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Certolizumab Pegol Use in the Treatment of Moderate-to-Severe Psoriasis: Real-World Data From Two Canadian Centers

Ronald B. Vender[1,2] and Charles W. Lynde[3,4,5]

Abstract

Background: Certolizumab pegol (CZP) is a TNF-α inhibitor used to treat moderate-to-severe plaque psoriasis (PsO) in adult patients, including women of childbearing potential (WOCBP) and patients with psoriatic arthritis (PsA). There are currently limited real-world data on CZP for treatment of PsO.

Objectives: To examine the use of CZP for treatment of PsO in clinical practice at two dermatology clinics in Canada.

Methods: We conducted a retrospective chart analysis of 59 patients with moderate-to-severe psoriasis receiving CZP. Clinical efficacy was measured using the Psoriasis Area and Severity Index (PASI), Body Surface Area (BSA), and Physician Global Assessment (PGA). Drug survival was analyzed using Kaplan-Meier plots.

Results: Of the 59 patients, 36 (61%) were female, of whom 23 (63.9%) were WOCBP. Twenty-three (39.0%) patients received CZP as their first biologic treatment. The main reasons for choosing CZP were its efficacy in both PsO and PsA, and for WOCBP due to little or no cross-placental transfer. Improvement of symptoms was observed after 3 months of treatment and was maintained for the 12-month analysis period. After 12 months of treatment, the patients' mean PASI score decreased from 13.0 (±5.8) at baseline to 2.3 (±4.3), mean BSA score from 13.1% (±6.7%) to 1.7% (±2.6%), and mean PGA score from 3.0 (±0.6) to 0.8 (±0.6). Overall CZP drug survival rate was 76.3% at 12 months, with no difference between biologic-naive and biologic-experienced patients.

Conclusions: CZP was effective and well tolerated in this cohort of patients with moderate-to-severe PsO in a real-world setting.

Keywords

psoriasis, certolizumab pegol, real-world data, biologics, TNF-alpha inhibitor

Introduction

Psoriasis is a chronic inflammatory condition of the skin, for which there is currently no cure. It is estimated that approximately 500,000 Canadians are diagnosed with psoriasis.[1] Psoriasis is an immune-mediated inflammatory condition, and as such, immune cells and inflammatory cytokines are the main drivers of its pathogenesis. IL-17 works in synergy with TNF-α to drive keratinocyte differentiation and proliferation, as well as further immune cell activation. These inflammatory responses contribute to a positive feedback loop and the persistence of psoriatic plaques.[2]

While mild psoriasis can be managed with topical treatments, systemic treatments are the mainstay of moderate-to-severe psoriasis management. The advent of biologics in the last 15 years has transformed the treatment of psoriasis, leading to improved control of symptoms and quality of life. Biologic therapies act to decrease the inflammatory cascade, which is key to the pathogenesis of psoriasis.[2] There are a number of biologics indicated for the treatment of moderate-to-severe psoriasis, allowing the physicians and patients to choose the treatment best suited for the individual patient's clinical situation and to have alternative options if a primary or secondary treatment failure develops.[3,4]

[1]Division of Dermatology, Department of Medicine, McMaster University, Hamilton, ON, Canada
[2]Dermatrials Research Inc. & Venderm Innovations in Psoriasis, Hamilton, ON, Canada
[3]Division of Dermatology, University of Toronto, Toronto, ON, Canada
[4]Lynde Institute for Dermatology, Markham, ON, Canada
[5]Probity Medical Research Inc., Waterloo, ON, Canada

Corresponding Author:
Ronald B. Vender, Dermatrials Research Inc., 25 Charlton Ave E Suite 707, Hamilton, ON L8N 1Y2, Canada.
Email: ron.vender@me.com

