Sponsor
Novartis Pharmaceuticals

Generic Drug Name
Secukinumab

Trial Indication(s)
Psoriasis

Protocol Number
CAIN457AUS31

Protocol Title
Impact of Secukinumab on Clinical and Patient Reported Outcomes in Patients with Psoriasis in a Real World Setting in the US (Bionaive Secukinumab Users NVS 521)

Clinical Trial Phase
NA

Phase of Drug Development
NA

Study Start/End Dates
Study start date: 21/03/2021

Study Completion date: 31/08/2021

Reason for Termination

NA

Study Design/Methodology

This was a retrospective analysis of a prospective observational cohort using CorEvitas' PsO registry of adult PsO patients. This study described clinical and patient reported outcomes among adult patients initiating Secukinumab (SEC). Biologic experienced and naïve patients were examined separately. This study also described changes in clinical and patient reported outcomes over time.

CorEvitas' Psoriasis Registry is a prospective, observational cohort of adult PsO patients starting systemic therapy, launched in April 2015 with sites in the US and Canada. Data collection occurs every ~6 months at routine dermatology visits. This study included US PsO patients who initiated secukinumab at or after enrollment and had a subsequent 6- and/or 12-month follow-up visit (Apr 2015 to Dec 2020).The index date is defined as the date of the first SEC initiation at or after enrollment.

Centers

Novartis Investigative Site

Objectives:

Primary objective(s)

In Milestone 1, The objective was to characterize the demographics, disease characteristics, comorbidities, disease specific measures, patient reported outcomes (PROs), and reasons for initiation at baseline among PsO patients initiating SEC.

Secondary objective(s)

For Milestone 1:

- To characterize the demographics, disease characteristics, comorbidities, and patient reported outcomes (PROs) of the patients initiating SEC in the PsO Registry, stratified by prior exposure to biologic therapies (i.e. classified as Biologic Naïve or Biologic Experienced).
- To describe change in clinical and patient reported outcomes relative to baseline at both 6- and 12-month follow-up visits. Change will be reported for all patients with follow-up visits, as well as stratified by prior exposure to biologic therapies (i.e. classified as Biologic Naïve or Biologic Experienced).
- To characterize reasons for discontinuation of SEC among patients who discontinued at or before the 6-month and 12-month follow-up visits.

For Milestone 2a:
In Milestone 2A, the objective was to explore evolving treatment approach with SEC over the years, by summarizing:
1. Percent of Bio-naive vs. Bio experienced patients initiating treatment with SEC by year of initiation
2. Patient and disease characteristics at the time of SEC initiation by year of initiation.

In addition, inclusion of only patients who remain on SEC at the follow-up visit (as was done for Milestone 1) has the potential for bias, since patients who remain on SEC may be doing better than those who discontinue and/or switch. To address this, a limited sensitivity analysis were performed, evaluating change from baseline to follow-up for the BSA (continuous, clinical outcome) and DLQI (continuous, PRO), based on the following criteria:

- Patients who discontinue SEC and begin a new biologic prior to the follow-up visit were excluded. This was necessary to avoid conflating the impact of SEC with that of other biologics.
- Patients who remain on SEC until the follow-up visit were included.
- Patients who discontinue SEC before the follow-up visit but have not begun treatment with a new biologic prior to the follow-up visit were included, in order to capitalize on as much information as possible and to mitigate possible bias due to only including persistent SEC patients.

Change was evaluated at appropriate follow-up visits for the 6-month, 12-month, and 6 + 12-month cohorts.

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

Statistical Methods

Primary Statistical Analyses

Milestone 1: Summary tables include selected baseline characteristics among SEC initiators with an index visit.

Secondary Statistical Analyses

Milestone 1: Summary tables for selected baseline characteristics among SEC initiators with an index visit were stratified by prior biologic usage (biologic naive versus experienced). For continuous variables, the tables included the mean, standard deviation, median, first and third quartiles (interquartile range, IQR), minimum, maximum, and non-missing n. For categorical variables, the tables included the percent, the number of observations in each category, and the number of non-missing observations.

Milestone 1: Information on change in clinical and patient reported outcomes relative to baseline at both 6- and 12-month follow-up visits were presented. Change was reported for all patients, as well as stratified by prior biologic usage. For continuous variables, the tables included the mean, standard deviation, median, IQR, minimum, maximum, and non-missing n. For categorical variables, the tables included the percent, the number of observations in each category, and the number of non-missing observations.

Milestone 1: Reasons for discontinuation were reported for patients who discontinued at or before their 6- or 12-month follow-up visit.

Milestone 2a: Summary by year of SEC initiation was presented for bionaive status and patient and disease characteristics, as described above.

Milestone 2a: Information on change in BSA and DLQI relative to baseline at both 6- and 12-month follow-up visits was presented as described among the sensitivity analysis cohort. Change was reported for all patients, as well as stratified by prior biologic usage.

Study Population: Key Inclusion/Exclusion Criteria

Inclusion criteria

The patient must:

- Have been diagnosed with PsO by a dermatologist.
- Be at least 18 years of age.
- Be willing and able to provide written informed consent for participation in the registry.
- Have started on or switched to an eligible systemic PsO treatment at enrollment1 or within the previous 12 months of the date of enrollment.

Exclusion criteria

- Patient is participating in or planning to participate in an interventional clinical trial with a nonmarketed or marketed investigational drug (i.e. phase I-IV drug trial).

