

Sponsor

Novartis Pharmaceuticals

Generic Drug Name

Secukinumab

Trial Indication(s)

Plaque Psoriasis

Protocol Number

CAIN457AGB06

Protocol Title

An analysis of the improvement and quality of life trends for UK/ROI patients treated with Cosentyx (Secukinumab) in a retrospective analysis of the BADBIR data source

Clinical Trial Phase

NA

Phase of Drug Development

NA

Study Start/End Dates

Study start date: 07/12/2020

Study Completion date: 06/05/2021

Reason for Termination

NA

Study Design/Methodology

This was a retrospective, observational study of psoriasis patients treated with secukinumab, using secondary data from BADBIR. BADBIR is a UK/ROI pharmacovigilance registry that was initiated in 2007 to monitor the long-term safety of biologic drugs used to treat psoriasis. The study used longitudinal data within the registry to track the trends relating to the disease. For the analysis of improvement and patient reported QoL, patients with a minimum of one follow-up visit were included. The index date was defined as the date of initiation of secukinumab treatment, and follow-up visits were at 6-, 12-, 18-, & 24-months post-index.

The BADBIR data was current up until the 31st August 2019 for this analysis.

Study period: From 1st July 2015, as secukinumab was included in BADBIR in January 2016 and patients backdated 6 months, to 31st August 2019.

Identification period: From 1st July 2015 to 31st August 2019 was used to identify applicable patients for analysis.

Index date: Initiation of secukinumab treatment within the BADBIR database.

Centers

Novartis Investigative Site

Objectives:

Primary objective(s)

- To assess the patient reported QoL for five specific DLQI domains from baseline up to 24 months of UK/ROI psoriasis patients enrolled in BADBIR who were initiated on secukinumab treatment.

Secondary objective(s)

- To describe the baseline demographics, of all psoriasis patients, to be stratified by PsA or not, and stratified by no nail involvement and nail involvement further stratified by <5 nails, ≥ 5 nails or all nails involved at baseline.
- To assess the improvement and patient reported QoL changes from baseline up to 24 months of UK/ROI psoriasis patients enrolled in BADBIR who were initiated on secukinumab treatment, using absolute Psoriasis Area Severity Index (aPASI) and total DLQI scores stratified by no nail involvement and nail involvement further stratified by <5 nails, ≥ 5 nails or all nails involved at baseline.
- To assess improvement and patient reported QoL changes of patients with PsA diagnosis at baseline enrolled in BADBIR who were initiated on secukinumab treatment, using aPASI and total DLQI scores at defined intervals from baseline up to 24 months.
- To assess the improvement and patient reported QoL changes from baseline up to 24 months of UK/ROI psoriasis patients with PsA enrolled in BADBIR who were initiated on secukinumab treatment, using aPASI and total DLQI scores stratified by no nail involvement and nail involvement, further stratified by <5 nails, ≥ 5 nails or all nails involved at baseline.
- To assess the improvement and patient reported QoL changes from baseline of psoriasis patients enrolled in BADBIR, initiated on secukinumab treatment, using aPASI and total DLQI scores, stratified by biologic naive/experienced status at Baseline (BL).

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

NA

Statistical Methods

All planned analysis for the primary and secondary objectives were descriptive with no comparison of patient groups.

For descriptive analyses:

- Continuous variables were summarized using patient counts, missing, mean, standard deviation, range, median, and interquartile range (25%, 75%).
- Categorical variables were summarized using frequency counts and percentages.
- Missing data were considered a separate category in all analyses and were described using frequency counts and percentages

Study Population: Key Inclusion/Exclusion Criteria

Inclusion criteria

Inclusion criteria for the biologic cohort:

- Age ≥ 18 years at initiation of secukinumab.
- At least one follow-up visit post-registry enrollment.
- On-label dosing of secukinumab of 300mg.

Inclusion criteria for the PsA biologic cohort:

- Age ≥ 18 years at initiation of secukinumab.
- At least one follow-up visit post-registry enrollment.
- On-label dosing of secukinumab of 300mg.
- Diagnosis of PsA at baseline.

Exclusion criteria

- The patient did not meet the criteria stated above.

Participant Flow

A total of 1093 patients were ≥ 18 years old and contained within the BADBIR database for the study period. A further 783 patients had at least one follow-up visit post-registry enrollment. Overall, 767 patients were prescribed an on-label secukinumab dose of 300mg with a weekly loading dose for five consecutive weeks followed by monthly dosing and were included in our main study cohort.