Certolizumab pegol (CZP, Cimzia®, UCB) is a polyethylene glycol-conjugated (PEGylated) humanized antibody Fab' fragment with specificity to TNF-α. Phase 2 and phase 3 trials of CZP in psoriasis have previously demonstrated improvements in efficacy and quality of life that were maintained over time, regardless of previous TNF-α inhibitor exposure.[5-7] Due to the absence of the Fc region, CZP is not actively transported into the placenta.[8,9] CZP is the only biologic therapy approved for treatment of plaque psoriasis in Canada that has been extensively researched in studies of pregnancy outcomes, breastfeeding, and placental transfer.[8-10] As a result, the Canadian Product Monograph for CZP contains recommendations on the treatment of women of childbearing potential (WOCBP).[11] In Canada, CZP is indicated for treatment of adults with moderate-to-severe plaque psoriasis (PsO) who are candidates for systemic therapy, as well as for adults with moderate-to-severe psoriatic arthritis (PsA) and who have failed one or more disease-modifying antirheumatic drugs.[11]

CZP has been used in Canada for the treatment of PsO since its approval for this indication in 2018, and for the treatment of patients with PsA, since the approval for this indication in 2014. Despite the longstanding use of CZP, there are only limited real-world data on its use in the treatment of psoriasis[12] and none that have been published for its use in Canadian patients. We present a retrospective chart analysis of CZP use in patients with largely moderate-to-severe PsO in two dermatology clinics in Ontario, Canada.

Patients and Methods

Patient Selection

We conducted a retrospective chart review of patients diagnosed with PsO who started treatment with CZP between January 1, 2018 and February 28, 2021, regardless of the duration of treatment. Data collection was undertaken on April 3, 2021 by RBV and April 16, 2021 by CWL. A total of 62 patients were enrolled from two tertiary private dermatology clinics in Ontario, Canada (37 from a solo practice [RBV] and 22 from a group practice [CWL]). Three patients were excluded from the analysis due to the missing discontinuation date of CZP treatment.

At baseline, patients' demographic data, disease characteristics and previous treatments, comorbidities, and medical history were collected. These included: age; gender; for women, childbearing potential and future pregnancy planning; severity of PsO (evaluated by Psoriasis Area and Severity Index [PASI], body surface area [BSA], and Physician Global Assessment [PGA]), presence of concomitant morbidities, including psoriatic arthritis, axial spondyloarthritis, diabetes mellitus, fatty liver, hypertension, inflammatory bowel disease and obesity; previous systemic therapies; previous biologic experience and reason for discontinuation; reasons for starting CZP.

Outcomes

Clinical efficacy of CZP was evaluated using the PASI, BSA, and PGA scores at baseline and at 3, 6, 9, and 12 months after CZP initiation. Drug survival was defined as the duration of time a patient was treated with CZP, from initiation to discontinuation of treatment. Drug survival analysis included only those patients who started CZP treatment 12 months or more prior to data collection.

Statistical Analysis

Data are presented as mean ± standard deviation (SD) for continuous variables, and frequency (n) and percentage for categorical variables. Descriptive, unadjusted, drug survival Kaplan-Meier plots were generated with GraphPad Prism 9.1. Mantel-Cox test was used for the comparison of drug survival curves between biologic-naïve (CZP as first biologic treatment) vs. non-naïve patients.

Results

Demographics and Baseline Clinical Characteristics

This retrospective analysis included 59 patients with PsO who were treated with CZP. The characteristics of the study population are described in Table 1. The mean patient age was 46.2 ± 13.3 years. Thirty-six (61.0%) patients were female, of whom 23 (63.9%) were WOCBP (defined as females who have experienced menarche and who are not permanently sterile or postmenopausal). The majority of patients were diagnosed with moderate-to-severe PsO.[1] At baseline, the mean (±SD) PASI score was 13.0 (±5.8), the mean BSA score was 13.0% (±6.7%), and the mean PGA score was 3.0 (±0.6). More than half of the patients (34; 57.6%) had a concomitant diagnosis of PsA.

