Real-world data on the use of certolizumab pegol for the treatment of moderate to severe plaque psoriasis: 1-year results from a prospective non-interventional cohort study

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Objective

This study assessed the clinical outcomes (skin and quality of life [QoL] improvements) and safety at 3-months and 1-year after certolizumab pegol (CZP) treatment start in routine practice in patients with moderate to severe plaque psoriasis.

Introduction

- Plaque psoriasis is a chronic, immune-mediated, inflammatory skin disease affecting 2–6% of the adults in Europe, and 3% of the adults in US.[1]
- CZP is a PEGylated, fragment crystallisable (Fc)-free -tumour necrosis alpha (TNFα) inhibitor with an established efficacy and safety profile in patients with moderate to severe plaque psoriasis.[1,2]
- Efficacy and safety of CZP has been reported in several randomized clinical trials[2]; however, there is very limited data available related to the real-world effectiveness of CZP in patients with plaque psoriasis.
- CIMREAL provides insights to the real-world effectiveness of CZP in patients with moderate to severe plaque psoriasis.

Methods

Study Design

CIMREAL[3] is a multicenter, international, non-interventional, prospective study.

Patients and Treatment

- Adults with moderate to severe plaque psoriasis, who had been newly and independently prescribed CZP as per local prescribing information, were eligible for the enrolment from sites in Belgium, Canada, Czech Republic, France, Germany, Greece, Italy, Spain, and the United Kingdom.
- Patients receiving 400 mg CZP every 2 weeks (Q2W) or CZP 200 mg Q2W as maintenance dose with 400 mg initial doses at Weeks 0, 2 and 4 were followed for 1 year.

Study Assessment and Endpoints

- There were four observational points (OPs) aligned with routine practice visits (**Figure 1**).
- The primary outcome of the study was the proportion of patients achieving a Psoriasis Area and Severity Index improvement of 75% (PASI 75) at Month 3, secondary outcomes pertain to effectiveness (PASI response and Dermatology Life Quality Index [DLQI] remission [0/1]) at Month 3 and 12, and other outcomes involved safety.
- Data are presented from Safety Analysis Set (SAS, patients receiving ≥1 dose CZP) and Full Analysis Set (FAS, patients with baseline and ≥1 post-baseline PASI assessment) as observed cases (OC) at Month 3 and 12. Additionally, missing data were analysed using Markov Chain Monte Carlo method of multiple imputation (MI).

Results

- 93.7% (374/399) and 77.9% (311/399) of patients completed Month 3 and 12 of the study. Baseline characteristics of the included patients are presented in **Table 1**.

Effectiveness

- PASI 75 and PASI 90 response rates improved over time up to Month 12 in overall population and in the subgroups (presence of comorbidities and previous exposure to biologics, **Figure 2**).
- Applying MI, similar PASI 75 (Month 3: 45.0%, Month 12: 70.2%) and PASI 90 (Month 3: 23.7%, Month 12: 50.0%) response rates were observed for the overall population and across subgroups.
- Responses were durable with PASI 75 and PASI 90 responses achieved at Month 3 being maintained by 89.3% (108/121) and 75.9% (44/58) patients at Month 12 (OC analysis), respectively.
- General skin control in terms of patient achieving PASI ≤3 and PASI ≤2 (**Figure 3**) and DLQI remission (0/1, **Figure 4**) improved over time up to Month 12.

Safety

- Incidence of adverse events (AEs) are presented in (**Table 2**).
- A total of 22.1% (88/399) patients discontinued the study treatment; 2.8% (11/399) discontinued due to AEs.
- There were no incidences of serious cardiovascular events, haematopoietic cytopenias, bleeding events, hypersensitivity reactions (including anaphylactic reactions), or demyelinating-like disorders.
- There was one death due to hypoglycemic shock reported for a female patient with diabetes mellitus that was assessed as unrelated to CZP treatment by the investigator.
- The safety profile was consistent with that known for CZP.[4]

Summary

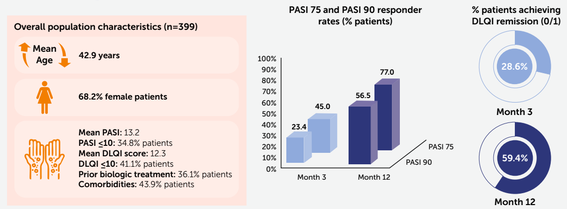
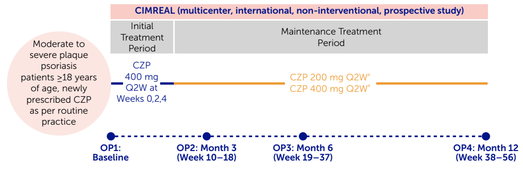


Figure 1 CIMREAL study design



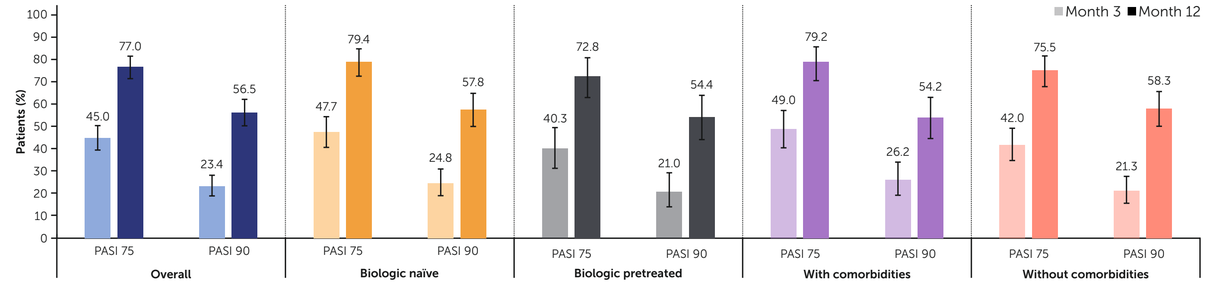
* As per routine practice and label, patients could be prescribed CZP 200 mg Q2W or 400 mg Q2W as maintenance dosing or switch between the doses.