Baseline Characteristics

Refer to secondary outcome results for baseline characteristics

Primary Outcome Result(s)

Patient reported QoL in five specific DLQI domains from baseline up to 24 months

		N	%
Cohort: Incidence cohort		767	
Patients with a Baseline DLQI Score		758	100.00%
Proportion of subjects with total DLQI score of >10 at baseline achieving a score of 0 or 1 at 6-month intervals to 24 months		243	
Total DLQI Score at baseline	>10	528	69.66%
	≤10	230	30.34%
	Missing	0	0.00%
Changes in QoL			
Baseline	Embarrassment and/or self-consciousness	2	122
		3	227
		Other	209
		Missing	200
	Social and leisure activities	2	137
		3	158
		Other	262
		Missing	201
	Work/study	2	71
		3	82
		Other	378
		Missing	227
	Problems relating to partner, friends, and relatives	2	96
		3	95
		Other	366
		Missing	201
	Sexual difficulties	2	81
		3	86
		Other	388
		Missing	203

			N	%
6 months	Embarrassment and/or self-consciousness	0 Other Missing	141 57 560	18.60% 7.52% 73.88%
	Social and leisure activities	0 Other Missing	164 34 560	21.64% 4.49% 73.88%
	Work/study	0 Other Missing	163 23 572	21.50% 3.03% 75.46%
	Problems relating to partner, friends, and relatives	0 Other Missing	171 27 560	22.56% 3.56% 73.88%
	Sexual difficulties	0 Other Missing	175 22 561	23.09% 2.90% 74.01%
Proportion of patients reporting high/very high QoL changes from BL (from 2 or 3 at BL to 0)	Embarrassment and/or self-consciousness-Reported high/very high QoL changes from BL	Yes No Missing	78 36 235	22.35% 10.32% 67.34%
	Social leisure-Reported high/very high QoL changes from BL	Yes No Missing	79 22 194	26.78% 7.46% 65.76%
	Work/study-Reported high/very high QoL changes from BL	Yes No Missing	39 10 104	25.49% 6.54% 67.97%
	Problems relating to partner, friends and relatives-Reported high/very high QoL changes from BL	Yes No Missing	53 14 124	27.75% 7.33% 64.92%
	Sexual difficulties-Reported high/very high QoL changes from BL	Yes No Missing	39 11 117	23.35% 6.59% 70.06%

			N	%
12 months	Embarrassment and/or self-consciousness	0	160	21.11%
		Other	59	7.78%
		Missing	539	71.11%
	Social and leisure activities	0	179	23.61%
		Other	39	5.15%
		Missing	540	71.24%
	Work/study	0	175	23.09%
		Other	24	3.17%
		Missing	559	73.75%
	Problems relating to partner, friends, and relatives	0	187	24.67%
		Other	32	4.22%
		Missing	539	71.11%
	Sexual difficulties	0	197	25.99%
		Other	22	2.90%
		Missing	539	71.11%
Proportion of patients reporting high/very high QoL changes from BL (from 2 or 3 at BL to 0)	Embarrassment and/or self-consciousness-Reported high/very high QoL changes from BL	Yes	99	28.37%
		No	34	9.74%
		Missing	216	61.89%
	Social leisure-Reported high/very high QoL changes from BL	Yes	89	30.17%
		No	21	7.12%
		Missing	185	62.71%
	Work/study-Reported high/very high QoL changes from BL	Yes	55	35.95%
		No	12	7.84%
		Missing	86	56.21%
	Problems relating to partner, friends and relatives-Reported high/very high QoL changes from BL	Yes	63	32.98%
		No	12	6.28%
		Missing	116	60.73%
	Sexual difficulties-Reported high/very high QoL changes from BL	Yes	54	32.34%
		No	13	7.78%
		Missing	100	59.88%