The most common previous systemic treatment was methotrexate (30; 50.8% patients). Thirty-seven (62.7%) patients had been previously treated with one or more biologic therapies, most commonly another TNF-α inhibitor (29; 49.2%). CZP was the first-line biologic treatment for 23 (39.0%) patients (biologic-naïve). Nearly all (35/36; 97.2%) patients who were previously treated with one or more biologics switched to CZP due to failure of the previous biologic treatment. It should be noted that of the 36 patients who had previously failed a biologic treatment, 15 (41.7%) have remained on treatment with CZP for at least 12 months. Twelve of the biologic-naïve patients were WOCBP, which makes up approximately half (52.2%) of all WOCBP patients.

Exposure and Dosing

For the whole analysis population of 59 patients, the mean duration of CZP treatment per patient was 376.9 ± 230.3

Table 1. Characteristics of the Study Population.

Clinical characteristics	N = 59
General	
Age, mean ± SD (years)	46.2 ± 13.3
Female, *n* (%)	36 (61.0)
Women of childbearing potential, *n* (%)[a]	23 (63.9)
Planning pregnancy, *n* (%)[a]	0 (0)
Pregnant, *n* (%)[a]	3 (8.3)
Breastfeeding, *n* (%)[a]	1 (2.8)
Disease characteristics, mean ± SD [range]	
PASI at baseline	13.0 ± 5.8 [0.8, 28.8]
BSA at baseline, %	13.1 ± 6.7 [2.0, 30.0]
PGA at baseline	3.0 ± .6 [1.0, 4.0]
Comorbidities, *n* (%)	
Psoriatic arthritis	34 (57.6)
Diabetes mellitus	8 (13.6)
Hypertension	8 (13.6)
Fatty liver	5 (8.5)
Inflammatory bowel disease	4 (6.8)
Obesity	2 (3.4)
Axial spondyloarthritis	0 (0)
Prior systemic treatment, *n* (%)	
Methotrexate	30 (50.8)
Apremilast	8 (13.6)
Cyclosporine A	5 (8.5)
Acitretin	5 (8.5)
Previously failed biologic therapies, *n* (%)	
Biologic-naïve	23 (39.0)
1 biologic	17 (28.8)
≥2 biologics	19 (32.2)
Prior biologic treatment, *n* (%)	
TNF-α inhibitor	29 (49.2)
IL-17 inhibitor	21 (35.6)
IL-23 inhibitor	10 (16.9)
IL-12/23 inhibitor	9 (15.3)
Characteristics of biologic-naïve patients, *n* (%)[b]	
Female	13 (59.1)
Women of childbearing potential[a]	12 (92.3)
Psoriatic arthritis	8 (36.4)
Diabetes	5 (22.7)
Hypertension	3 (13.6)
Fatty liver	2 (9.1)

Abbreviations: BSA, Body Surface Area; IL, interleukin; *N*, number of individuals; PASI, Psoriasis Area and Severity Index; PGA, Physician Global Assessment; TNF, tumor necrosis factor.
[a]Male patients were excluded from calculations of percentages of women of childbearing potential.
[b]Percentages were calculated out of biologic-naive patients (*n* = 23).

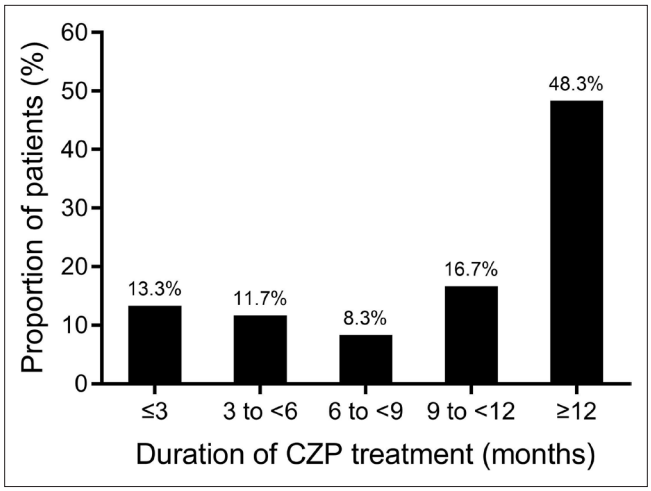

Figure 1. Duration of treatment with CZP. *N* = 59. Duration of treatment is shown for the whole population irrespective of how long prior to the data collection date the patient started CZP treatment. CZP, certolizumab pegol; N, number of patients.