Participant Flow

This study was based on the February 10, 2021 data download with a cutoff date for visits of December 10, 2020. In total, there were 1,518 individuals who initiated SEC at or after enrolment in the PsO registry and had baseline visit information, 980 (65%) of whom were biologic experienced and 538 (35%) of whom were biologic naïve. There were 652 individuals with both a baseline and 6-month visit (43% of individuals with a baseline visit): 460 (71%) biologic experienced, and 192 (29%) biologic naïve. Further, 390 (26%) patients had both a baseline and 12-month visit: 288 (74%) biologic experienced, 102 (26%) biologic naïve. The majority of individuals with a visit at 12 months also had a 6-month visit (n=326 overall, 244 biologic experienced, and 82 biologic naïve).

Baseline Characteristics

Baseline characteristics are reported in the primary outcome results section

Primary Outcome Result(s)

Baseline characteristics of all SEC initiators in PsO registry by prior biologic usage

Characteristics	Total	Biologic Experienced	Biologic Naive
	N = 1,518	N = 980	N = 538
Sociodemographic Characteristics			
Age (years)	N = 1,518	N = 980	N = 538
Mean (SD)	50.5 (14.5)	51.2 (14.3)	49.2 (14.8)
Median [p25, p75]	52 [39, 61]	52 [41, 61]	50 [38, 60]
Min	18	20	18
Max	96	89	96
Age at diagnosis of PsO (years)	N = 1,097	N = 582	N = 515
Mean (SD)	36.1 (17.0)	33.3 (16.7)	39.4 (16.7)
Median [p25, p75]	35 [22, 49]	31 [20, 46]	39 [27, 53]
Min	0	0	1
Max	84	82	84
Gender, n (%)	N = 1,517	N = 980	N = 537
Female	763 (50%)	493 (50%)	270 (50%)
Race, n (%)	N = 1,518	N = 980	N = 538
White	1,224 (81%)	793 (81%)	431 (80%)
Black	63 (4.2%)	39 (4%)	24 (4.5%)
Asian	119 (7.8%)	82 (8.4%)	37 (6.9%)
Other/unknown[3]	112 (7.4%)	66 (6.7%)	46 (8.6%)
Ethnicity, n (%)	N = 1,495	N = 967	N = 528
Hispanic	160 (11%)	91 (9.4%)	69 (13%)
Non-Hispanic	1,335 (89%)	876 (91%)	459 (87%)

Body weight (kg)	N = 1,497	N = 962	N = 535
Mean (SD)	91.2 (24.2)	91.9 (23.8)	89.8 (24.7)
Median [p25, p75]	88 [74, 105]	88 [76, 106]	86 [72, 104]
Min	39	40	39
Max	213	213	206
Weight category, n (%)	N = 1,497	N = 962	N = 535
< 90kg	787 (53%)	498 (52%)	289 (54%)
>= 90kg	710 (47%)	464 (48%)	246 (46%)
CDC BMI categories[1], n (%)	N = 1,494	N = 959	N = 535
Underweight/Normal (<25.0)	296 (20%)	171 (18%)	125 (23%)

Characteristics	Total	Biologic Experienced	Biologic Naive
	N = 1,518	N = 980	N = 538
Overweight (25.0-29.9)	450 (30%)	292 (30%)	158 (30%)
Obese (≥30.0)	748 (50%)	496 (52%)	252 (47%)
Smoking history, n (%)	N = 1,495	N = 963	N = 532
Never	742 (50%)	472 (49%)	270 (51%)
Former smoker	470 (31%)	308 (32%)	162 (30%)
Current smoker	283 (19%)	183 (19%)	100 (19%)
Alcohol use history, n (%)	N = 1,430	N = 923	N = 507
None/ <1 drink per week	871 (61%)	586 (63%)	285 (56%)
1-3 drinks per week	193 (13%)	116 (13%)	77 (15%)
4-6 drinks per week	144 (10%)	91 (9.9%)	53 (10%)
1-2 drinks per day	130 (9.1%)	76 (8.2%)	54 (11%)
>2 drinks per day	92 (6.4%)	54 (5.9%)	38 (7.5%)
Insurance type, n (%)	N = 1,505	N = 974	N = 531
Private insurance	1,079 (72%)	689 (71%)	390 (73%)
Medicare insurance	271 (18%)	193 (20%)	78 (15%)
Medicaid insurance	221 (15%)	161 (17%)	60 (11%)
No insurance	49 (3.3%)	21 (2.2%)	28 (5.3%)
Provider region (US Census Bureau), n (%)	N = 1,518	N = 980	N = 538
Northeast	349 (23%)	248 (25%)	101 (19%)
Midwest	271 (18%)	155 (16%)	116 (22%)
South	648 (43%)	414 (42%)	234 (43%)
West	250 (16%)	163 (17%)	87 (16%)
Disease Characteristics			
Psoriasis duration (years)	N = 1,515	N = 978	N = 537
Mean (SD)	14.2 (13.3)	16.5 (13.4)	9.8 (12.1)

