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Characterization of Disease Burden, Comorbidities and Therapy Use of Patients with Psoriasis at Enrollment: Results from the Corrona Psoriasis Registry

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Background

- Psoriasis (PsO) is an immune mediated chronic inflammatory disease with severe disease burden associated with several comorbidities and impact on quality of life.
- The Corrona PsO registry, in collaboration with the National Psoriasis Foundation (NPF), was launched in April 2015 targeting to recruit approximately 200 sites with ~10,000 patients and an expected follow-up of at least 8 years and to study the comparative effectiveness, safety and treatment patterns of approved systemic therapies in a real world setting.

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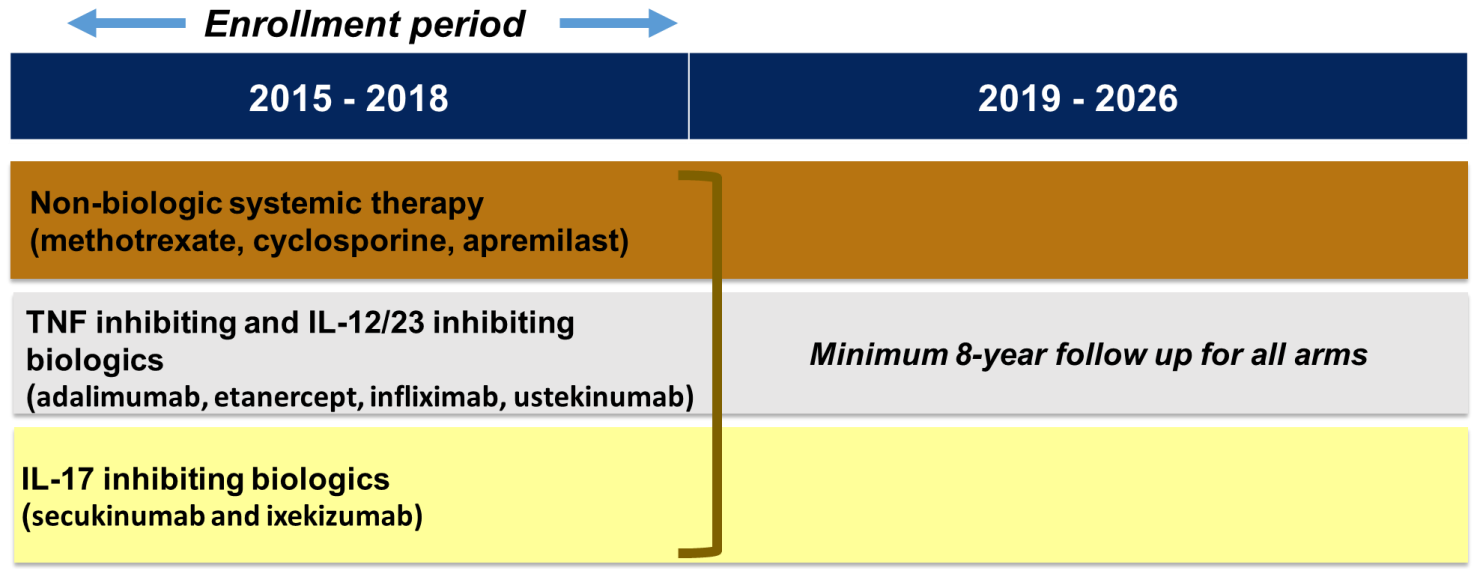
This study is sponsored by Corrona, LLC

Registry Design

Corrona Psoriasis Registry Design

A large prospective observation disease based registry launched in April 2015 to study the comparative safety and effectiveness of approved systemic therapies in Psoriasis.



Note: Target enrollments for the non-biologic systemic therapy arm, TNF-inhibitor and IL-12/23 inhibitor biologic arm, and IL-17-inhibitor biologic arm are 500 subjects, 4000 subjects, and 7000 subjects, respectively.