days (range 40-974 days). Of these, 29 patients (49.2%) were treated for at least 12 months. CZP treatment duration, from start of treatment to data collection date, is shown by 3-month intervals in Figure 1. It should be noted that the length of treatment does not reflect CZP treatment discontinuations, as there was no minimum treatment duration required for inclusion in the analysis.

Forty-one (69.5%) patients were treated with 400 mg of CZP every 2 weeks, and the remaining 18 (30.5%) patients received 200 mg of CZP every 2 weeks (after the loading doses of 400 mg[11]) (Table 2). No patients required an increase in CZP dosing.

In terms of physician and patient preferences for starting CZP, in addition to its proven efficacy in the treatment of PsO, the most common reason for commencing CZP treatment was cited as diagnosis of PsA (35 [59.3%] patients). For 19 out of 36 female patients (52.8%), CZP was selected due to the patient's status as a WOCBP (Table 2).

In the analysis population, 14 (23.7%) patients discontinued treatment with CZP. Eight patients discontinued due to

Table 2. CZP Treatment Characteristics.

	N = 59
CZP dosing regimen, *n* (%)	
200 mg every 2 weeks[a]	18 (30.5)
400 mg every 2 weeks	41 (69.5)
Reason for choosing CZP, n (%)[b]	
Psoriatic arthritis	35 (59.3)
Women of childbearing potential[c]	19 (52.8)
Failure of previous treatment	5 (8.5)

Abbreviations: CZP, certolizumab pegol; N, number of patients.
[a]Patients were treated with a loading dose of 400 mg at week 0, 2 and 4, before reducing to a maintenance dose of 200 mg.
[b]More than one reason could have been selected.
[c]Male patients were excluded from calculations of percentages for women of childbearing potential.