Characteristics	Total	Biologic Experienced	Biologic Naive
	N = 1,518	N = 980	N = 538
Median [p25, p75]	10 [3, 21]	14 [6, 24]	5 [1, 15]
Min	0	0	0
Max	73	73	68
Age at onset of PsO symptoms (years)	N = 1,093	N = 581	N = 512
Mean (SD)	33.6 (17.0)	30.8 (16.7)	36.7 (16.9)
Median [p25, p75]	32 [20, 46]	27 [18, 43]	37 [24, 49]
Min	0	0	0
Max	83	82	83
Morphology, n (%)	N = 1,518	N = 980	N = 538
Plaque	1,458 (96%)	955 (97%)	503 (93%)
Guttate	80 (5.3%)	51 (5.2%)	29 (5.4%)
Erythrodermic	24 (1.6%)	21 (2.1%)	3 (.56%)
Pustular	16 (1.1%)	9 (.92%)	7 (1.3%)
Localized	11 (.73%)	7 (.71%)	4 (.74%)
Generalized	4 (.26%)	2 (.2%)	2 (.37%)
Inverse/Intertriginous	93 (6.1%)	71 (7.2%)	22 (4.1%)
Scalp	578 (38%)	390 (40%)	188 (35%)
Nail	231 (15%)	167 (17%)	64 (12%)
Palmoplantar	149 (9.8%)	100 (10%)	49 (9.1%)
Genital	107 (8.9%)	77 (11%)	30 (6.3%)
Comorbid psoriatic arthritis (PsA), n (%)	N = 1,501	N = 970	N = 531
Yes	762 (51%)	569 (59%)	193 (36%)
Psoriatic arthritis duration (years)	N = 762	N = 569	N = 193
Mean (SD)	7.1 (8.7)	8.0 (8.8)	4.5 (7.7)
Median [p25, p75]	4 [1, 10]	5 [2, 11]	1 [0, 5]

Characteristics	Total	Biologic Experienced	Biologic Naive
	N = 1,518	N = 980	N = 538
Min	0	0	0
Max	55	55	50
Medical History			
History of comorbidities/toxicities, n (%)	N = 1,517	N = 979	N = 538
Cancer (excluding nonmelanoma skin cancer)[2]	78 (5.1%)	55 (5.6%)	23 (4.3%)
Cardiovascular disease[4]	179 (12%)	130 (13%)	49 (9.1%)
Hypertension	575 (38%)	397 (41%)	178 (33%)
Diabetes mellitus	236 (16%)	180 (18%)	56 (10%)
Metabolic syndrome	11 (.73%)	10 (1%)	1 (.19%)
Hepatic event-biopsy/hospitalization	7 (.46%)	7 (.72%)	0 (0%)
Hepatic event-no biopsy/hospitalization	6 (.4%)	4 (.41%)	2 (.37%)
GI perforation	2 (.13%)	2 (.2%)	0 (0%)
Peptic ulcer	25 (1.6%)	18 (1.8%)	7 (1.3%)
Other gastrointestinal disorder	138 (9.1%)	115 (12%)	23 (4.3%)
Depression	322 (21%)	230 (23%)	92 (17%)
Anxiety	346 (23%)	234 (24%)	112 (21%)
History of IBD, n (%)	N = 1,517	N = 979	N = 538
Crohn's disease	3 (.2%)	3 (.31%)	0 (0%)
Ulcerative colitis	8 (.53%)	6 (.61%)	2 (.37%)
Indeterminate IBD	17 (1.6%)	11 (1.8%)	6 (1.3%)
Any infection[3], n (%)	N = 1,518	N = 980	N = 538
Yes	551 (36%)	407 (42%)	144 (27%)
Patient Reported Outcomes*			
DLQI (Score: 0–30)	N = 1,512	N = 976	N = 536

Characteristics	Total	Biologic Experienced	Biologic Naive
	N = 1,518	N = 980	N = 538
Mean (SD)	8.0 (6.0)	7.7 (6.1)	8.6 (5.7)
Median [p25, p75]	7 [3, 12]	6 [3, 12]	8 [4, 12]
Min	0	0	0
Max	30	30	25
DLQI: Effect on life, n (%)	N = 1,512	N = 976	N = 536
No effect at all	197 (13%)	151 (15%)	46 (8.6%)
Small effect	439 (29%)	298 (31%)	141 (26%)
Moderate effect	408 (27%)	244 (25%)	164 (31%)
Very large effect	418 (28%)	250 (26%)	168 (31%)
Extremely large effect	50 (3.3%)	33 (3.4%)	17 (3.2%)
Patient global assessment	N = 1,515	N = 979	N = 536
Mean (SD)	49.6 (29.1)	48.6 (29.5)	51.4 (28.2)
Median [p25, p75]	50 [25, 75]	50 [22, 75]	50 [30, 75]
Min	0	0	0
Max	100	100	100
Patient itch assessment (VAS: 0–100)	N = 1,515	N = 979	N = 536
Mean (SD)	52.2 (33.7)	50.1 (33.6)	56.2 (33.4)
Median [p25, p75]	60 [20, 80]	50 [17, 80]	65 [23, 85]
Min	0	0	0
Max	100	100	100
Patient fatigue assessment (VAS: 0–100)	N = 1,512	N = 977	N = 535
Mean (SD)	38.3 (30.1)	39.7 (30.2)	35.8 (29.7)
Median [p25, p75]	35 [10, 64]	37 [10, 65]	33 [5, 60]
Min	0	0	0
Max	100	100	100

Characteristics	Total	Biologic Experienced	Biologic Naive
	N = 1,518	N = 980	N = 538
Patient skin pain assessment (VAS: 0–100)	N = 1,512	N = 978	N = 534
Mean (SD)	34.7 (32.7)	34.6 (32.7)	34.8 (32.7)
Median [p25, p75]	25 [2, 65]	25 [3, 65]	25 [1, 65]
Min	0	0	0
Max	100	100	100
Patient health state today (EQ-5D VAS: 0–100)	N = 1,509	N = 976	N = 533
Mean (SD)	69.4 (21.8)	68.8 (22.2)	70.5 (21.2)
Median [p25, p75]	75 [60, 85]	73 [55, 85]	75 [60, 88]
Min	0	0	0
Max	100	100	100
Mobility problems, n (%)	N = 1,506	N = 972	N = 534
No problems	1,004 (67%)	614 (63%)	390 (73%)
Some problems	501 (33%)	357 (37%)	144 (27%)
Confined to bed	1 (.066%)	1 (.1%)	0 (0%)
Self-care problems, n (%)	N = 1,499	N = 966	N = 533
No problems	1,343 (90%)	845 (87%)	498 (93%)
Some problems	152 (10%)	118 (12%)	34 (6.4%)
Unable	4 (.27%)	3 (.31%)	1 (.19%)
Usual activities problems, n (%)	N = 1,502	N = 969	N = 533
No problems	987 (66%)	601 (62%)	386 (72%)
Some problems	477 (32%)	344 (36%)	133 (25%)
Unable	38 (2.5%)	24 (2.5%)	14 (2.6%)
Pain or discomfort, n (%)	N = 1,508	N = 972	N = 536
None	503 (33%)	304 (31%)	199 (37%)
Moderate	882 (58%)	577 (59%)	305 (57%)

