	-	-	-	-	-	-	-	-	-
Multiple sclerosis	-	-	-	-	-	-	-	-	-	-
Depression	2,725	15.37%	1,409	14.46%	1,316	16.47%	1,018	14.53%	1,707	15.91%
Diabetes	2,845	16.04%	1,469	15.08%	1,376	17.22%	1,076	15.36%	1,769	16.49%
Hypertension	5,205	29.35%	2,780	28.53%	2,425	30.35%	1,947	27.80%	3,258	30.36%
Hyperlipidemia	2,734	15.42%	1,448	14.86%	1,286	16.09%	1,010	14.42%	1,724	16.07%

Obesity	111	0.63%	48	0.49%	63	0.79%	33	0.47%	78	0.73%
Psoriatic Arthritis (PsA)	4,410	24.87%	2,124	21.80%	2,286	28.61%	1,523	21.74%	2,887	26.91%
Rheumatoid arthritis	73	0.41%	44	0.45%	-	-	34	0.49%	39	0.36%
Malignancies	2,155	12.15%	1,180	12.11%	975	12.20%	795	11.35%	1,360	12.67%
Peripheral vascular disease	-	-	-	-	-	-	-	-	-	-
Psoriasis-related therapy measured in 12 months pre-index NOT including index date (n, %)										
Biologics										
Overall (i.e., all bioligics)	5,466	30.82%	-	-	5,466	68.40%	-	-	5,466	50.94%
TNF inhibitors (certolizumab, etanercept, adalimumab, infliximab, golimumab)	3,290	60.19%			3,290	60.19%			3,290	60.19%
IL-17 inhibitors (ixekizumab, brodalumab)	717	13.12%			717	13.12%			717	13.12%
IL-12/23 inhibitor (ustekinumab)	1,481	27.09%			1,481	27.09%			1,481	27.09%
IL-23 inhibitor (guselkumab, risankizumab)	693	12.68%			693	12.68%			693	12.68%
T cell inhibitor (abatacept)	-	-			-	-			-	-
Methotrexate	1,307	7.37%	669	6.87%	638	7.98%	-	-	1,307	12.18%
Corticosteroids (oral/injection)	1,115	6.29%	559	5.74%	556	6.96%	-	-	1,115	10.39%
Topical therapy	11,509	64.90%	5,909	60.65%	5,600	70.08%	3,680	52.54%	7,829	72.96%
Phototherapy and Psoralen plus ultraviolet A photochemotherapy (PUVA)	444	2.50%	270	2.77%	174	2.18%	162	2.31%	282	2.63%
NSAID/Salicylates	-	-	24	0.25%	-	-	16	0.23%	-	-
Other systemic plaque psoriasis therapy (Acitretin)	192	1.08%	122	1.25%	70	0.88%	-	-	192	1.79%
Apremilast (PDE 4 inhibitor)	1,490	8.40%	962	9.87%	528	6.61%	-	-	1,490	13.89%

Clinical Characteristics in the 12-Month Pre-Index Period among the subset with pre/post satisfaction scores at 6 months post-index

	Overall cohort	**Biologic-naïve**	**Biologic-experienced**	**Systemic Naïve**	**Systemic experienced**
	(N=766)	**(N= 331)**	**(N=435)**	**(N= 183)**	**(N=583)**