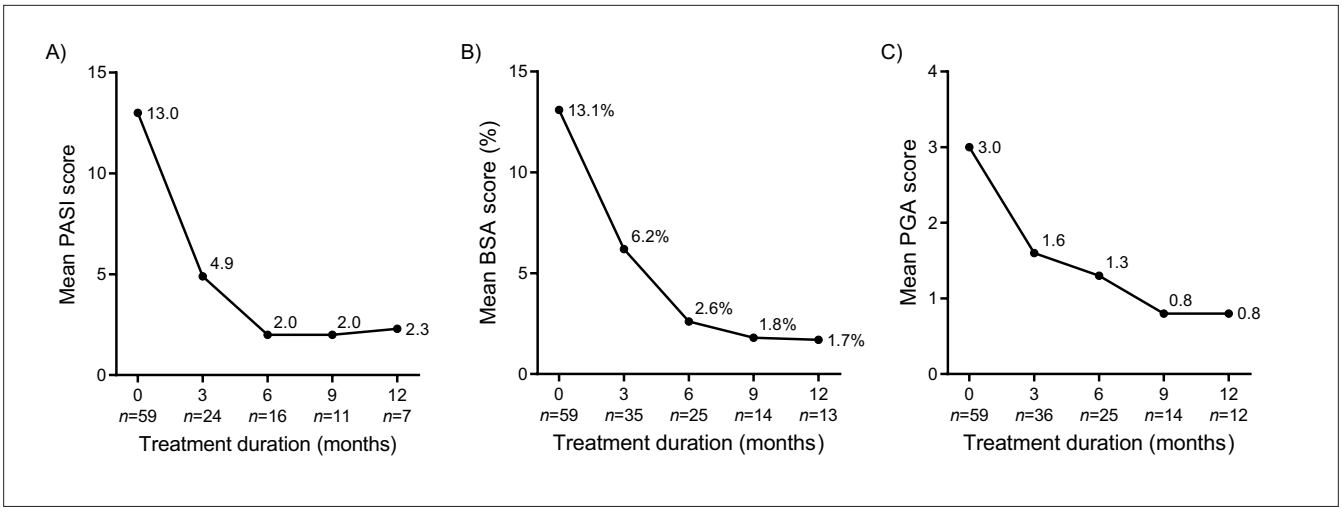

Figure 2. Effect of treatment with CZP in patients with PsO over 12 months. Data are means. Only patients with available assessments at each time point were included in the analysis. (A) PASI; (B) BSA; (C) PGA. BSA, Body Surface Area; CZP, certolizumab pegol; n, number of patients; PASI, Psoriasis Area and Severity Index; PGA, Physician's Global Assessment; PsO, plaque psoriasis.

primary failure (i.e., lack of initial efficacy) and 4 due to secondary failure (loss of continued efficacy). Of the 12 patients who discontinued due to lack of efficacy, 10 (83.3%) had failed at least one previous biologic treatment. One additional patient discontinued due to contraindication with diagnosis of multiple sclerosis, and one temporarily discontinued due to illness, but resumed treatment after resolution of illness (after the data collection date).

Efficacy

Only patients with available assessments at each time point were included in the analysis (see Figure 2 legend for details). In almost all patients, severity of PsO decreased over 12 months of CZP treatment, as evaluated by PASI, BSA and PGA scores (Figure 2A, B and C). The mean (±SD) PASI score decreased from 13.0 (±5.8) at baseline to 2.3 (±4.3) at 12 months. Similarly, the mean BSA score decreased from 13.1% (±6.7%) to 1.7% (±2.6%) and the mean PGA score decreased from 3.0 (±0.6) to 0.8 (±0.6). The sharpest decline in the scores was observed in the first 3 months after the start of treatment, continuing at a somewhat less steep slope through month 6 and then levelling off between months 9 and 12.

Drug Survival

The 12-month drug survival curve for CZP is shown in Figure 3. Patients were included for analysis only if they started CZP treatment at least 12 months prior to data collection date ($n = 38$). In this analysis, 9 (23.7%) patients discontinued CZP treatment. At 12 months, the overall CZP drug survival rate was 76.3% ($n = 29$; Figure 3A). The median survival could not be estimated because less than half of the patients discontinued CZP at the time of data collection.

When comparing drug survival over 12 months for the patients who received previous biologic treatment with those who did not (i.e., biologic-naïve), the survival rate was 72.7% and 81.3%, respectively. However, the difference was not significant ($P > .05$, log-rank Mantel-Cox test) (Figure 3B).

Safety and Tolerability

CZP was generally well tolerated and the analysis did not reveal any new safety signals. Patients did not proactively report nasopharyngitis, upper respiratory tract infections (URTI), or other adverse events (AE). No patients discontinued or interrupted treatment due to adverse events or tolerability issues related to CZP.

Discussion

There are only limited data on the real-world use of CZP in the treatment of PsO. Two real-world analyses conducted in Italy examined cohorts of patients diagnosed with concomitant PsA and PsO, and a third chart review analyzed patients with PsO in Turkey.[12-14] Our analysis is the first to provide valuable real-world insight into the use of CZP treatment of North American (Canadian) patients with PsO.