Characteristics	Total	Biologic Experienced	Biologic Naive
	N = 1,518	N = 980	N = 538
Extreme	123 (8.2%)	91 (9.4%)	32 (6%)
WPAI summary scores, n (%)	N = 1,515	N = 978	N = 537
Currently employed	967 (64%)	602 (62%)	365 (68%)
Absenteeism due to psoriasis (0-100%)	N = 867	N = 550	N = 317
Mean (SD)	3.9 (13.2)	3.5 (11.8)	4.6 (15.2)
Median [p25, p75]	0 [0, 0]	0 [0, 0]	0 [0, 0]
Min	0	0	0
Max	100	100	100
Presenteeism due to psoriasis (0-100%)	N = 862	N = 547	N = 315
Mean (SD)	16.0 (22.2)	15.3 (21.8)	17.2 (22.7)
Median [p25, p75]	5 [0, 25]	5 [0, 25]	5 [0, 28]
Min	0	0	0
Max	100	100	97
Work impairment due to psoriasis (0-100%)	N = 859	N = 546	N = 313
Mean (SD)	17.7 (23.8)	16.9 (23.5)	19.0 (24.3)
Median [p25, p75]	5 [0, 28]	5 [0, 25]	7 [0, 30]
Min	0	0	0
Max	100	100	100
Activity impairment due to psoriasis (0-100%)	N = 1,496	N = 962	N = 534
Mean (SD)	24.6 (28.0)	24.8 (28.6)	24.3 (27.0)
Median [p25, p75]	11 [0, 47]	10 [0, 50]	15 [0, 45]

Characteristics	Total	Biologic Experienced	Biologic Naive
	N = 1,518	N = 980	N = 538
Min	0	0	0
Max	100	100	100
PsO Specific Measures*			
PASI (Score: 0–72)	N = 1,517	N = 979	N = 538
Mean (SD)	8.0 (8.0)	7.4 (7.6)	9.1 (8.8)
Median [p25, p75]	5.5 [2.8, 11]	5.2 [2.6, 9.9]	6 [3.5, 12]
Min	0	0	0
Max	54	52	54
BSA (% involvement)	N = 1,517	N = 979	N = 538
Mean (SD)	15.3 (17.6)	13.9 (16.8)	17.8 (18.7)
Median [p25, p75]	10 [4, 20]	9 [3, 16]	10 [5, 20]
Min	0	0	0
Max	100	98	100
BSA categorical, n (%)	N = 1,517	N = 979	N = 538
Mild disease [0,3)	239 (16%)	178 (18%)	61 (11%)
Moderate disease [3,10]	665 (44%)	441 (45%)	224 (42%)
Severe disease (10,100]	613 (40%)	360 (37%)	253 (47%)
Investigator Global Assessment, n (%)	N = 1,509	N = 976	N = 533
Clear	67 (4.4%)	51 (5.2%)	16 (3%)
Almost clear	70 (4.6%)	54 (5.5%)	16 (3%)
Mild	288 (19%)	183 (19%)	105 (20%)
Moderate	817 (54%)	518 (53%)	299 (56%)
Severe	267 (18%)	170 (17%)	97 (18%)
PEST Score, n (%)	N = 1,502	N = 968	N = 534
Negative screen [0, 3)	939 (63%)	552 (57%)	387 (72%)

Characteristics	Total	Biologic Experienced	Biologic Naive
	N = 1,518	N = 980	N = 538
Positive screen [3, 5]	563 (37%)	416 (43%)	147 (28%)
Therapies: Prior and Concomitant Drugs			
Unique prior biologic count[6], n (%)		N = 980	
1		500 (51%)	
2		266 (27%)	
3 or more		214 (22%)	
Prior biologic exposures, n (%)		N = 980	
1		477 (49%)	
2		271 (28%)	
3 or more		232 (24%)	
Unique prior non-biologic count[7], n (%)	N = 830	N = 619	N = 211
1	593 (71%)	423 (68%)	170 (81%)
2	193 (23%)	159 (26%)	34 (16%)
3 or more	44 (5.3%)	37 (6%)	7 (3.3%)
Prior non-biologic exposures, n (%)	N = 831	N = 620	N = 211
1	582 (70%)	413 (67%)	169 (80%)
2	192 (23%)	157 (25%)	35 (17%)
3 or more	57 (6.9%)	50 (8.1%)	7 (3.3%)
Nonbiologic naïve, n (%)	N = 1,518	N = 980	N = 538
Yes	688 (45%)	361 (37%)	327 (61%)
Current or prior topical use, n (%)	N = 1,517	N = 980	N = 537
Yes	1,113 (73%)	646 (66%)	467 (87%)
Concomitant non-biologic systemics, n (%)	N = 1,518	N = 980	N = 538
Yes	135 (8.9%)	94 (9.6%)	41 (7.6%)