Study Population*

- ≥18 years with a dermatologist diagnosed psoriasis
- Initiating or switching to a systemic therapy at registry enrollment (incident user) or in the previous 12 months (prevalent user)
- Systemic therapy includes FDA –approved **biologics** (adalimumab, etanercept, infliximab, ustekinumab, secukinumab and ixekizumab) and **non-biologic** (methotrexate, cyclosporine, and apremilast only) treatments for psoriasis

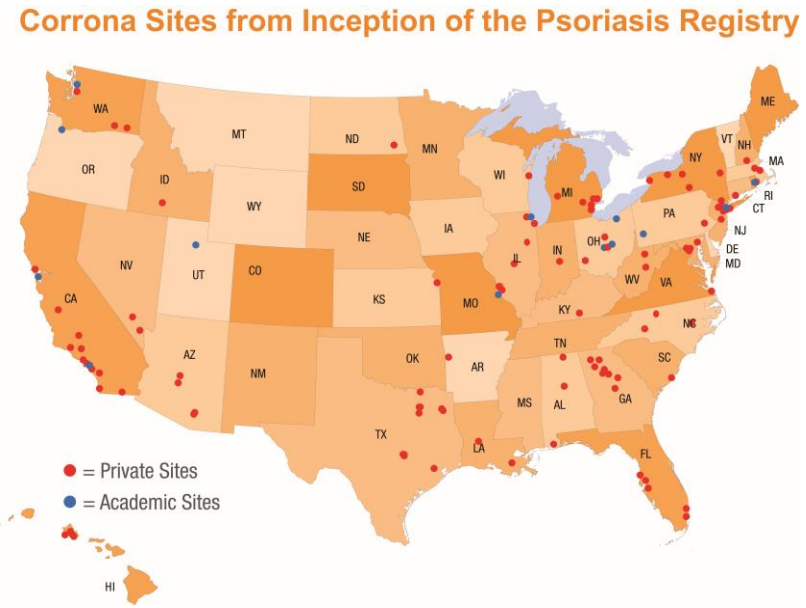
*This is also the registry inclusion criteria.

Objectives and Methods

Objective: To describe the disease burden for PsO patients at registry enrollment

Data Source: Corrona Psoriasis Registry

- As of October 31 2016, the NPF and Corrona have recruited 90 private and academic practice sites across 33 states in the United States, with 189 participating dermatologists.
- There were n=2095 patients with psoriasis participating in the registry at the time of study.
- Data is collected from both the participating dermatologists and patients approximately **every 6 months** during routine outpatient visits.



Descriptive analysis

- Patient demographics, disease characteristics, history of comorbidities, quality of life measures (QoL) and patient reported outcomes (PROs) are presented descriptively for the overall population and cohorts of biologic monotherapy, biologic combination therapy and non-biologic systemic therapy at registry enrollment.

- The biologics and non-biologic (NB) systemic groups are mutually exclusive; and within the biologic systemic treatments, monotherapy/combination therapy groups are also mutually exclusive. For a patient enrolled into the registry on a NB systemic, they will be grouped under the respective NB.

- Means and standard deviations (SD) are reported for continuous variables. Counts and proportions are reported for categorical variables in addition to mean (SD).

Study Measures and Assessments

Demographics*	• Age • Gender • Height • Weight • Education	• Body Mass Index (BMI) • Work status • Insurance type • Smoking Status
Treatment History	• Prior Medication (Biologic and Non-biologic systemics) • Treatment initiation at enrollment visit (incident user) • Treatment initiation in the previous 12 months (prevalent user)	
Disease Characteristics	Disease Severity: • Body Surface Area (BSA) • Investigator's Global Assessment (IGA) • Psoriasis Area and Severity Index (PASI): 0-72 • Psoriasis disease duration • History of comorbidities	
Patient Reported Outcomes	• Pain, Itch and Fatigue (VAS 0-100) • Euro-QoL Overall health state VAS (0-100) • Dermatology Quality of Life Index (DLQI) • Work Productivity and Activity Impairment (WPAI)	

Patient Reported

Physician Reported

Patient Reported

BSA: Affected percent of body surface area 0-100%.
IGA: 0= Clear, 1= Almost Clear, 2= Mild, 3= Moderate, 4= Severe.
EQ-VAS: Self-rated "health state today" is reported on a visual analogue scale from 0-100. The recall period is 1 day.
DLQI: Dermatology Quality of Life 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.
WPAI**:** Four subdomains measure absenteeism, presenteeism, work productivity, and activity impairment. WPAI scores range from 0–100%; higher scores indicate greater impairment and less productivity. The recall period is 1 week.
*All Demographics are patient reported with the exception of height, weight and BMI.