In this retrospective chart analysis, we present data from 59 Canadian patients with moderate-to-severe PsO who were treated with CZP for up to 2.7 years. Overall, the analysis showed treatment benefits in line with those reported in

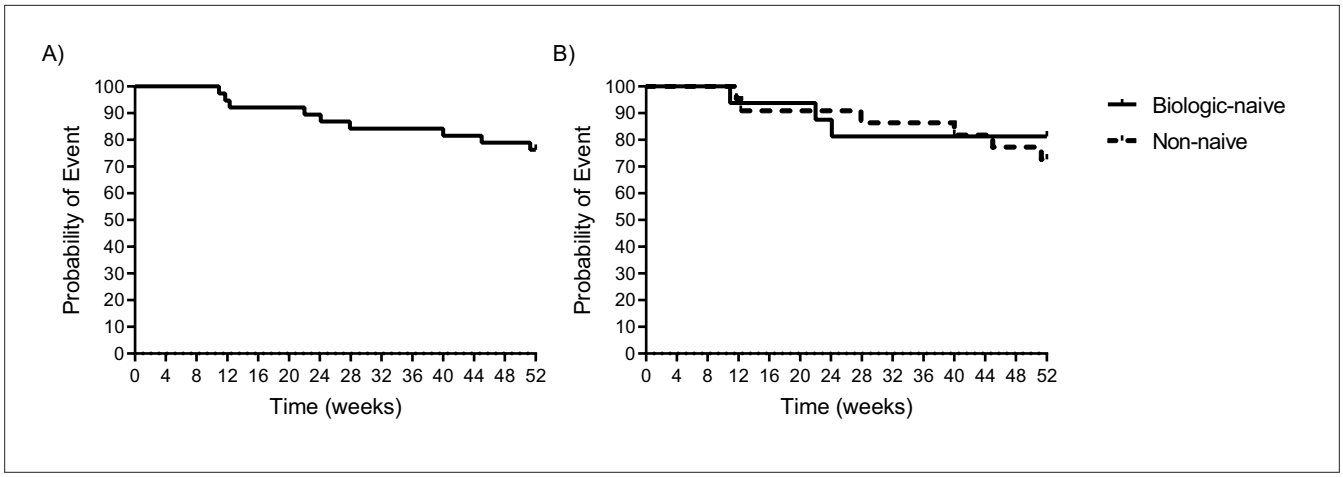

Figure 3. Kaplan-Meier plot of drug survival of CZP over 12 months. *n* = 38. Drug survival analysis included patients who started CZP treatment at least 12 months prior to data collection date. (A) Overall drug survival curve. (B) Biologic-naive (CZP as first biologic treatment) vs. non-naive patients. CZP, certolizumab pegol; *N*, number of patients.

clinical studies with CZP in patients with PsO, suggesting that these results translate well into everyday clinical practice in Canada.

The severity of PsO in this patient population, while on average lower than for the populations in clinical studies, was consistent with other real-world analyses with biologic treatments for PsO, suggesting that it is a good representation of the patients receiving biologic treatment for this condition.[15-18]

PASI, BSA, and PGA scores decreased sharply during the first 3 months of CZP treatment and this decrease continued over 6 to 9 months of treatment, with benefits maintained for at least 1 year. These results are in line with the previously published clinical studies with CZP in the treatment of PsO.[5,6,19]

At 12 months, the CZP drug survival probability was 76.3% for the 38 patients who had at least 12 months of follow-up at the time of data collection. This is similar to what has been reported for other biologics.[20] The 12-month drug survival probability of guselkumab at two hospitals in Ontario was reported to be 80.4%.[18] For secukinumab and ixekizumab, the probabilities were 84.2% and 87.1%, respectively, in an analysis of a nationwide registry in Denmark.[15] While these probabilities are somewhat higher than what we observed, it is difficult to compare the results due to different patient populations and treatment regimens.

This analysis included patients treated with both approved doses of CZP, with 74% of patients in one practice treated with the 200 mg dose and 95% of patients in the other practice treated with the 400 mg dose. This difference may reflect physician's or patient's preference for addressing the individual patient's clinical situation. No differences in effectiveness or drug retention were observed and no patient required a dose increase. This is in contrast to analyses with guselkumab, where dose frequency was increased for patients in whom improvement of symptoms was deemed insufficient.[17,21]

The proportion of biologic-naïve patients in our analysis population was 39.0% and there was no significant difference in CZP drug survival between biologic-naïve and non-naïve patients, suggesting that CZP can be effectively used in patients with PsO regardless of their previous biologic exposure.