Characteristics	Total	Biologic Experienced	Biologic Naive
	N = 1,518	N = 980	N = 538
Concomitant phototherapy use, n (%)	N = 1,518	N = 980	N = 538
Yes	48 (3.2%)	30 (3.1%)	18 (3.3%)
Concomitant topical use, n (%)	N = 1,517	N = 980	N = 537
Yes	735 (48%)	436 (44%)	299 (56%)

The following variable(s) have non-missing counts that do not match the header shown in the table: pustular morphology (localized) (n total=1517, n biologic naïve=537) , pustular morphology (generalized) (n total=1517, n biologic naïve=537), genital morphology (n total=1200, n biologic experienced=722, n biologic naïve=478), history of indeterminate IBD (n total=1088, n biologic experienced=618, n biologic naïve=470)

	Total	Biologic Experienced	Biologic Naive
	N = 1,518	N = 980	N = 538
SEC Initiation Details			
Primary reason for SEC initiation, n (%)	N=1,515	N=979	N=536
Efficacy	29 (1.9%)	24 (2.5%)	5 (0.9%)
Safety	1 (0.1%)	1 (0.1%)	0 (0.0%)
Other reasons	171 (11.3%)	123 (12.6%)	48 (9.0%)
Insurance	9 (0.6%)	7 (0.7%)	2 (0.4%)
Active disease	1,304 (86.1%)	824 (84.2%)	480 (89.6%)
Patient doing well	1 (0.1%)	0 (0.0%)	1 (0.2%)

Secondary Outcomes Result(s)

Disposition of SEC initiators remaining on SEC at their 6-month follow-up visit in PsO registry, by prior biologic usage

Characteristics	Total	Experienced	Naive
Disposition at 6-month follow-up, n (%)	N = 1,518	N = 980	N = 538
On SEC at 6 month visit	652 (43%)	460 (47%)	192 (36%)
No follow-up visit recorded	735 (48%)	427 (44%)	308 (57%)
Discontinued SEC prior to 6 month visit, without starting new treatment	35 (2.3%)	26 (2.7%)	9 (1.7%)
Started new treatment with other biologics prior to 6 month visit	30 (2%)	22 (2.2%)	8 (1.5%)
Other[3]	66 (4.3%)	45 (4.6%)	21 (3.9%)
Primary reason for discontinuation/switching by 6-month follow-up[1], n (%) [2]	N=114	N=78	N=36
Efficacy	39 (29.8%)	33 (35.5%)	6 (15.8%)
Safety	17 (13.0%)	13 (14.0%)	4 (10.5%)
Other reasons	26 (19.8%)	18 (19.4%)	8 (21.1%)
Insurance	26 (19.8%)	11 (11.8%)	15 (39.5%)
Active disease	3 (2.3%)	3 (3.2%)	0 (0.0%)
Patient doing well	2 (1.5%)	0 (0.0%)	2 (5.3%)
Covid concern	1 (0.8%)	0 (0.0%)	1 (2.6%)

[1] Efficacy reasons: IR-inadequate initial response, FR-failure to maintain initial response; Safety reasons: SE-serious side effect, ME-minor side effect; Other reasons: FE-fear of future side effect, TI-temporary interruption, PP-patient preference, IC-to improve compliance, IT-to improve tolerability, FA-frequency of administration, RA-route of administration, AM-alternate mechanism of action, OT-other; Insurance reasons: CP-co-pay/patient cost, DI-denied by the insurance; AD-Active disease (for starts or increasing dose); DW-Patient doing well.
[2]Numbers shown include the total number of patients who discontinued SEC or switched to a new drug prior to the follow up visit, and who also had information available on their discontinuation reason.
[3] "Other" includes patients with non-continuous SEC use (i.e. who stopped SEC prior to follow up and then restarted) and patients who stopped SEC prior to follow-up and started a new drug at the follow-up visit

Disposition of SEC initiators remaining on SEC at their 12-month follow-up visit in PsO registry, by prior biologic usage

Characteristics	Total	Experienced	Naive
Disposition at 12-month follow-up, n (%)	N = 1,518	N = 980	N = 538
On SEC at 12 month visit	390 (26%)	288 (29%)	102 (19%)
No follow-up visit recorded	953 (63%)	557 (57%)	396 (74%)
Discontinued SEC prior to 12 month visit, without starting new treatment	13 (.86%)	7 (.71%)	6 (1.1%)
Started new treatment with other biologics prior to 12 month visit	86 (5.7%)	69 (7%)	17 (3.2%)
Other[3]	76 (5%)	59 (6%)	17 (3.2%)
Primary reason for discontinuation/switching by 12-month follow-up[1], n (%) [2]	N=159	N=122	N=37
Efficacy	80 (45.7%)	62 (45.9%)	18 (45.0%)
Safety	20 (11.4%)	17 (12.6%)	3 (7.5%)
Other reasons	38 (21.7%)	31 (23.0%)	7 (17.5%)
Insurance	11 (6.3%)	5 (3.7%)	6 (15.0%)
Active disease	7 (4.0%)	6 (4.4%)	1 (2.5%)
Patient doing well	3 (1.7%)	1 (0.7%)	2 (5.0%)
Covid concern	0 (0.0%)	0 (0.0%)	0 (0.0%)

[1] Efficacy reasons: IR-inadequate initial response, FR-failure to maintain initial response; Safety reasons: SE-serious side effect, ME-minor side effect; Other reasons: FE-fear of future side effect, TI-temporary interruption, PP-patient preference, IC-to improve compliance, IT-to improve tolerability, FA-frequency of administration, RA-route of administration, AM-alternate mechanism of action, OT-other; Insurance reasons: CP-co-pay/patient cost, DI-denied by the insurance; AD-Active disease (for starts or increasing dose); DW-Patient doing well.
[2]Numbers shown include the total number of patients who discontinued SEC or switched to a new drug prior to the follow up visit, and who also had information available on their discontinuation reason.
[33] "Other" includes patients with non-continuous SEC use (i.e. who stopped SEC prior to follow up and then restarted) and patients who stopped SEC prior to follow-up and started a new drug at the follow-up visit