Table 1 Baseline characteristics – SAS

Characteristics	Overall (N=399)
Age (years), mean±SD	42.9±13.5
Female, n (%)	272 (68.2)
BMI (kg/m^2), mean±SD	28.5±6.8
Time since initial diagnosis of plaque psoriasis (years), mean±SD	16±11.8
PASI, mean±SD	13.2±8.7
PASI ≤10, n (%)	139 (34.8)
Missing PASI, n (%)	10 (2.5)
DLQI score, mean±SD	12.3±7.5
DLQI ≤10, n (%)	164 (41.1)
Missing DLQI, n (%)	23 (5.8)
Any plaque psoriasis medication history, n (%)	369 (92.5)
Prior systemic treatment with a non-biologic, n (%)	272 (68.2)
Prior biologic treatment[a], n (%)	144 (36.1)
1	85 (59.0)[b]
≥2	59 (41.0)[b]
Comorbidities, n (%)	175 (43.9)
Vascular disorders, n (%)	53 (13.3)
Musculoskeletal and connective tissue disorders, n (%)	58 (14.5)
Metabolism and nutrition disorders, n (%)	59 (14.8)
Psychiatric disorders, n (%)	35 (8.8)

[a]Only biologic agents with potential impact on plaque psoriasis. [b]Percentages are computed based on patients with 'prior biologic treatment'.

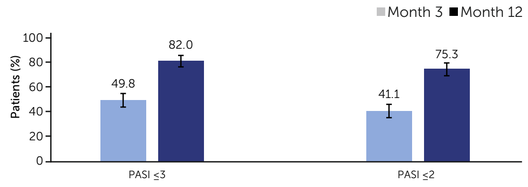
Figure 2 PASI 75 and PASI 90 responder rates at Month 3 and 12 – FAS (OC)[a]



	Overall		Biologic naïve		Biologic pretreated		With comorbidities		Without comorbidities	
Month 3, n/N	150/333	78/333	102/214	53/214	48/119	25/119	71/145	38/145	79/188	40/188
Month 12, n/N	218/283	160/283	143/180	104/180	75/103	56/103	95/120	65/120	123/163	95/163

[a]Error bars represent the 95% confidence interval.

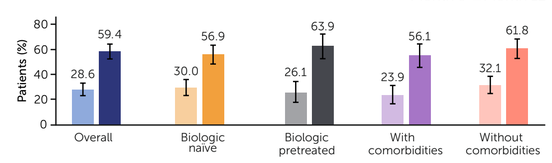
Figure 3 Patients achieving PASI ≤3 and PASI ≤2 – FAS (OC)[a]



	PASI ≤3	PASI ≤2
Month 3, n/N	166/333	137/333
Month 12, n/N	232/283	213/283

[a]Error bars represent the 95% confidence interval.

Figure 4 Patients achieving a DLQI remission (0/1) – FAS (OC)[a]



	Overall	Biologic naïve	Biologic pretreated	With comorbidities	Without comorbidities
Month 3, n/N	92/322	62/207	30/115	33/138	59/184
Month 12, n/N	161/271	99/174	62/ 97	64/114	97/157

[a]Error bars represent the 95% confidence interval.

Table 2 Incidence of AEs at Month 12 in overall patients – SAS

Variable, n(%)	N=399
Any TEAEs	122 (30.6)
Serious TEAEs	37 (9.3)
Treatment-emergent ADRs	36 (9.0)
Serious treatment-emergent ADRs	9 (2.3)
Deaths (TEAEs leading to death)	1 (0.3)

Conclusions

- **Continuous improvement in skin clearance and QoL was observed in the overall cohort and across subgroups (with/without previous biologic treatment, with/without comorbidities) up to 1 year of treatment with CZP.**
- **No new safety signal was identified for CZP. The safety findings were consistent with that known for CZP.**
- **Outcomes from CIMREAL, the largest observational study of CZP in patients with plaque psoriasis, suggest CZP improves plaque psoriasis-specific outcomes in routine clinical practice.**

ADR: adverse drug reaction; **BMI**: body mass index; **CZP**: certolizumab pegol; **DLQI**: Dermatology Life Quality Index (scores: 0–30; higher score: greater impact of plaque psoriasis on patients life); **FAS**: full analysis set; **Fc**: fragment crystallisable; **MI**: multiple imputation; **OC**: observed cases; **OP**: observation point; **PASI**: Psoriasis Area and Severity Index; **QoL**: quality of life; **Q2W**: every 2 weeks; **SAS**: safety analysis set; **SD**: standard deviation; **TEAE**: treatment-emergent adverse event; **TNFα**: tumour necrosis factor alpha.

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References: 1. Lebwohl M, et al. *J Am Acad Dermatol*. 2018:266-276. 2. EMA, June 2022, Summary of Product Characteristics, available at: https://www.ema.europa.eu/documents/product-information/cimzia-epar-productinformation_en.pdf. Last accessed March 2023. 3. ClinicalTrials.gov Identifier: NCT04053881. Available at: https://classic.clinicaltrials.gov/ct2/show/NCT04053881. Last accessed: September 2023. 4. Curtis JR, et al. *RMD Open*. 2019;5(1):e000942. doi: 10.1136/rmdopen-2019-000942.

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