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Disease characteristics, clinical and patient reported outcomes in psoriasis patients treated with secukinumab in a US real-world setting: Effectiveness Results from the Corrona Psoriasis Registry

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Background

- Psoriasis is a chronic, immune-mediated disease whose key clinical symptoms include skin itching, pain, and scaling. Many psoriasis patients have reported decreases in their quality of life (QoL) and work productivity[1, 2]
- Secukinumab is a fully human monoclonal antibody that selectively neutralizes IL-17A, clinical trials have shown significant efficacy in the treatment of moderate to severe - psoriasis (PsO) and psoriatic arthritis (PsA) [3-6]
- Little is known on secukinumab's effectiveness on psoriasis in a real world setting

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Methods

Study Objectives:

- Characterize the demographics, disease characteristics, comorbidities, and patient reported outcomes (PROs) of patients initiating secukinumab at enrollment in the Corrona Psoriasis Registry
- Examine the reasons for initiating secukinumab treatment at enrollment
- Examine secukinumab's effectiveness; the change in clinical outcomes and PROs from enrollment to first follow-up (FU) visit (~ 6 months) in patients initiating secukinumab treatment at enrollment

Study Design:

- Retrospective study examining clinical outcomes and PROs at the first follow-up visit post-enrollment

Data Source:

- The Corrona Registry is an independent, prospective observational cohort launched in April 2015 with an enrollment target of 10,000 psoriasis patients from 200 sites across the United States. Follow-up data collection occurs every six (6) months with a visit window of 5 to 9 months

Study population:

- All psoriasis patients ≥18 years of age who initiated secukinumab at enrollment in the Corrona Psoriasis Registry with at least one FU visit as of May 31, 2016 (~6 months from enrollment)

Clinical and Patient Reported Outcomes

- Mean change in body surface area (BSA), Investigator Global Assessment (IGA), Patient-reported pain and Itch
- Mean change in Dermatology Life Quality Index (DLQI), Work Productivity (WPAI), EQ VAS, patient fatigue, and change status in IGA, BSA, and DLQI

Data analysis

- Categorical variables summarized using frequency counts and percentages; Continuous variables summarized by mean, standard deviation, median, and inter-quartile range (IQR)
- Paired t-tests for continuous outcomes, Wilcoxon signed rank tests for interval/ordinal outcomes, and generalized McNemar tests for nominal outcomes to examine univariate differences (enrollment-to-6-month FU visit) test statistics (and p-values)

* Subjects are eligible for enrollment in Corrona if they are diagnosed by a dermatologist and if they are currently receiving (started within the previous 12 months) or are being prescribed at enrollment, a biologic or non-biologic systemic drug for the treatment of psoriasis.

Baseline demographics for secukinumab initiators

- As of May 31 2016, there were 1529 patients enrolled in the registry with 336 patients being treated with secukinumab
  - Out of these, 138 patients initiated secukinumab at enrollment and 53 patients had at least one FU visit, 47 patients were on secukinumab treatment at the first FU visit
  - Out of the 6 secukinumab patients who discontinued prior to the FU visit: 4 discontinued due to insurance denial/co-pay and 2 due to inadequate response
- Median time from enrollment date for the 47 secukinumab patients with use at FU visit was 5.9 months
- Secukinumab patients had mean age of 51.3 years, 57% were male, mean BMI of 30.6 and approximately 49% were obese

Demographics	Secukinumab Initiators
	N=47
Age (yrs), mean (SD)	51.3 (14.8)
Gender: Male, n (%)	27 (57%)
Body weight (kg), mean (SD)	89.8 (18.3)
BMI (kg/m^2), mean (SD)	30.6 (6.6)
BMI categorical, n (%)	
Normal/Underweight (<25)	8 (17%)
Overweight (25.0 < 30)	16 (34%)
Obese (≥ 30)	23 (49%)
Insurance Type, n (%)	
Private	37 (79%)
Medicare	6 (13%)
Medicaid	3(6%)
No Insurance	2(4%)
Smoking, n (%)	
Current smoker	11 (23%)
Former smoker	15 (32%)
Never smoked	21 (45%)