			N	%
18 Months	Embarrassment and/or self-consciousness	0	149	19.66%
		Other	52	6.86%
		Missing	557	73.48%
	Social and leisure activities	0	168	22.16%
		Other	33	4.35%
		Missing	557	73.48%
	Work/study	0	164	21.64%
		Other	22	2.90%
		Missing	572	75.46%
	Problems relating to partner, friends, and relatives	0	177	23.35%
		Other	24	3.17%
		Missing	557	73.48%
	Sexual difficulties	0	182	24.01%
		Other	15	1.98%
		Missing	561	74.01%
Proportion of patients reporting high/very high QoL changes from BL (from 2 or 3 at BL to 0)	Embarrassment and/or self-consciousness-Reported high/very high QoL changes from BL	Yes	81	23.21%
		No	30	8.60%
		Missing	238	68.19%
	Social leisure-Reported high/very high QoL changes from BL	Yes	85	28.81%
		No	17	5.76%
		Missing	193	65.42%
	Work/study-Reported high/very high QoL changes from BL	Yes	43	28.10%
		No	10	6.54%
		Missing	100	65.36%
	Problems relating to partner, friends and relatives-Reported high/very high QoL changes from BL	Yes	52	27.23%
		No	7	3.66%
		Missing	132	69.11%
	Sexual difficulties-Reported high/very high QoL changes from BL	Yes	53	31.74%
		No	4	2.40%
		Missing	110	65.87%

			N	%
24 months	Embarrassment and/or self-consciousness	0 Other Missing	100 42 616	13.19% 5.54% 81.27%
	Social and leisure activities	0 Other Missing	116 25 617	15.30% 3.30% 81.40%
	Work/study	0 Other Missing	119 17 622	15.70% 2.24% 82.06%
	Problems relating to partner, friends, and relatives	0 Other Missing	124 18 616	16.36% 2.37% 81.27%
	Sexual difficulties	0 Other Missing	127 14 617	16.75% 1.85% 81.40%
Proportion of patients reporting high/very high QoL changes from BL (from 2 or 3 at BL to 0)	Embarrassment and/or self-consciousness-Reported high/very high QoL changes from BL	Yes No Missing	57 15 277	16.33% 4.30% 79.37%
	Social leisure-Reported high/very high QoL changes from BL	Yes No Missing	57 10 228	19.32% 3.39% 77.29%
	Work/study-Reported high/very high QoL changes from BL	Yes No Missing	30 6 117	19.61% 3.92% 76.47%
	Problems relating to partner, friends and relatives-Reported high/very high QoL changes from BL	Yes No Missing	40 3 148	20.94% 1.57% 77.49%
	Sexual difficulties-Reported high/very high QoL changes from BL	Yes No Missing	33 3 131	19.76% 1.80% 78.44%

Secondary Outcome Result(s)

Demographic and clinical characteristics of psoriasis patients

Overall cohort		N	%
# of Patients		767	100.00%
Age (Years) at index date - Continuous	N(% non-missing)	767	100.00%
	Mean	46.3	
	Std. Dev	12.97	
	Min	19	
	Max	81	
	25% Percentile	37	
	Median	46	
	75% Percentile	55	
Age - Categorical	<40 years	242	31.55%
	≥40 years	525	68.45%
Age (Years) at diagnosis - Continuous	N(% non-missing)	767	100.00%
	Mean	24.7	
	Std. Dev	12.94	
	Min	0	
	Max	69	
	25% Percentile	15	
	Median	22	
	75% Percentile	33	
Time from diagnosis to end of data cut - Continuous (Years)	N(% non-missing)	767	100.00%
	Mean	23.6	
	Std. Dev	13.07	
	Min	1	
	Max	71	
	25% Percentile	13	
	Median	22	

	75% Percentile	32	
Sex - Categorical	Male	477	62.19%
	Female	290	37.81%
Ethnicity - Categorical	White	665	86.70%
	Black African	2	0.26%
	Black Caribbean	2	0.26%
	Black British	4	0.52%
	Chinese	6	0.78%
	Indian	32	4.17%
	Pakistani	22	2.87%
	Other/Missing	34	4.43%
Employment status - Categorical	Working part time	95	12.39%
	Retired	76	9.91%
	Working full time	451	58.80%
	Unemployed but seeking work	25	3.26%
	Not working due to disability/ill health	70	9.13%
	Working full time in the home	28	3.65%
	Student	11	1.43%
	Missing	11	1.43%
Smoking Characteristics - Categorical	Current smoker	181	23.60%
	Previous smoker	290	37.81%
	Never smoker	290	37.81%
	Unknown	6	0.78%

