Baseline Demographic and Clinical Characteristics of Patients with Plaque Psoriasis treated with Brodalumab in the Canadian Real-World Setting: Results from the CARE Study

CARE
CanDerm Study

PCR258

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INTRODUCTION

- Plaque psoriasis (PsO) is a chronic, inflammatory skin condition affecting 2-3% of the Canadian population (1,2), and 125 million people worldwide (3,4). In recent years, management of PsO using biologic therapies has been found to be of significant benefit to patients.
- Brodalumab, an interleukin 17 receptor A antagonist (IL-17RA), is indicated in Canada for the treatment of moderate-to-severe PsO in adult patients who are candidates for systemic therapy or phototherapy (5). A phase III clinical program, the AMAGINE studies, established the efficacy and safety of brodalumab in a number of trials (6, 7).
- Since receiving marketing authorization in Canada in March 2018 (5), there have been limited studies demonstrating brodalumab's real-world effectiveness, safety, and impact on patients' quality of life, and no studies demonstrating its impact on work productivity in Canada.

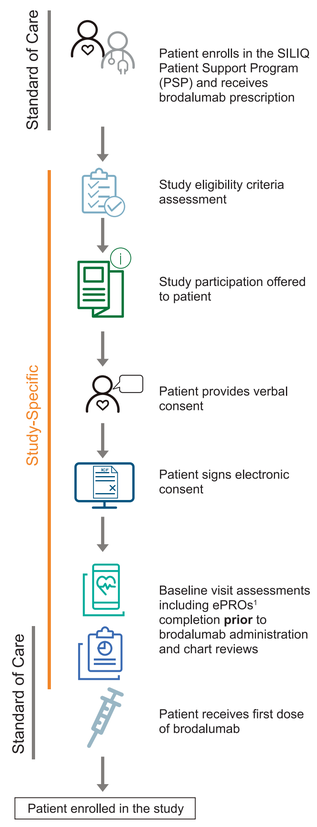
OBJECTIVE

- The CARE study aims to evaluate the real-world effectiveness, safety, and impact of brodalumab on the quality of life and work productivity of adult patients with PsO in Canada.
- In this first interim analysis, we describe the baseline demographic and clinical characteristics of patients enrolled in the CARE study.

METHODS

- This prospective observational multi-center phase IV study included adult patients with PsO who initiated brodalumab as part of routine clinical care in Canada **(Figure 1)**.

Figure 1. Patient Enrollment Pathway



[1]Patient has to complete the baseline ePROs (DLQI, WPAI:PSO, HUI2, TSQM, PSI, and HCRU) after providing electronic informed consent and prior to receiving their first dose of brodalumab in order to qualify for enrollment in the study.

DLQI: Dermatology Life Quality Index, HCRU: Healthcare Resource Utilization, HUI2: Healthy Utilities Index 2, PSI: Psoriasis Symptom Inventory, TSQM: Treatment Satisfaction Questionnaire for Medication, WPAI:PSO: Work Productivity and Activity Impairment.

- Per study eligibility requirements, the decision to treat with brodalumab must have been reached prior to and independently of recruitment in the study.
- Data collection began in October 2021 and is expected to continue until January 2025. The initial data described were collected at Baseline, which represents the measure closest to, but before the initiation of brodalumab.
- Baseline demographics (i.e., age, sex, race, BMI (body mass Index), employment status, income, and insurance provider) were collected from patient medical charts or provided by the patient, while baseline clinical characteristics (i.e., disease duration, disease location, disease severity, comorbidities, and prior treatment history) were obtained from patient medical charts, physician assessments and patient reported outcomes.
- Unless otherwise stated, missing data was dropped from the interim analysis. Descriptive analysis was performed using all available data (Complete Case Analysis).

RESULTS

Baseline Demographics

- At the time of this interim analysis, a total of 166 patients with verified Baseline data were enrolled in the CARE study.

Table 1. Baseline Demographics

Baseline Demographics	N	Baseline
Age (years), mean ± SD	166	51.0 ± 13.2
Sex - male, n (%)	166	99 (59.6)
Race - Caucasian, n (%)	166	131 (78.9)
BMI (kg/m^2), mean ± SD	121	30.2 (6.7)
Employed[1], n (%)	145	106 (73.1)
Income <$100,000, n (%)	144	85 (59.0)
Medication Insurance (N=142)		
Public, n (%)		40 (28.2)
Private, n (%)		86 (60.6)

[1]Patients are considered employed if either part-time, full-time, or self-employed
BMI: Body Mass Index, SD: Standard Deviation

- Most patients were recruited from centers in Ontario (53.6%, n=89/166) or Quebec (30.7%, n=51/166).
- Over 70% of patients were employed (n=106/145), and 60.6% (n=86/142) had private health insurance **(Table 1)**.

Baseline Clinical Characteristics

- At Baseline, nearly two-thirds of patients (63.3%, n=100/158) reported a disease duration ≥10 years.
- Most patients had one or more comorbidities (71.1%, n=118/166), with hypertension being the most prevalent (26.5%, n=44/166) **(Table 2)**.