BMI: Body mass index

Disease duration and comorbidities for secukinumab initiators at enrollment

- Patients had a mean disease duration of 24.8 years and 46% had concurrent PsA diagnosis
- Approximately 34% had hypertension, 30% hyperlipidemia, and 26% anxiety

Disease Duration and comorbidities at enrollment	Secukinumab Initiators
	N=47
Psoriasis duration (yrs), n	
mean (SD)	24.8 (16.6)
median (IQR)	21 (11, 33)
Psoriatic Arthritis, n (%)	21 (46%)
Psoriatic Arthritis, duration (yrs), n	N=21
mean (SD)	10.7 (11.9)
median (IQR)	9 (2, 15)
Comorbidities* *(Provider reported)*	
Cardiovascular disease, n (%)	4 (9%)
Hypertension, n (%)	16 (34%)
Hyperlipidemia, n (%)	14 (30%)
Diabetes Mellitus, n (%)	7 (15%)
Lymphoma/Malignancy, n (%)	3 (6%)
Depression, n (%)	9 (19%)
Anxiety, n (%)	23 (26%)

*Comorbidities. CVD: Revascularization procedures (CABG, stent, angioplasty), Ventricular arrhythmia, Cardiac arrest, Acute coronary syndrome, Coronary artery disease, Transient ischemic attack, Hemorrhage with/without hospitalization (serious bleed), Deep vein thrombosis, Peripheral arterial disease, Pulmonary embolism, Carotid artery disease. Malignancy: Breast, Lung, Skin (excluding non-melanoma skin cancer) & Other

Treatment history for secukinumab initiators

- Almost all of the secukinumab patients were biologic experienced (96%), with nearly half having ≥3 prior biologics
  - 33% (n=15) of biologic-experienced patients were treated with ustekinumab prior to secukinumab initiation; other prior biologics included: 35% (n=16) TNF inhibitors (adalimumab, etanercept, certolizumab pegol), 2% (n=1) infliximab, and 29% (n=13) other biologics

Prior Medication	Secukinumab Initiators N=47
Biologic Naïve, n (%)	2 (4%)
Prior biologic usage count	
Biologic experienced, n (%)	45 (96%)
Count of drugs: median (IQR)	2 (2,3)
Prior biologic count, categorical, n (%)	
1 biologic:	10 (22%)
2 biologics:	14 (31%)
3 or more biologics:	21 (47%)