Weight - Continuous	N(% non-missing)	744	97.00%
	Mean	92.54	
	Std. Dev	23.304	
	Min	46.9	
	Max	220.0	
	25% Percentile	76.4	
	Median	89.0	
	75% Percentile	106.8	
Height - Continuous	N(% non-missing)	751	97.91%
	Mean	171.28	
	Std. Dev	10.711	
	Min	117.0	
	Max	201.0	
	25% Percentile	163.0	
	Median	172.0	
	75% Percentile	180.0	
Body Mass Index (BMI) - Continuous	N(% non-missing)	731	95.31%
	Mean	31.430	
	Std. Dev	7.4092	
	Min	16.13	
	Max	62.35	
	25% Percentile	26.42	
	Median	30.19	
	75% Percentile	34.90	

BMI - Categorical	Underweight <18.5	5	0.65%
	Normal \geq 18.5 and < 25	121	15.78%
	Overweight \geq 25 and <30	233	30.38%
	Obese \geq 30.0	372	48.50%
	Unknown	36	4.69%
Waist circumference - Continuous	N(% non-missing)	662	86.31%
	Mean	103.2	
	Std. Dev	18.03	
	Min	30	
	Max	187	
	25% Percentile	92	
	Median	101	
	75% Percentile	112	
aPASI at BL - Continuous	N(% non-missing)	684	89.18%
	Mean	15.21	
	Std. Dev	8.183	
	Min	0.0	
	Max	57.9	
	25% Percentile	10.6	
	Median	13.4	
	75% Percentile	18.4	

aPASI at BL - Categorical	Mild, 0 ≤ PASI ≤5	45	5.87%
	Moderate, 5 < PASI ≤12	233	30.38%
	Severe, 12 < PASI ≤20	275	35.85%
	Very severe, 20 < PASI	131	17.08%
Total DLQI at BL - Continuous	N(% non-missing)	758	98.83%
	Mean	14.7	
	Std. Dev	8.58	
	Min	0	
	Max	30	
	25% Percentile	9	
	Median	15	
	75% Percentile	21	
Total DLQI at BL - Categorical	No effect on patient's life, 0-1	82	10.69%
	Small effect, 2-5	65	8.47%
	Moderate effect, 6-10	83	10.82%
	Very large effect, 11-20	311	40.55%
	Extremely large effect, 21-30	217	28.29%
	Missing	9	1.17%
DQLI Domain - 2) embarrassment and/or self-consciousness - proportion of those who reported high or very high at baseline	2	122	15.91%
	3	227	29.60%
	Other	209	27.25%
	Missing	209	27.25%
DQLI Domain - 5) social and leisure activities - proportion of those who reported high or very high at baseline	2	137	17.86%
	3	158	20.60%
	Other	262	34.16%
	Missing	210	27.38%

DQLI Domain - 7) work/study - proportion of those who reported high or very high at baseline	2	71	9.26%
	3	82	10.69%
	Other	378	49.28%
	Missing	236	30.77%
	2	96	12.52%
	3	95	12.39%
	Other	366	47.72%
DQLI Domain - 8) problems relating to partner, friends, and relatives - proportion of those who reported high or very high at baseline	Missing	210	27.38%
DQLI Domain - 9) sexual difficulties - proportion of those who reported high or very high at baseline	2	81	10.56%
	3	86	11.21%
	Other	388	50.59%
	Missing	212	27.64%
Biologic naïve/experienced - Categorical	Biologic naïve	581	75.75%
	Biologic experienced	186	24.25%
PsA at BL - Categorical	PsA	193	25.16%
	No PsA	574	74.84%
Time to PsA diagnosis - Continuous	N(% non-missing)	192	25.03%
	Mean	12.7	
	Std. Dev	14.09	
	Min	-44	
	Max	59	
	25% Percentile	1	
	Median	10	
	75% Percentile	20.25	
No PsA and nail involvement - Categorical	Any	271	35.33%
	<5	57	7.43%
	≥5	214	27.90%
	All	86	11.21%
	None	303	39.50%

Number of nails involved - Continuous	N(% non-missing)	391	50.98%
	Mean	11.4	
	Std. Dev	6.85	
	Min	1	
	Max	20	
	25% Percentile	5	
	Median	10	
	75% Percentile	20	
Number of patients with at least one Comorbidity (by MedDRA PT) - Integer	Has a comorbidity	517	67.41%
	Does not have a comorbidity	250	32.59%
Five most common comorbidities at BL (by MedDRA PT)	Hypertension	191	24.90%
	Depression	151	19.69%
	Diabetes Mellitus	80	10.43%
	Psoriatic Arthropathy	75	9.78%
	Asthma	72	9.39%
Frequency of on-label 300mg prescription - Categorical	N/A (new convention for licensed dose)	189	24.64%
	Once a week (induction)	28	3.65%
	Once monthly	251	32.72%
	Once every four weeks	299	38.98%