Demographics

- There were N=1,529 patients enrolled in the registry as of May 31st 2016, with 59.3% (n=906) on biologic monotherapy, 8.6% (n=131) on biologic combination therapy and 32.2% on non-biologic systemic therapy.
- Overall, patients had mean age of 50.6 years, 47% female, mean BMI of 30.5 and mean disease duration of 15.7 years.
- Overall 40% had a concurrent diagnosis of psoriatic arthritis and mean PsA duration of 7.9 years. About 54% (N=828) were biologic experienced, 8% with history of ≥3 prior biologics.

Demographics	Overall N=1529(100%)	Biologic Monotherapy N=906 (59.3%)	Biologic Combination Therapy N=131 (8.6%)	Non-Biologic Systemic Therapy N=492 (32.2%)
Age in years, *mean (SD)*	50.6 (14.4)	48.7 (14.2)	52.7 (12.5)	53.4 (14.7)
Female, *n (%)*	718 (47%)	414 (46%)	63 (48%)	241 (49%)
Body Mass Index (kg/m^2), *mean (SD)*	30.6 (7.3)	30.9 (7.5)	31.4 (7.2)	29.7 (7.0)
Percent Obese (≥30)	689 (45%)	427 (48%)	69 (53%)	193 (39%)
History of Comorbidities, n (%)				
Diabetes Mellitus	216 (14%)	125 (14%)	25 (19%)	66 (13%)
Hypertension	596 (39%)	320 (35%)	66 (50%)	210 (43%)
Hyperlipidemia	433 (28%)	244 (27%)	36 (27%)	153 (31%)
Cardiovascular disease	148 (10%)	72 (8%)	17 (13%)	59 (12%)
Depression	292 (19%)	164 (18%)	39 (30%)	89 (18%)
Anxiety	276 (18%)	164 (18%)	37 (28%)	75 (15%)
Psoriasis disease duration, mean (SD)	15.7 (13.6)	16.9 (13.5)	15.2 (14.1)	13.8 (13.3)
Concurrent diagnosis of Psoriatic Arthritis, n (%)	619 (40%)	345 (38%)	74 (56%)	200 (41%)
Psoriatic arthritis disease duration, mean (SD)	7.9 (8.4)	8.4 (8.2)	8.9 (9.9)	6.7 (7.9)
Biologic experienced, n (%)	828 (54%)	555 (61%)	95 (73%)	178 (36%)
History of ≥3 biologics	59 (8%)	32 (8%)	21 (16%)	6 (4%)

Clinical Characteristics

- Overall, about half of patients had moderate/severe disease severity measured by IGA, with an overall average score of 2.2. Average IGA score was lower in prevalent users as compared to incident users in overall patients and across treatment groups.

Clinical Characteristics	Overall	Biologic Monotherapy	Biologic Combination Therapy	Non-Biologic Systemic Therapy
	N=1529(100%)	N=906 (59.3%)	N=131 (8.6%)	N=492 (32.2%)
Investigator Global Assessment (IGA), mean (SD)				
All Patients	2.2 (1.1)	2.1 (1.2)	2.6 (1.1)	2.3 (1.1)
Incident Users	2.9 (0.9)	2.9 (0.8)	3.0 (1.0)	2.8 (0.8)
Prevalent Users	1.9 (1.1)	1.7 (1.2)	2.4 (1.1)	2.1 (1.1)
IGA Categorical, n (%)				
0: Clear	164 (11%)	114 (13%)	10 (8%)	40 (8%)
1: Almost Clear	211 (14%)	145 (16%)	10 (8%)	56 (11%)
2: Mild	404 (26%)	231 (25%)	29 (22%)	144 (29%)
3: Moderate	586 (38%)	327 (36%)	54 (41%)	205 (42%)
4: Severe	162 (11%)	89 (10%)	28 (21%)	45 (9%)

Clinical Characteristics

- The overall mean BSA was 9.1%, with two-thirds of patients in moderate/severe disease as defined by BSA.
- The average PASI was 5.7 and approximately 17% of patients had a score of >10 at registry enrollment. Average scores were lower in prevalent users compared to the incident users overall and across treatment groups.