Reasons for initiating secukinumab at enrollment

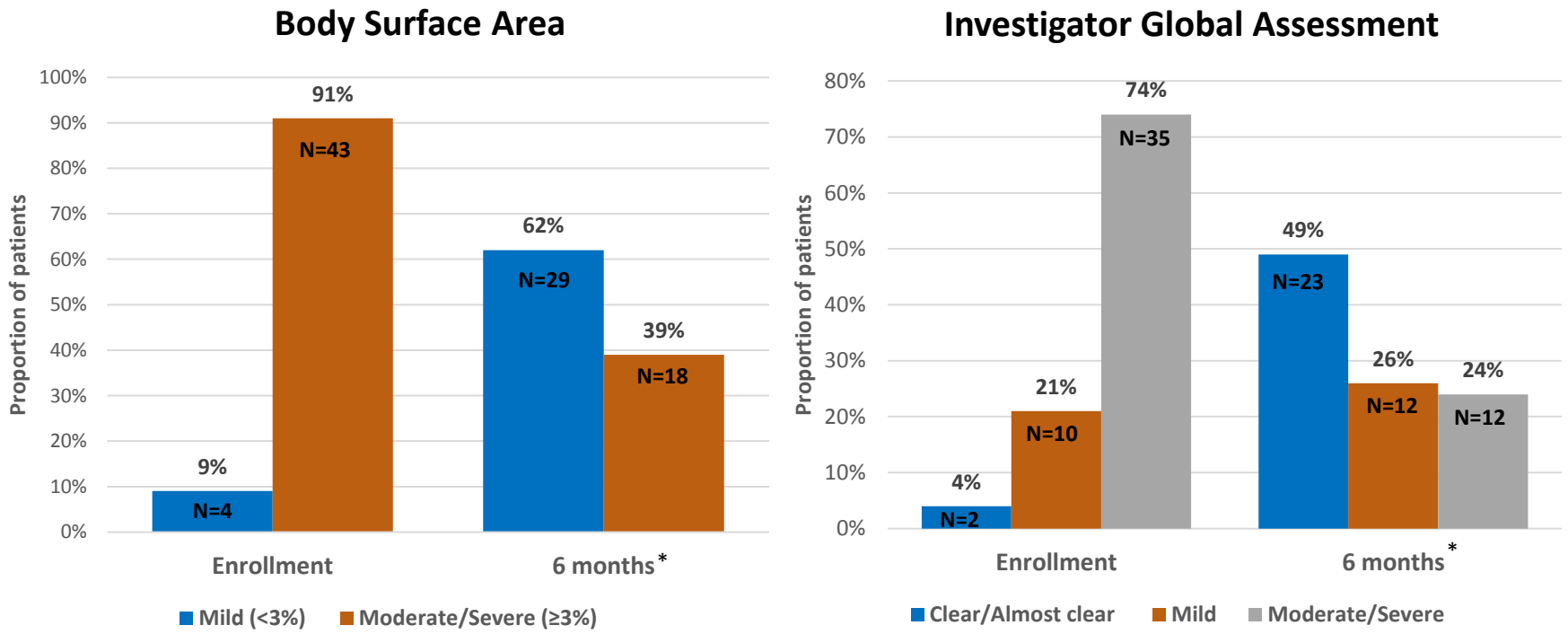
Reasons for drug initiation were provided by the physicians at the time of drug initiation (multiple reasons can be provided)

- Out of the 55 reasons provided for N=47 patients, 85% of the reasons reported were active disease (n=40); 21% (n=10) other reasons, which included patient preference (n=2), alternate mechanism of action (n=6), other (n=1) and improve compliance (n=1); 9% reported efficacy (n=4) and 2% insurance (n=1)

Effectiveness results (BSA and IGA) for secukinumab initiators at 6-month FU visit

- Mean (SD) / median (IQR) psoriasis-affected BSA significantly improved at 6-month FU visit vs enrollment: 3.7% (5.6) / 2 (0, 4) vs. 11.8 % (12.3) / 9 (4, 14), respectively (p<0.0001)
  - The proportion of secukinumab patients with mild disease severity largely increased in the 6-month FU visit vs. enrollment (62% vs. 9%, respectively)