QoL changes from baseline up to 24 months, stratified by no nail involvement and nail involvement

Any Nail cohort	Any Nail cohort		Less than 5 Nails cohort		5 or more Nails cohort		All Nails		No Nail Involvement		
	N	%	N	%	N	%	N	%	N	%	
# of Patients	391		80		311		129		376		
Patients with a Baseline DLQI Score	385		78		307		127		373		
Total DLQI score of >10 at BL											
>10	283	73.51%	57	73.08%	226	73.62%	98	77.17%	245	65.68%	
≤10	102	26.49%	21	26.92%	81	26.38%	29	22.83%	128	34.32%	
Missing	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	
Total DLQI score at 6 months	0	54	14.03%	6	7.69%	48	15.64%	21	16.54%	56	15.01%
1	16	4.16%	1	1.28%	15	4.89%	8	6.30%	15	4.02%	
Other	54	14.03%	16	20.51%	38	12.38%	12	9.45%	50	13.40%	
Missing	261	67.79%	55	70.51%	206	67.10%	86	67.72%	252	67.56%	
Total DLQI score at 12 months	0	84	21.82%	12	15.38%	72	23.45%	30	23.62%	66	17.69%
1	25	6.49%	2	2.56%	23	7.49%	10	7.87%	32	8.58%	
Other	68	17.66%	22	28.21%	46	14.98%	15	11.81%	59	15.82%	
Missing	208	54.03%	42	53.85%	166	54.07%	72	56.69%	216	57.91%	
Total DLQI score at 18 months	0	63	16.36%	10	12.82%	53	17.26%	23	18.11%	53	14.21%
1	23	5.97%	3	3.85%	20	6.51%	9	7.09%	19	5.09%	
Other	62	16.10%	18	23.08%	44	14.33%	20	15.75%	43	11.53%	
Missing	237	61.56%	47	60.26%	190	61.89%	75	59.06%	258	69.17%	
Total DLQI score at 24 months	0	45	11.69%	8	10.26%	37	12.05%	14	11.02%	36	9.65%
1	19	4.94%	5	6.41%	14	4.56%	2	1.57%	14	3.75%	
Other	40	10.39%	5	6.41%	35	11.40%	15	11.81%	36	9.65%	
Missing	281	72.99%	60	76.92%	221	71.99%	96	75.59%	287	76.94%	
Patients with a Baseline PASI Score	364	100.00%	75	100.00%	289	100.00%	122	100.00%	100.00%	320	
aPASI score at BL	0	3	0.82%	1	1.33%	2	0.69%	2	1.64%	2	0.63%
1	1	0.27%	0	0.00%	1	0.35%	1	0.82%	4	1.25%	
2	4	1.10%	1	1.33%	3	1.04%	0	0.00%	1	0.31%	
3	3	0.82%	1	1.33%	2	0.69%	1	0.82%	4	1.25%	
>3	353	96.98%	72	96.00%	281	97.23%	118	96.72%	309	96.56%	
Missing	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	
aPASI score at 6 months	0	86	23.63%	11	14.67%	75	25.95%	24	19.67%	64	20.00%
1	28	7.69%	7	9.33%	21	7.27%	12	9.84%	31	9.66%	
2	22	6.04%	3	4.00%	19	6.57%	5	4.10%	28	8.75%	
3	23	6.32%	6	8.00%	17	5.88%	8	6.56%	21	6.56%	
>3	30	8.24%	9	12.00%	21	7.27%	8	6.56%	29	9.06%	
Missing	175	48.08%	39	52.00%	136	47.06%	65	53.28%	147	45.94%	