Clinical Characteristics	Overall	Biologic Monotherapy	Biologic Combination Therapy	Non-Biologic Systemic Therapy
	N=1529(100%)	**N=906 (59.3%)**	**N=131 (8.6%)**	**N=492 (32.2%)**
Body Surface Area (BSA) (% Involvement)				
All Patients, *mean (SD)*	9.1 (13.5)	9.2 (13.7)	10.5 (14.7)	8.6 (12.8)
Incident Users, *mean (SD)*	14.8 (16.6)	14.4 (15.1)	16.7 (20.6)	14.9 (18.2)
Prevalent Users, *mean (SD)*	6.3 (10.6)	6.3 (12.0)	6.7 (7.4)	6.1 (8.6)
BSA Categorical, n (%)				
Mild disease [0,3)	519 (34%)	331 (37%)	39 (30%)	149 (30%)
Moderate disease [3,10)	670 (44%)	367 (41%)	55 (42%)	248 (51%)
Severe disease (10,100)	336 (22%)	207 (23%)	37 (28%)	92 (19%)
Psoriasis Area and Severity Index (PASI) (Score 0-72)				
Overall mean (SD)	5.7 (6.9)	5.9 (7.2)	6.6 (6.6)	5.1 (6.2)
Score >10, n (%)	259 (17%)	176 (19%)	29 (22%)	54 (11%)
Incident users				
Overall mean (SD)	8.8 (8.1)	9.5 (8.2)	8.3 (7.2)	7.5 (7.8)
Score >10, n (%)	157 (31%)	117 (36%)	14 (28%)	26 (19%)
Prevalent users				
Overall mean (SD)	4.1 (5.5)	3.9 (5.6)	5.5 (6.1)	4.2 (5.3)
Score >10, n (%)	102 (10%)	59 (10%)	15 (19%)	28 (8%)

Patient Reported Outcomes

- Patients had an average of 31.1 and 23.6 on a VAS 0-100 scale for overall fatigue and pain respectively.
- Overall 65% were employed at the registry enrollment with 13.1% reporting overall work impairment.
- About 1 in 5 patients reported very large/extremely large effect on life as measured by DLQI.

Patient Reported Outcomes (PROs)	Overall N=1529 (100%)	Biologic Monotherapy N=906 (59.3%)	Biologic Combination Therapy N=131 (8.6%)	Non-Biologic Systemic Therapy N=492 (32.2%)
Overall Fatigue (VAS range 0-100), *mean (SD)*	31.1 (29.0)	28.9 (28.4)	39.8 (28.9)	33.0 (29.6)
Overall Pain (VAS range 0-100), *mean (SD)*	23.6 (29.9)	23.2 (30.1)	30.6 (31.7)	22.4 (29.0)
Overall health status (EQ-VAS range 0-100), mean (SD)	72.7 (22.2)	74.2 (21.6)	67.6 (22.3)	71.4 (23.2)
Work Productivity and Activity Impairment (WPAI)				
Currently employed, n (%)	996 (65%)	628 (69%)	81 (62%)	287 (59%)
% Work time missed, *mean (SD)*	2.9 (11.7)	2.9 (11.7)	3.4 (12.6)	2.7 (11.4)
% Impairment while working, *mean (SD)*	11.8 (20.8)	10.9 (20.0)	11.3 (19.1)	14.3 (22.9)
% Overall work hours affected, *mean (SD)*	13.1 (21.9)	12.0 (21.1)	13.5 (21.3)	15.5 (23.8)
% Activity impairment, *mean (SD)*	18.7 (26.3)	16.9 (25.4)	26.9 (31.1)	20.0 (26.1)
Dermatology Life Quality Index (DLQI) (0-30)				
DLQI, *mean (SD)*	6.6 (6.1)	6.6 (6.3)	7.7 (6.4)	6.4 (5.6)
DLQI "Effect on life", *n (%)*				
0-1: None	349 (23%)	232 (26%)	19 (15%)	98 (20%)
2-5: Small	495 (32%)	268 (30%)	46 (35%)	181 (37%)
6-10: Moderate	308 (20%)	178 (20%)	26 (20%)	104 (21%)
11-20: Very large	311 (20%)	182 (20%)	34 (26%)	95 (19%)
21-30: Extremely large	62 (4%)	42 (5%)	6 (5%)	14 (3%)

Conclusions

This disease-based registry cohort represents a population that is exposed to multiple therapies, longer duration and multiple comorbidities. The registry has the ability to capture real-world data which can be utilized to examine comparative safety and efficacy of various therapies.

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