Table 2. Clinical Characteristics

Clinical Characteristics	Baseline (N=166)
Disease Duration (N=158)	
0 to <10 years, n (%)	58 (36.7)
10 to < 20 years, n (%)	46 (29.1)
20 years, n (%)	54 (34.2)
Number of Comorbidities of Interest	
None, n (%)	48 (28.9)
1, n (%)	48 (28.9)
2 - 4, n (%)	60 (36.1)
5+, n (%)	10 (6.0)
Comorbidities of Interest[1]	
Hypertension, n (%)	44 (26.5)
Psoriatic arthritis, n (%)	29 (17.5)
Type 2 diabetes mellitus, n (%)	23 (13.9)
Depression, n (%)	23 (13.9)
Obesity, n (%)	18 (10.8)
Anxiety, n (%)	17 (10.2)

[1]More than one comorbidity could be selected for each patient

- Reported rates of special site involvement were scalp (69.3%, n=115/166), hands (56.6%, n=94/166), face (54.8%, n=91/166), feet (45.2%, n=75/166), and genitalia (31.3%, n=52/166) **(Figure 2)**.

Figure 2. Disease Location

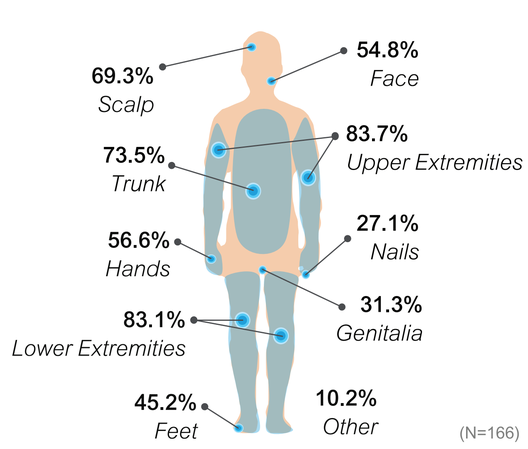
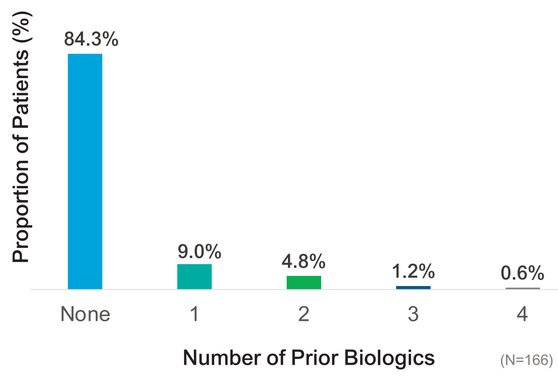


Figure 3. Number of Prior Biologics



- 84.3% of patients had not received any prior biologic systemic therapy for PsO (n=140/166) **(Figure 3)**.
- Of the 15.7% (n=26/166) of patients with prior biologic experience, the most prevalent prior biologic systemic therapies were ustekinumab (42.3%, n=11/26), secukinumab (30.8%, n=8/26), and adalimumab (30.8%, n=8/26).
- The most common prior PsO treatments included topical corticosteroids (55.4%, n=92/166), methotrexate (49.4%, n=82/166), topical fixed combination betamethasone dipropionate + calcipotriol (30.7%, n=51/166), UVB phototherapy (30.1%, n=50/166), or acitretin (21.7%, n=36/166).

Disease Severity at Baseline

- Based on physician assessments (Psoriasis Area Severity Index (PASI) and Static Physician's Global Assessment (sPGA)) and self-reported measures (Psoriasis Symptom Inventory (PSI) and Dermatology Life Quality Index (DLQI)), most patients had moderate or severe disease that affected their quality of life at Baseline **(Table 3)**.

Table 3. Disease Severity at Baseline

Patient Reported Outcomes	Baseline
Dermatology Life Quality Index (DLQI) (N=145)[1]	
Mean (SD)	14.0 (7.4)
Median (IQR)	14.0 (8.0, 19.0)
Psoriasis Area and Severity Index (PASI) (N=166)	
Mean (SD)	13.9 (9.5)
Median (IQR)	12.0 (8.0, 17.6)
Static Physician's Global Assessment (sPGA) (N=166)	
0 – Clear, n (%) [2]	1 (0.6)
1 – Almost clear, n (%)	0 (0.0)
2 – Mild, n (%)	6 (3.6)
3 – Moderate, n (%)	107 (64.5)
4 – Severe, n (%)	52 (31.3)
Psoriasis Symptom Inventory score (PSI) (N=160)[3]	
Mean (SD)	18.7 (7.1)
Median (IQR)	18.5 (14.0, 24.0)
Min - Max	1 - 32

SD: Standard deviation, IQR: inter-quartile range, Min: minimum, Max: maximum
[1]Total scores missing for patients who did not answer two or more of the ten items.
[2]Patient provided treatment for psoriasis despite 'Clear' rating based on physician discretion.
[3]Total scores missing for patients who did not answer one or more of the eight items.

CONCLUSIONS

- Preliminary assessment of patients with moderate to severe PsO in the CARE study demonstrated that the disease had an impact on quality of life prior to the initiation of treatment.
- While the patient population with PsO in this study herein is comparable to other baseline data from recently published real-world studies (8, 9), the CARE study includes a proportionately higher number of bio-naïve PsO patients.
- Limitations associated with the real-world observational nature of the study design, such as inconsistencies regarding the availability of data in patient charts across sites, are the main limitations of these preliminary findings.
- Following brodalumab initiation, additional data will be collected over a 12-month period for patients enrolled in the CARE study. Further analyses of these data will provide a comprehensive evaluation of the impact of brodalumab therapy on quality of life and work productivity.

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Kalia S, Wiseman MC, Loo WJ, Brassard D, Adam DN, Kelly V, and Wong R are investigators involved in the CARE study.

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