Changes in continuous outcomes between baseline and 6-month follow-up visit among patients remaining on SEC at 6 months, by prior biologic use

Characteristics	Bio-experienced Baseline	Bio-experienced 6mon FU	Bio-experienced Change	Bionaive Baseline	Bionaive 6mon FU	Bionaive Change
	N = 460	N = 460	N = 460	N = 192	N = 192	N = 192
Investigator Global Assessment	N = 460	N = 460	N = 460	N = 192	N = 192	N = 192
Mean (SD)	2.7 (0.9)	1.3 (1.2)	-1.4 (1.3)	2.8 (0.8)	1.1 (1.2)	-1.7 (1.4)
Median [p25, p75]	3 [2, 3]	1 [0, 2]	-1 [-2, 0]	3 [2.5, 3]	1 [0, 2]	-2 [-3, -1]
Min	0	0	-4	0	0	-4
Max	4	4	3	4	4	3
PASI (Score: 0–72)	N = 460	N = 460	N = 460	N = 192	N = 192	N = 192
Mean (SD)	7.3 (6.9)	2.1 (3.9)	-5.2 (6.6)	8.2 (7.8)	1.5 (2.8)	-6.7 (7.8)
Median [p25, p75]	5.4 [2.7, 10]	.9 [0, 2.4]	-3.6 [-7.5, -.95]	5.7 [3.3, 11]	.4 [0, 1.7]	-4.6 [-9.6, -1.8]
Min	0	0	-40	0	0	-45
Max	49	38	18	54	15	10
BSA (% involvement)	N = 459	N = 459	N = 459	N = 192	N = 192	N = 192
Mean (SD)	13.1 (15.2)	3.8 (8.5)	-9.3 (14.5)	15.2 (17.5)	3.5 (8.6)	-11.7 (16.6)
Median [p25, p75]	10 [4, 15]	1 [0, 4]	-5 [-13, -1]	10 [5, 20]	1 [0, 3]	-7.5 [-15, -2]
Min	0	0	-80	0	0	-90
Max	98	80	67	100	60	31
Patient health state today (EQ-5D VAS: 0–100)	N = 459	N = 459	N = 459	N = 189	N = 189	N = 189
Mean (SD)	69.2 (23.2)	75.7 (20.4)	6.5 (22.9)	73.2 (20.6)	80.0 (18.6)	6.9 (22.7)
Median [p25, p75]	75 [60, 90]	80 [70, 90]	5 [-5, 19]	79 [60, 90]	85 [70, 91]	5 [-2, 19]
Min	1	3	-80	0	8	-90
Max	100	100	89	100	100	67
WPAI summary scores						
Presenteeism due to psoriasis (0-100%)	N = 220	N = 220	N = 220	N = 94	N = 94	N = 94

Characteristics	Bio-experienced Baseline	Bio-experienced 6mon FU	Bio-experienced Change	Bionaive Baseline	Bionaive 6mon FU	Bionaive Change
	N = 460	N = 460	N = 460	N = 192	N = 192	N = 192
Mean (SD)	15.9 (21.3)	8.8 (17.8)	-7.1 (19.6)	16.0 (21.1)	7.3 (16.4)	-8.7 (23.8)
Median [p25, p75]	5 [0, 25]	0 [0, 8]	0 [-10, 0]	5 [0, 25]	0 [0, 5]	0 [-20, 0]
Min	0	0	-80	0	0	-70
Max	80	85	60	70	80	72
Activity impairment due to psoriasis (0-100%)	N = 452	N = 452	N = 452	N = 188	N = 188	N = 188
Mean (SD)	24.7 (28.6)	15.9 (24.8)	-8.8 (27.2)	22.6 (26.4)	11.3 (21.2)	-11.3 (27.1)
Median [p25, p75]	10 [0, 50]	3 [0, 20]	0 [-20, 0]	10 [0, 40]	0 [0, 10]	-2.5 [-25, 0]
Min	0	0	-100	0	0	-100
Max	100	100	86	100	100	73
Absenteeism due to psoriasis (0-100%)	N = 220	N = 220	N = 220	N = 97	N = 97	N = 97
Mean (SD)	3.0 (9.5)	1.6 (9.0)	-1.4 (12.7)	3.6 (12.9)	2.2 (12.1)	-1.4 (16.3)
Median [p25, p75]	0 [0, 0]	0 [0, 0]	0 [0, 0]	0 [0, 0]	0 [0, 0]	0 [0, 0]
Min	0	0	-67	0	0	-100
Max	67	100	100	100	100	100
Work impairment due to psoriasis (0-100%)	N = 219	N = 219	N = 219	N = 94	N = 94	N = 94
Mean (SD)	17.7 (23.4)	9.6 (18.8)	-8.1 (22.0)	17.9 (22.7)	8.3 (17.9)	-9.6 (25.1)
Median [p25, p75]	5 [0, 30]	0 [0, 10]	0 [-10, 0]	5 [0, 33]	0 [0, 5]	0 [-20, 0]
Min	0	0	-80	0	0	-78
Max	85	90	60	78	80	73
DLQI (Score: 0–30)	N = 458	N = 458	N = 458	N = 191	N = 191	N = 191
Mean (SD)	7.5 (6.3)	3.2 (4.3)	-4.3 (6.3)	8.4 (5.6)	2.8 (4.6)	-5.6 (6.7)
Median [p25, p75]	6 [2, 11]	2 [0, 5]	-3 [-8, 0]	7 [4, 13]	1 [0, 3]	-5 [-10, -2]