	Any nails		Less than 5 nails cohort		5 or more nails cohort		All Nails		No nail involvement		
	N	%	N	%	N	%	N	%	N	%	
aPASI score at 12 months	0	90	24.73%	13	17.33%	77	26.64%	31	25.41%	65	20.31%
	1	29	7.97%	6	8.00%	23	7.96%	7	5.74%	23	7.19%
	2	33	9.07%	11	14.67%	22	7.61%	9	7.38%	22	6.88%
	3	16	4.40%	3	4.00%	13	4.50%	8	6.56%	12	3.75%
	>3	31	8.52%	8	10.67%	23	7.96%	9	7.38%	30	9.38%
	Missing	165	45.33%	34	45.33%	131	45.33%	58	47.54%	168	52.50%
aPASI score at 18 months	0	54	14.84%	8	10.67%	46	15.92%	18	14.75%	41	12.81%
	1	17	4.67%	4	5.33%	13	4.50%	8	6.56%	17	5.31%
	2	25	6.87%	3	4.00%	22	7.61%	9	7.38%	16	5.00%
	3	20	5.49%	5	6.67%	15	5.19%	9	7.38%	9	2.81%
	>3	33	9.07%	5	6.67%	28	9.69%	11	9.02%	25	7.81%
	Missing	215	59.07%	50	66.67%	165	57.09%	67	54.92%	212	66.25%
aPASI score at 24 months	0	39	10.71%	3	4.00%	36	12.46%	15	12.30%	26	8.13%
	1	19	5.22%	4	5.33%	15	5.19%	7	5.74%	6	1.88%
	2	16	4.40%	4	5.33%	12	4.15%	6	4.92%	17	5.31%
	3	10	2.75%	2	2.67%	8	2.77%	3	2.46%	6	1.88%
	>3	19	5.22%	4	5.33%	15	5.19%	6	4.92%	16	5.00%
	Missing	261	71.70%	58	77.33%	203	70.24%	85	69.67%	249	77.81%

QoL changes of patients with and without PsA diagnosis at baseline, using aPASI and total DLQI scores at defined intervals

	Patients with PsA diagnosis at BL		Patients without PsA diagnosis at BL		
	N	%	N	%	
# of Patients	193		574		
Patients with a Baseline DLQI Score	191	100.00%	567	100.00%	
Total DLQI score at BL	>10	136	71.20%	392	69.14%
	≤10	55	28.80%	175	30.86%
	Missing	0	0.00%	0	0.00%
Total DLQI score at 6 months	0	24	12.57%	86	15.17%
	1	6	3.14%	25	4.41%
	Other	24	12.57%	80	14.11%
	Missing	137	71.73%	376	66.31%
Total DLQI score at 12 months	0	40	20.94%	110	19.40%
	1	12	6.28%	45	7.94%
	Other	37	19.37%	90	15.87%
	Missing	102	53.40%	322	56.79%

Total DLQI score at 18 months	0	25	13.09%	91	16.05%
	1	9	4.71%	33	5.82%
	Other	35	18.32%	70	12.35%
	Missing	122	63.87%	373	65.78%
Total DLQI score at 24 months	0	17	8.90%	64	11.29%
	1	16	8.38%	17	3.00%
	Other	22	11.52%	54	9.52%
	Missing	136	71.20%	432	76.19%
Patients with a Baseline PASI Score		172	100.00%	512	100.00%
aPASI score at BL	0	0	0.00%	5	0.98%
	1	2	1.16%	3	0.59%
	2	2	1.16%	3	0.59%
	3	1	0.58%	6	1.17%
	>3	167	97.09%	495	96.68%
	Missing	0	0.00%	0	0.00%
aPASI score at 6 months	0	42	24.42%	108	21.09%
	1	17	9.88%	42	8.20%
	2	13	7.56%	37	7.23%
	3	6	3.49%	38	7.42%
	>3	18	10.47%	41	8.01%
	Missing	76	44.19%	246	48.05%
aPASI score at 12 months	0	48	27.91%	107	20.90%
	1	13	7.56%	39	7.62%
	2	13	7.56%	42	8.20%
	3	4	2.33%	24	4.69%
	>3	22	12.79%	39	7.62%
	Missing	72	41.86%	261	50.98%
aPASI score at 18 months	0	29	16.86%	66	12.89%
	1	11	6.40%	23	4.49%
	2	10	5.81%	31	6.05%
	3	7	4.07%	22	4.30%
	>3	14	8.14%	44	8.59%
	Missing	101	58.72%	326	63.67%
aPASI score at 24 months	0	19	11.05%	46	8.98%
	1	7	4.07%	18	3.52%
	2	9	5.23%	24	4.69%
	3	4	2.33%	12	2.34%
	>3	15	8.72%	20	3.91%
	Missing	118	68.60%	392	76.56%

QoL changes from baseline of PsA patients, using aPASI and total DLQI scores, stratified by nail involvement