Characteristic	n	%	n	%	n	%	n	%	n	%
Psoriasis subtype, not mutually exclusive (n, %)										
ACRODERMATITIS CONTINUA	-	-	-	-	-	-	-	-	-	-
DERMATITIS REPENS	-	-	-	-	-	-	-	-	-	-
ERYTHRODERMIC PSORIASIS	-	-	-	-	-	-	-	-	-	-
GENERALIZED PLAQUE PSORIASIS	105	13.71%	45	13.60%	60	13.79%	22	12.02%	83	14.24%
GUTTATE PSORIASIS	5	0.65%	-	-	-	-	-	-	5	0.86%
INVERSE PSORIASIS	10	1.31%	6	1.81%	-	-	-	-	7	1.20%
LOCALIZED PLAQUE PSORIASIS	19	2.48%	10	3.02%	9	2.07%	-	-	16	2.74%
LOCALIZED SCALP PSORIASIS	16	2.09%	8	2.42%	8	1.84%	5	2.73%	11	1.89%
NAIL PSORIASIS	-	-	-	-	-	-	-	-	-	-
OSTRACEOUS PSORIASIS	-	-	-	-	-	-	-	-	-	-
PALMOPLANTAR PSORIASIS	18	2.35%	12	3.63%	6	1.38%	5	2.73%	13	2.23%
PALMOPLANTAR PUSTULOSIS	-	-	-	-	-	-	-	-	-	-
PSORIASIFORM DERMATITIS	-	-	-	-	-	-	-	-	-	-
PSORIASIS VULGARIS	55	7.18%	23	6.95%	32	7.36%	12	6.56%	43	7.38%
PUSTULAR PSORIASIS	-	-	-	-	-	-	-	-	-	-
PSORIASIS	559	72.98%	237	71.60%	322	74.02%	140	76.50%	419	71.87%
Plaque psoriasis with unknown subtype during 12 months pre-index (including index date)	-	-	-	-	-	-	-	-	-	-
Plaque location, not mutually exclusive (n, %)										
Hand (includes hand, finger, wrist)	70	9.14%	30	9.06%	40	9.20%	12	6.56%	58	9.95%
Arm	194	25.33%	86	25.98%	108	24.83%	37	20.22%	157	26.93%
Leg (includes feet, toe)	215	28.07%	97	29.31%	118	27.13%	46	25.14%	169	28.99%
Trunk	172	22.45%	76	22.96%	96	22.07%	37	20.22%	135	23.16%
Scalp	106	13.84%	50	15.11%	56	12.87%	28	15.30%	78	13.38%

Head and neck (includes face, ear, eyelid, nose, lip)	73	9.53%	36	10.88%	37	8.51%	16	8.74%	57	9.78%
Axillae	-	-	-	-	-	-	-	-	-	-
Nail	8	1.04%	-	-	-	-	-	-	6	1.03%
Genitalia	-	-	-	-	-	-	-	-	-	-
Others†	-	-	-	-	-	-	-	-	-	-
Unknown	434	56.66%	192	58.01%	242	55.63%	115	62.84%	319	54.72%
Psoriasis severity										
Physician global assessment (PGA) (n, %)	448	58.49%	188	56.80%	260	59.77%	97	53.01%	351	60.21%
0 = clear	28	6.25%	12	6.38%	16	6.15%	10	10.31%	18	5.13%
1 = almost clear	59	13.17%	18	9.57%	41	15.77%	11	11.34%	48	13.68%
2 = mild	82	18.30%	30	15.96%	52	20.00%	14	14.43%	68	19.37%
3 = moderate	186	41.52%	91	48.40%	95	36.54%	47	48.45%	139	39.60%
4 = severe	93	20.76%	37	19.68%	56	21.54%	15	15.46%	78	22.22%
Mean (among those with available measure)	2.57		2.65		2.52		2.47		2.60	
SD	1.14		1.10		1.17		1.19		1.13	
Median	3.00		3.00		3.00		3.00		3.00	
Patient-reported global assessment (n, %)	694	90.60%	297	89.73%	397	91.26%	164	89.62%	530	90.91%
0 = clear	40	5.76%	12	4.04%	28	7.05%	9	5.49%	31	5.85%
1 = almost clear	132	19.02%	45	15.15%	87	21.91%	22	13.41%	110	20.75%
2 = mild	167	24.06%	74	24.92%	93	23.43%	49	29.88%	118	22.26%
3 = moderate	252	36.31%	117	39.39%	135	34.01%	60	36.59%	192	36.23%
4 = severe	103	14.84%	49	16.50%	54	13.60%	24	14.63%	79	14.91%
Mean (among those with available measure)	2.35		2.49		2.25		2.41		2.34	
SD	1.12		1.06		1.15		1.07		1.14	
Total body surface area (TBSA) (n, %)	493	64.36%	202	61.03%	291	66.90%	103	56.28%	390	66.90%
<3% (mild)	79	16.02%	24	11.88%	55	18.90%	14	13.59%	65	16.67%
3–10% (moderate)	171	34.69%	64	31.68%	107	36.77%	37	35.92%	134	34.36%
>10% (severe)	243	49.29%	114	56.44%	129	44.33%	52	50.49%	191	48.97%