Characteristics	Bio-experienced Baseline	Bio-experienced 6mon FU	Bio-experienced Change	Bionaive Baseline	Bionaive 6mon FU	Bionaive Change
	N = 460	N = 460	N = 460	N = 192	N = 192	N = 192
Min	0	0	-28	0	0	-22
Max	30	23	15	23	27	24
Patient global assessment	N = 459	N = 459	N = 459	N = 190	N = 190	N = 190
Mean (SD)	47.2 (30.1)	26.5 (27.5)	-20.7 (34.9)	49.6 (28.7)	21.1 (27.9)	-28.5 (34.7)
Median [p25, p75]	50 [20, 75]	15 [5, 45]	-17 [-45, 0]	50 [25, 75]	6 [2, 35]	-30 [-53, -5]
Min	0	0	-100	0	0	-100
Max	100	100	100	100	100	85
Patient itch assessment (VAS: 0–100)	N = 460	N = 460	N = 460	N = 189	N = 189	N = 189
Mean (SD)	47.5 (33.6)	24.2 (29.3)	-23.3 (37.6)	53.8 (33.6)	20.0 (28.1)	-33.8 (38.0)
Median [p25, p75]	50 [15, 80]	10 [0, 40]	-15 [-50, 0]	60 [20, 82]	5 [0, 35]	-35 [-67, -5]
Min	0	0	-100	0	0	-100
Max	100	100	100	100	100	77
Patient fatigue assessment (VAS: 0–100)	N = 458	N = 458	N = 458	N = 189	N = 189	N = 189
Mean (SD)	37.8 (29.9)	30.6 (28.8)	-7.2 (27.9)	34.4 (30.6)	23.1 (28.8)	-11.3 (31.1)
Median [p25, p75]	35 [10, 63]	25 [5, 50]	-5 [-21, 5]	30 [5, 60]	8 [0, 45]	-5 [-27, 0]
Min	0	0	-80	0	0	-93
Max	100	100	100	100	100	75
Patient skin pain assessment (VAS: 0–100)	N = 460	N = 460	N = 460	N = 187	N = 187	N = 187
Mean (SD)	33.3 (31.9)	16.1 (24.4)	-17.1 (34.5)	32.1 (31.6)	12.3 (23.0)	-19.8 (34.6)
Median [p25, p75]	25 [2, 60]	4.5 [0, 25]	-9.5 [-40, 0]	20 [0, 63]	0 [0, 10]	-11 [-45, 0]
Min	0	0	-100	0	0	-100
Max	100	100	100	100	100	95

Changes between baseline and 12-month follow-up among SEC initiators remaining on SEC at 12 months by prior biologic use

Characteristics	Bio-experienced Baseline	Bio-experienced 12mon FU	Bio-experienced Change	Bionaive Baseline	Bionaive 12mon FU	Bionaive Change
	N = 288	N = 288	N = 288	N = 102	N = 102	N = 102
Investigator Global Assessment	N = 288	N = 288	N = 288	N = 101	N = 101	N = 101
Mean (SD)	2.7 (0.9)	1.2 (1.2)	-1.6 (1.3)	2.8 (0.8)	0.9 (1.1)	-1.9 (1.3)
Median [p25, p75]	3 [2, 3]	1 [0, 2]	-2 [-3, -1]	3 [3, 3]	0 [0, 2]	-2 [-3, -1]
Min	0	0	-4	0	0	-4
Max	4	4	2	4	4	3
PASI (Score: 0–72)	N = 288	N = 288	N = 288	N = 101	N = 101	N = 101
Mean (SD)	7.0 (6.6)	1.9 (3.6)	-5.1 (6.7)	8.1 (7.0)	1.2 (2.7)	-6.9 (7.2)
Median [p25, p75]	5.4 [3, 9.4]	.6 [0, 2.4]	-3.6 [-7, -1.2]	6 [3.5, 11]	0 [0, 1.2]	-5.2 [-9.2, -2.2]
Min	0	0	-44	0	0	-35
Max	49	29	16	35	20	6.5
BSA (% involvement)	N = 287	N = 287	N = 287	N = 101	N = 101	N = 101
Mean (SD)	12.9 (13.8)	3.4 (8.2)	-9.5 (13.4)	13.3 (14.9)	1.7 (3.4)	-11.5 (15.0)
Median [p25, p75]	10 [4, 15]	1 [0, 3]	-6 [-12, -2]	10 [4, 15]	0 [0, 1]	-8 [-13, -3]
Min	0	0	-73	0	0	-90
Max	75	80	40	90	15	11
Patient health state today (EQ-5D VAS: 0–100)	N = 284	N = 284	N = 284	N = 99	N = 99	N = 99
Mean (SD)	68.5 (23.5)	75.5 (20.4)	7.0 (24.1)	73.1 (19.0)	83.3 (14.6)	10.3 (16.9)
Median [p25, p75]	75 [53, 90]	80 [70, 90]	3 [-5, 20]	76 [60, 90]	90 [80, 95]	8 [0, 20]
Min	0	5	-82	20	25	-51
Max	100	100	95	100	100	60
WPAI summary scores						