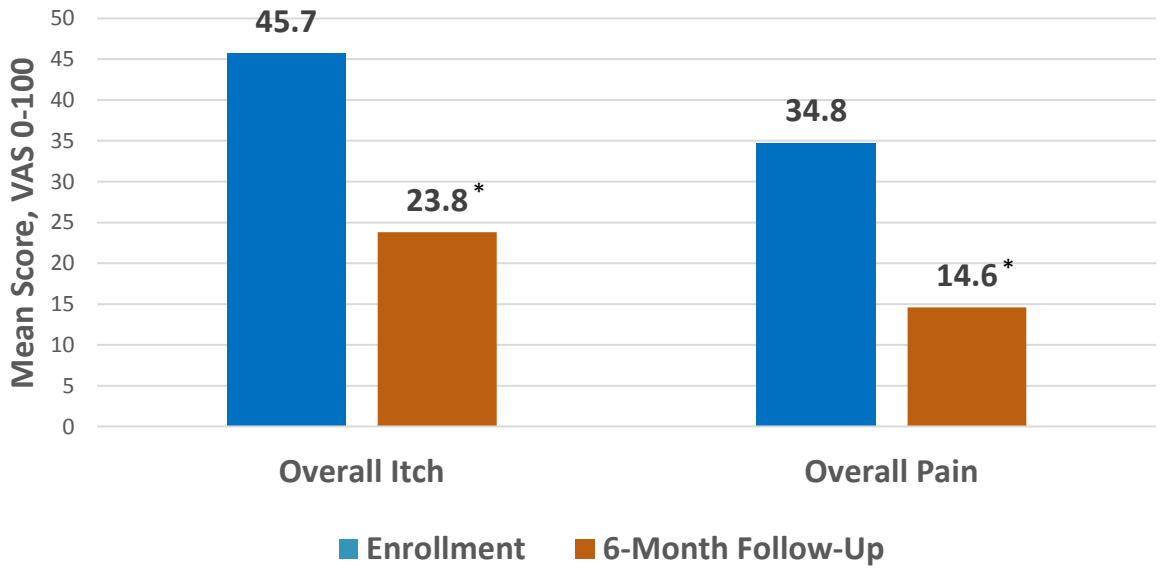
- Mean (SD) /median (IQR) for overall IGA significantly improved at 6-month FU visit vs enrollment: 1.6 (1.2) / 2 (0,3) vs. 2.8 (0.9) / 3(2,3), respectively (p<0.0001)
  - The proportion of secukinumab patients with IGA status clear/almost clear (score 0 or 1) largely increased in the 6-month FU visit vs. enrollment (49% vs. 4%, respectively)



*p<0.0001, significant improvement at 6 m follow-up visit. Body Surface Area (BSA): A disease severity measure characterized by the amount of body surface area affected. It is reported as percent involvement on a scale of 0-100%. Investigator Global Assessment (IGA): A 5-point tool used to measure disease severity on a scale of 0-4, where 0=clear, 1=almost clear, 2=mild, 3=moderate and 4=severe.

Improvements in patient-reported pain, itch, and fatigue for secukinumab initiators at 6-month FU visit

- Mean and median scores for overall patient-reported pain and itch in n=47 patients decreased at the 6-month FU visit
- Mean difference (SD) at 6-month FU visit was -22.0 (38.8) for patient-reported itch and -20.3 (31.4) for patient-reported pain which were statistically significant (p<0.0001)