Any Nail cohort	Any nail		Less than 5 nails		5 or more nails		All Nails		No nail involvement	
	N	%	N	%	N	%	N	%	N	%
# of Patients	120		23		97		43		73	
Patients with a Baseline DLQI Score	118	100.00%	23	100.00%	95	100.00%	41	100.00%	73	100.00%
Total DLQI score of >10 at BL	>10	75.42%	16	69.57%	73	76.84%	33	80.49%	47	64.38%
	≤10	24.58%	7	30.43%	22	23.16%	8	19.51%	26	35.62%
	Missing	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%
Total DLQI score at 6 months	0	11.86%	1	4.35%	13	13.68%	5	12.20%	10	13.70%
	1	3.39%	0	0.00%	4	4.21%	3	7.32%	2	2.74%
	Other	12.71%	8	34.78%	7	7.37%	1	2.44%	9	12.33%
	Missing	72.03%	14	60.87%	71	74.74%	32	78.05%	52	71.23%
Total DLQI score at 12 months	0	24.58%	5	21.74%	24	25.26%	8	19.51%	11	15.07%
	1	5.08%	0	0.00%	6	6.32%	4	9.76%	6	8.22%
	Other	18.64%	7	30.43%	15	15.79%	7	17.07%	15	20.55%
	Missing	51.69%	11	47.83%	50	52.63%	22	53.66%	41	56.16%
Total DLQI score at 18 months	0	14.41%	4	17.39%	13	13.68%	3	7.32%	8	10.96%
	1	4.24%	2	8.70%	3	3.16%	2	4.88%	4	5.48%
	Other	19.49%	6	26.09%	17	17.89%	8	19.51%	12	16.44%
	Missing	61.86%	11	47.83%	62	65.26%	28	68.29%	49	67.12%

	Any nails		Less than 5 nails		5 or more nails		All nails		No nail involvement		
	N	%	N	%	N	%	N	%	N	%	
Total DLQI score at 24 months	0	13	11.02%	1	4.35%	12	12.63%	4	9.76%	4	5.48%
	1	10	8.47%	3	13.04%	7	7.37%	2	4.88%	6	8.22%
	Other	14	11.86%	0	0.00%	14	14.74%	5	12.20%	8	10.96%
	Missing	81	68.64%	19	82.61%	62	65.26%	30	73.17%	55	75.34%
Patients with a Baseline PASI Score		111	100.00%	22	100.00%	89	100.00%	40	100.00%	61	100.00%
aPASI score at BL	0	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%
	1	1	0.90%	0	0.00%	1	1.12%	1	2.50%	1	1.64%
	2	2	1.80%	1	4.55%	1	1.12%	0	0.00%	0	0.00%
	3	1	0.90%	0	0.00%	1	1.12%	1	2.50%	0	0.00%
	>3	107	96.40%	21	95.45%	86	96.63%	38	95.00%	60	98.36%
	Missing	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%
aPASI score at 6 months		31	27.93%	2	9.09%	29	32.58%	10	25.00%	11	18.03%
aPASI score at 6 months	1	9	8.11%	3	13.64%	6	6.74%	4	10.00%	8	13.11%
	2	5	4.50%	0	0.00%	5	5.62%	0	0.00%	8	13.11%
	3	2	1.80%	0	0.00%	2	2.25%	0	0.00%	4	6.56%
	>3	13	11.71%	6	27.27%	7	7.87%	4	10.00%	5	8.20%
	Missing	51	45.95%	11	50.00%	40	44.94%	22	55.00%	25	40.98%