Characteristics	Bio-experienced Baseline	Bio-experienced 12mon FU	Bio-experienced Change	Bionaive Baseline	Bionaive 12mon FU	Bionaive Change
	N = 288	N = 288	N = 288	N = 102	N = 102	N = 102
Presenteeism due to psoriasis (0-100%)	N = 134	N = 134	N = 134	N = 53	N = 53	N = 53
Mean (SD)	13.8 (20.0)	6.8 (14.6)	-7.0 (19.7)	11.7 (17.4)	4.2 (10.8)	-7.6 (17.5)
Median [p25, p75]	2.5 [0, 22]	0 [0, 5]	0 [-10, 0]	0 [0, 20]	0 [0, 2]	0 [-15, 0]
Min	0	0	-70	0	0	-65
Max	75	90	90	70	56	26
Activity impairment due to psoriasis (0-100%)	N = 281	N = 281	N = 281	N = 96	N = 96	N = 96
Mean (SD)	22.6 (28.2)	12.6 (22.2)	-10.0 (28.2)	22.7 (26.8)	4.6 (11.8)	-18.1 (27.1)
Median [p25, p75]	6 [0, 40]	2 [0, 15]	0 [-20, 0]	10 [0, 43]	0 [0, 5]	-5 [-33, 0]
Min	0	0	-90	0	0	-100
Max	100	100	100	100	75	50
Absenteeism due to psoriasis (0-100%)	N = 136	N = 136	N = 136	N = 54	N = 54	N = 54
Mean (SD)	2.9 (8.7)	1.9 (12.2)	-1.0 (15.2)	4.4 (15.4)	0.0 (0.0)	-4.4 (15.4)
Median [p25, p75]	0 [0, 0]	0 [0, 0]	0 [0, 0]	0 [0, 0]	0 [0, 0]	0 [0, 0]
Min	0	0	-64	0	0	-100
Max	64	100	100	100	0	0
Work impairment due to psoriasis (0-100%)	N = 134	N = 134	N = 134	N = 53	N = 53	N = 53
Mean (SD)	15.5 (22.1)	7.1 (14.8)	-8.4 (21.5)	13.6 (19.5)	4.2 (10.8)	-9.5 (19.1)
Median [p25, p75]	5 [0, 25]	0 [0, 5]	0 [-10, 0]	0 [0, 25]	0 [0, 2]	0 [-15, 0]
Min	0	0	-80	0	0	-70
Max	85	90	90	75	56	21

Characteristics	Bio-experienced Baseline	Bio-experienced 12mon FU	Bio-experienced Change	Bionaive Baseline	Bionaive 12mon FU	Bionaive Change
	N = 288	N = 288	N = 288	N = 102	N = 102	N = 102
DLQI (Score: 0–30)	N = 285	N = 285	N = 285	N = 102	N = 102	N = 102
Mean (SD)	7.0 (6.1)	3.0 (4.1)	-4.0 (6.1)	8.3 (5.9)	1.7 (3.1)	-6.6 (6.1)
Median [p25, p75]	5 [2, 11]	1 [0, 4]	-2 [-7, 0]	7 [4, 12]	1 [0, 1]	-5 [-10, -3]
Min	0	0	-21	0	0	-25
Max	26	25	24	25	15	7
Patient global assessment	N = 287	N = 287	N = 287	N = 101	N = 101	N = 101
Mean (SD)	45.6 (30.2)	22.2 (26.2)	-23.4 (33.3)	47.5 (27.7)	18.1 (27.0)	-29.4 (35.0)
Median [p25, p75]	45[20, 73]	10[3, 35]	-20 [-45, 0]	50 [25, 70]	5 [0, 20]	-30 [-55, -5]
Min	0	0	-100	0	0	-100
Max	100	100	77	100	100	95
Patient itch assessment (VAS: 0–100)	N = 287	N = 287	N = 287	N = 101	N = 101	N = 101
Mean (SD)	45.7 (34.2)	21.7 (28.2)	-24.0 (36.2)	53.8 (31.8)	15.4 (25.6)	-38.4 (35.9)
Median [p25, p75]	45 [15, 80]	6 [0, 35]	-15 [-49, 0]	63 [20, 80]	5 [0, 17]	-45 [-70, -5]
Min	0	0	-100	0	0	-100
Max	100	100	75	100	100	43
Patient fatigue assessment (VAS: 0–100)	N = 286	N = 286	N = 286	N = 101	N = 101	N = 101
Mean (SD)	37.0 (29.3)	29.0 (29.1)	-8.0 (27.9)	35.1 (28.5)	18.7 (22.7)	-16.4 (24.2)
Median [p25, p75]	35 [10, 60]	19 [5, 50]	-4.5 [-25, 5]	33 [7, 65]	9 [0, 37]	-10 [-30, 0]
Min	0	0	-95	0	0	-86
Max	100	100	80	90	90	50
Patient skin pain assessment (VAS: 0–100)	N = 287	N = 287	N = 287	N = 100	N = 100	N = 100
Mean (SD)	30.5 (31.0)	13.4 (23.6)	-17.1 (31.3)	30.6 (30.2)	8.5 (18.7)	-22.1 (32.7)
Median [p25, p75]	20 [2, 55]	2 [0, 10]	-5 [-30, 0]	20 [0, 60]	0 [0, 5]	-12 [-50, 0]

Characteristics	Bio-experienced Baseline	Bio-experienced 12mon FU	Bio-experienced Change	Bionaive Baseline	Bionaive 12mon FU	Bionaive Change
	N = 288	N = 288	N = 288	N = 102	N = 102	N = 102
Min	0	0	-100	0	0	-85
Max	100	100	90	90	100	80

Safety Results

NA

Other Relevant Findings
None

Conclusion
The proportion of SEC initiators who are biologic-naïve has increased since the approval of SEC in 2015. Among biologic experienced patients, their number of prior biologic exposures and use of concomitant non-biologic systemics have declined over time. There was no clear trend over time in PASI, IGA, or BSA.

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