Our analysis revealed that 61.0% of the patients treated with CZP were women, which is higher than what has been reported in real-world analyses of other biologics.[15-18,21-23] Approximately half of the WOCBP were biologic-naïve (52.2%), indicating that CZP is an effective treatment option for WOCBP, irrespective of their biologic treatment history. In more than half (52.8%) of the patients in this analysis, WOCBP was selected as one of the reasons for choosing CZP. CZP is the only biologic treatment for PsO that demonstrates little or no active placental transport,[9] and as the childbearing years overlap with the most common start of PsO symptoms,[10,24] CZP provides an option for women with PsO who might benefit from biologic treatment.

Our analysis also revealed a high proportion of patients with concomitant PsA (57.6%). For comparison, chart analyses of other biologics reported the presence of concomitant PsA in 25.4% to 31.3% of treated patients.[15,18] This is corroborated by our finding that the presence of concomitant PsA was selected as one of the reasons for choosing CZP treatment in more than half of the patients (59.3%). This may indicate that CZP is preferentially used in psoriatic patients who also have joint involvement.

In the clinical trials of CZP in patients with PsO, the most frequently reported AEs were nasopharyngitis and URTI,[19] neither of which were reported in this analysis. This is likely

because AEs in our retrospective study were documented only if they were reported by patients during the treatment period. It is encouraging that there were no treatment interruptions or discontinuations due to safety or tolerability issues, and no new safety signals emerged. The treatment period of this study overlapped with the global SARS-CoV-2 pandemic, which was associated with lockdowns in Ontario, Canada where this study took place. Although no patient in this study reported having COVID-19, this cannot be excluded. However, as demonstrated by the effectiveness and safety data in this study, the pandemic did not adversely impact the care of these patients' psoriatic conditions.

A benefit of a retrospective chart analysis is that it captures real-world treatment journeys of the patients. This, however, often results in incomplete data sets. Other limitations of the current study include the small patient population and the lack of long-term data. Future analyses that include a larger patient population and a longer follow-up time would add valuable information about CZP use in patients with PsO.

To our knowledge, this is the first study assessing the real-world usage and effectiveness of CZP in Canadian patients with psoriasis. This retrospective chart analysis showed that CZP used in the clinical practice setting is an efficacious systemic treatment for PsO, regardless of the patients' previous experience with biologic therapies. It also revealed that CZP is chosen among other biologic options due to its efficacy in the treatment of both PsO and PsA, and is the preferred treatment option for WOCBP with psoriasis. Therefore, our results show that the results obtained in randomized controlled clinical trials translate well into the real-world clinical practice.

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Declaration of Conflicting Interests

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: RBV has been a consultant, and/or scientific advisor, and/or investigator, and/or speaker for Amgen, AbbVie, Arcutis, Astellas, Bausch Health/Valeant, BMS, Boehringer Ingelheim, Celgene, Dermira, Eli Lilly, Galderma, GSK, Janssen, Leo Pharma, Merck (MSD), Merck Serono, Novartis, Pfizer, Regeneron, Roche, Sanofi-Aventis/Genzyme, Sun Pharma, Takeda and UCB; CWL has been a consultant, and/or scientific advisor, and/or investigator, and/or speaker for Amgen, AbbVie, Arcutis, Astellas, Bausch Health/Valeant, BMS, Boehringer Ingelheim, Celgene, Dermira, Eli Lilly, Galderma, GSK, Janssen, Leo Pharma, Merck (MSD), Merck Serono, Novartis, Pfizer, Regeneron, Roche, Sanofi-Aventis/Genzyme, Sun Pharma, Takeda and UCB.

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ORCID iDs

Ronald B. Vender https://orcid.org/0000-0002-2624-2724
Charles W. Lynde https://orcid.org/0000-0001-9163-5463

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