Less than 5 Nails cohort	Any Nails		Less than 5 nails		5 or more nails		All nails		No nail involvement		
	N	%	N	%	N	%	N	%	N	%	
aPASI score at 12 months	0	39	35.14%	7	31.82%	32	35.96%	13	32.50%	9	14.75%
	1	11	9.91%	2	9.09%	9	10.11%	2	5.00%	2	3.28%
	2	5	4.50%	2	9.09%	3	3.37%	2	5.00%	8	13.11%
	3	3	2.70%	1	4.55%	2	2.25%	2	5.00%	1	1.64%
	>3	12	10.81%	4	18.18%	8	8.99%	4	10.00%	10	16.39%
	Missing	41	36.94%	6	27.27%	35	39.33%	17	42.50%	31	50.82%
aPASI score at 18 months	0	21	18.92%	4	18.18%	17	19.10%	4	10.00%	8	13.11%
	1	9	8.11%	3	13.64%	6	6.74%	4	10.00%	2	3.28%
	2	6	5.41%	1	4.55%	5	5.62%	3	7.50%	4	6.56%
	3	6	5.41%	0	0.00%	6	6.74%	4	10.00%	1	1.64%
	>3	6	5.41%	2	9.09%	4	4.49%	1	2.50%	8	13.11%
	Missing	63	56.76%	12	54.55%	51	57.30%	24	60.00%	38	62.30%
aPASI score at 24 months	0	14	12.61%	0	0.00%	14	15.73%	4	10.00%	5	8.20%
	1	7	6.31%	1	4.55%	6	6.74%	3	7.50%	0	0.00%
	2	6	5.41%	2	9.09%	4	4.49%	3	7.50%	3	4.92%
	3	3	2.70%	0	0.00%	3	3.37%	0	0.00%	1	1.64%
	>3	7	6.31%	2	9.09%	5	5.62%	2	5.00%	8	13.11%
	Missing	74	66.67%	17	77.27%	57	64.04%	28	70.00%	44	72.13%

QoL changes from baseline of biologic naïve and experienced patients, using aPASI and total DLQI scores

		Patients biologic naïve at BL		Biologic experienced at BL	
		N	%	N	%
# of Patients		581		186	
Patients with a Baseline DLQI Score		574	100.00%		
Total DLQI score at BL	>10	416	72.47%	184	100.00%
	≤10	158	27.53%	112	60.87%
	Missing	0	0.00%	72	39.13%
				0	0.00%
Total DLQI score at 6 months	0	87	15.16%		
	1	26	4.53%	23	12.50%
	Other	67	11.67%	5	2.72%
	Missing	394	68.64%	37	20.11%
				119	64.67%
Total DLQI score at 12 months	0	116	20.21%		
	1	46	8.01%	34	18.48%
	Other	77	13.41%	11	5.98%
	Missing	335	58.36%	50	27.17%
				89	48.37%
Total DLQI score at 18 months	0	93	16.20%		
	1	31	5.40%	23	12.50%
	Other	69	12.02%	11	5.98%
	Missing	381	66.38%	36	19.57%
				114	61.96%
Total DLQI score at 24 months	0	66	11.50%		
	1	26	4.53%	15	8.15%
	Other	51	8.89%	7	3.80%
	Missing	431	75.09%	25	13.59%

Patients with a Baseline PASI Score	526	100.00%	158	100.00%
aPASI score at BL				
0	2	0.38%	3	1.90%
1	3	0.57%	2	1.27%
2	5	0.95%	0	0.00%
3	4	0.76%	3	1.90%
>3	512	97.34%	150	94.94%
Missing	0	0.00%	0	0.00%

	Biologic naive at BL		Biologic experienced at BL	
	N	%	N	%
aPASI score at 6 months				
0	122	23.19%	28	17.72%
1	46	8.75%	13	8.23%
2	34	6.46%	16	10.13%
3	33	6.27%	11	6.96%
>3	40	7.60%	19	12.03%
Missing	251	47.72%	71	44.94%
aPASI score at 12 months				
0	122	23.19%	33	20.89%
1	38	7.22%	14	8.86%
2	40	7.60%	15	9.49%
3	18	3.42%	10	6.33%
>3	35	6.65%	26	16.46%
Missing	273	51.90%	60	37.97%
aPASI score at 18 months				
0	76	14.45%	19	12.03%
1	25	4.75%	9	5.70%
2	30	5.70%	11	6.96%
3	22	4.18%	7	4.43%
>3	34	6.46%	24	15.19%
Missing	339	64.45%	88	55.70%
aPASI score at 24 months				
0	50	9.51%	15	9.49%
1	20	3.80%	5	3.16%
2	23	4.37%	10	6.33%
3	13	2.47%	3	1.90%
>3	26	4.94%	9	5.70%
Missing	394	74.90%	116	73.42%

Safety Results

NA

Other Relevant Findings

None

Conclusion

This analysis of real-world data from BADBIR suggested that many patients with psoriasis have a large QoL burden prior to starting biologic therapy. Secukinumab treatment up to 24 months produced a sustained improvement in QoL, including for those patients with PsA and nail involvement.

Date of Clinical Study Report

14 April, 2022