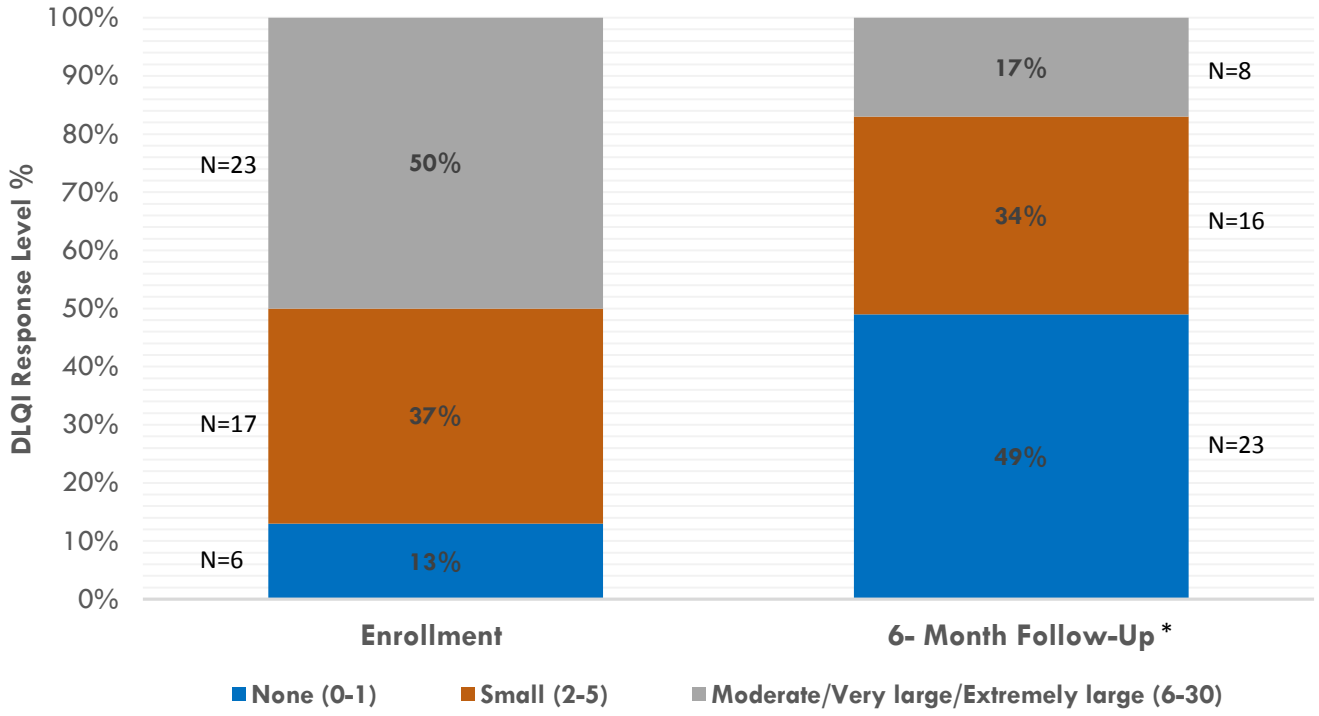
Overall fatigue

- Mean (SD) / median (IQR) for overall patient fatigue improved at 6-month FU visit vs enrollment: 29.2 (26.9) / 17 (5, 50) vs. 34.0 (30.9) / 25 (5, 67), respectively with a mean difference (SD) at 6-month FU visit: -5.2 (27.7) which was not statistically significant

*p<0.001. Patient reported pain and itch are measured on a visual analogue scale 0-100 The recall period is 1 week. Patient reported fatigue are measured on a visual analogue scale 0-100 The recall period is 1 week.

Improvement in quality of life (DLQI) at 6-month follow-up visit

- At enrollment, 13% reported no impact (DLQI 0-1) of the disease on quality of life vs 49% reporting no impact (DLQI 0-1) at 6-month follow-up visit
- Mean (SD) / median (IQR) DLQI score significantly improved at 6-month FU visit vs. enrollment: 2.6 (3.5) / 2 (0,3) vs. 7.4 (5.9) / 5.5 (3,12), respectively (p<0.0001), which is equivalent to the clinically meaningful difference of DLQI (Δ 5 points)



*p<0.001, showing significant improvement at 6 m follow-up visit; DLQI: Dermatology Life Quality Index. Overall DLQI scores range from 0–30; higher scores indicate greater effect on the patient's life (lower QoL). The recall period is 1 week.

Assessment of other PROs (WPAI and EQ-5D) at 6-month FU visit

Work productivity and activity impairment (WPAI)

- 68% (n=32) were currently employed, and n=26 had non-missing data on all the domains. Significant improvement in impairment while working and overall work hours affected were reported at the 6 months follow-up visit
- Patients also reported significant improvements in overall daily activities at 6 months, irrespective of work status

EQ VAS (0-100)

- Mean (SD) of EQ VAS improved at 6-month follow-up visit vs. at enrollment: 77.8 (17.2) vs 71.4 (23.0), with a mean (SD) change of 6.3 (22.0) units at 6 months

EQ-VAS: Self-rated "health state today" is reported on a visual analogue scale from 0-100. The recall period is 1 day; WPAI**:** Percentages are reported for the 4 domains, scores range from 0–100%; higher scores indicate greater impairment and less productivity. The recall period is 1 week.

Conclusions

- In a moderate to severe psoriasis population with high previous biologic use, secukinumab initiators reported significant improvement in disease severity and patient reported outcomes at 6 months
- Data presented in this report should be interpreted with caution due to small sample size. Additional analyses at different data cuts are needed to confirm the results with more patients and longer follow-up

Limitations

- Small sample of patients with 6 month follow up data
- No comparator arm was included in this analysis

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Author Disclosures

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