Mean, % (among those with available measure)	17.99		19.56		16.90		17.09		18.23	
SD	19.40		19.52		19.28		18.19		19.73	
PGA x TBSA (n, %)	304	39.69%	125	37.76%	179	41.15%	63	34.43%	241	41.34%
Mean (among those with available measure)	57.04		52.62		60.12		43.92		60.47	
SD	73.86		57.11		83.61		43.19		79.68	
Comorbidities of interest in the entire study period (n, %)										
Anxiety	123	16.06%	51	15.41%	72	16.55%	23	12.57%	100	17.15%
Cerebrovascular disease (including hemorrhagic stroke and transient ischemic attack [TIA])	15	1.96%	7	2.11%	-	-	-	-	11	1.89%
Coronary heart disease	21	2.74%	11	3.32%	10	2.30%	5	2.73%	16	2.74%
Ankylosing spondylitis	-	-	-	-	-	-	-	-	-	-
Crohn's disease or Ulcerative colitis	-	-	-	-	-	-	-	-	-	-
Multiple sclerosis	-	-	-	-	-	-	-	-	-	-
Depression	110	14.36%	54	16.31%	56	12.87%	25	13.66%	85	14.58%
Diabetes	138	18.02%	64	19.34%	74	17.01%	35	19.13%	103	17.67%
Hypertension	261	34.07%	113	34.14%	148	34.02%	56	30.60%	205	35.16%
Hyperlipidemia	123	16.06%	53	16.01%	70	16.09%	24	13.11%	99	16.98%
Obesity	-	-	-	-	-	-	-	-	-	-
Psoriatic Arthritis (PsA)	198	25.85%	78	23.56%	120	27.59%	42	22.95%	156	26.76%
Rheumatoid arthritis	-	-	-	-	-	-	-	-	-	-
Malignancies	91	11.88%	31	9.37%	60	13.79%	17	9.29%	74	12.69%
Peripheral vascular disease	-	-	-	-	-	-	-	-	-	-
Psoriasis-related therapy measured in 12 months pre-index NOT including index date (n, %)										
Biologics										
Overall (i.e., all bioligics)	345	45.04%	0	0.00%	345	79.31%	0	0.00%	345	59.18%

TNF inhibitors (certolizumab, etanercept, adalimumab, infliximab, golimumab)	211	61.16%			211	61.16%			211	61.16%
IL-17 inhibitors (ixekizumab, brodalumab)	39	11.30%			39	11.30%			39	11.30%
IL-12/23 inhibitor (ustekinumab)	103	29.86%			103	29.86%			103	29.86%
IL-23 inhibitor (guselkumab, risankizumab)	46	13.33%			46	13.33%			46	13.33%
T cell inhibitor (abatacept)	-	-			-	-			-	-
Methotrexate	86	11.23%	46	13.90%	40	9.20%	-	-	86	14.75%
Corticosteroids (oral/injection)	59	7.70%	24	7.25%	35	8.05%	-	-	59	10.12%
Topical therapy	600	78.33%	281	84.89%	319	73.33%	-	-	452	77.53%
Phototherapy and Psoralen plus ultraviolet A photochemotherapy (PUVA)	24	3.13%	14	4.23%	10	2.30%	-	-	23	3.95%
NSAID/Salicylates	-	-	-	-	-	-	-	-	-	-
Other systemic plaque psoriasis therapy (Acitretin)	15	1.96%	-	-	-	-	-	-	15	2.57%
Apremilast (PDE 4 inhibitor)	96	12.53%	56	16.92%	40	9.20%	-	-	96	16.47%

Safety Results
NA

Other Relevant Findings
None

Conclusion
This study provides real-world evidence that highlights high levels of sustained satisfaction with secukinumab treatment for improving and maintaining skin clearance in patients with moderate to severe disease, regardless of prior treatment experience.

Date of Clinical Study Report
January 31 2022