P2592

Real world data on the 1-year treatment of psoriasis with the use of certolizumab pegol in women of child-bearing potential

Khusru Asadullah[1,2] Maria C. Fargnoli,[3] Clara De Simone,[4] Thierry Boyé,[5] Tom Hillary,[6] Alena Machovcova,[7] Areti Makrygeorgou,[8] Kim Papp,[9] Ángeles Flórez,[10] Paulette Williams,[11] Inés D. Pousa,[12] Niamh Houston,[13] Frederik Fierens,[14] Evangelia Papadavid[15]

Objective

This analysis aims to present the effectiveness of certolizumab pegol (CZP) in patients with moderate to severe plaque psoriasis in clinical practice, including women of child-bearing potential (WoCBP).

Introduction

- CZP is an anti-tumour necrosis factor alpha (TNFα) drug approved for the treatment of moderate to severe plaque psoriasis.[1] CZP has demonstrated no-to-minimal placental transfer due to the absence of fragment crystallisable (Fc) region and showed no-to-minimal transfer to the breast milk.[2,3]
- CIMREAL assessed the clinical outcomes for CZP in routine clinical practice in adult patients with moderate to severe plaque psoriasis. The high enrolment of WoCBP in CIMREAL allows to describe specifically outcomes of effectiveness with CZP treatment for the first time in this specific population.

Methods

Study Design, Patients and Treatment

CIMREAL[4] is a multicenter, international, non-interventional, prospective study that observed clinical response to CZP treatment and safety over 1 year in a real-world plaque psoriasis cohort of patients newly prescribed as per local practice from sites in 8 European countries and Canada.

Study Assessment and Endpoints

- There were four observational points (OPs) in the study aligned with routine practice visits (**Figure 1**).
- The primary outcome of the study was the percentage of patients achieving Psoriasis Area and Severity Index improvement of 75% (PASI 75) response at OP2. Secondary outcomes pertain to effectiveness (PASI response, improvement in Dermatology Life Quality Index [DLQI]) and safety of CZP.
- Demographics and safety data are presented from the Safety Analysis Set (SAS; patients received ≥1 dose of CZP) and clinical outcomes as observed cases (OC) from the Full Analysis Set (FAS; SAS patients with valid Baseline and ≥1 valid post-Baseline PASI measurement). Additionally, missing data were analysed using Markov Chain Monte Carlo method of multiple imputation (MI).
- WoCBP (defined by investigators) is a subgroup of the overall population included in the study.

Results

- Of the 399 patients with plaque psoriasis who were enrolled (SAS) in the study, 272 (68.2%) were female and out of them 193 (71%) were WoCBP (**Table 1**). At baseline, 8 women (4.1%) were pregnant, 14 (7.3%) were breastfeeding.
- Higher proportion of men had DLQI≤10 at baseline than women; however, similar proportion of men and women had PASI≤10 at baseline.

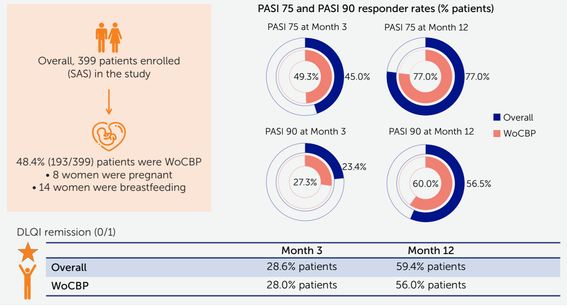
Effectiveness

- Similar response rates in terms of PASI 75, PASI 90 and DLQI remission (0/1) were observed between overall and WoCBP populations (**Figure 2**).
- Applying MI, similar PASI 75 (48.3% [Month 3] to 71.7% [Month 12]) and PASI 90 (27.1% [Month 3] to 53.6% [Month 12]) response rates were observed for the WoCBP population. This is consistent with the improvement in the overall population.
- In both overall and WoCBP, general skin control in terms of the proportion of patients achieving PASI ≤3 and PASI ≤2 improved over time up to Month 12 (**Figure 3**).
- In patients achieving PASI 75 and PASI 90 at Month 3, the vast majority of patients maintained their responses up to Month 12 (**Figure 4**).

Safety

- There was one death, unrelated to treatment. There were no new safety signals reported (**Table 2**).

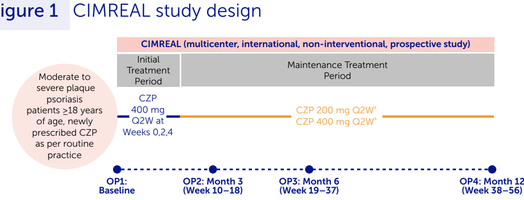
Summary



DLQI remission (0/1)

	Month 3	Month 12
Overall	28.6% patients	59.4% patients
WoCBP	28.0% patients	56.0% patients

Figure 1 CIMREAL study design



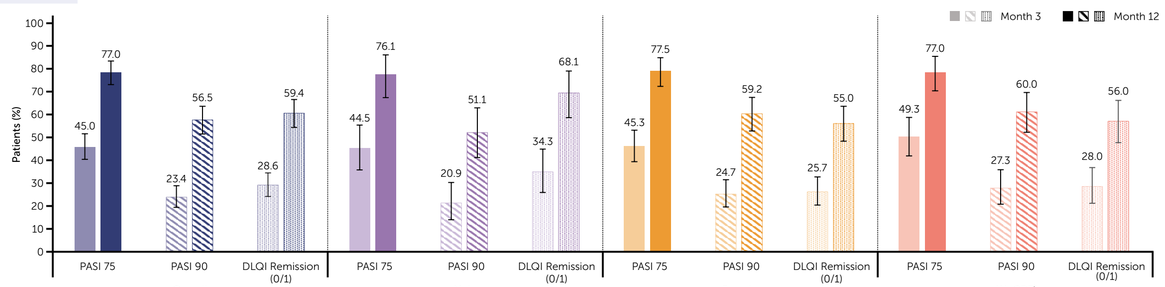
* As per routine practice and label, patients could be prescribed CZP 200 mg Q2W or 400 mg Q2W as maintenance dosing or switch between the doses.

Table 1 Baseline characteristics – SAS

Characteristics	Overall n=399	Male n=127	Female n=272	WoCBP[a] n=193
Age (years), mean±SD	42.9±13.5	48.2±12.4	40.4±13.2	33.8±7.3
BMI (kg/m^2), mean±SD	28.5±6.8	29.3±6.2	28.1±7.1	27.7±7.2
PASI, mean±SD	13.2±8.7	13.6±8.3	13.0±8.9	13.0±8.6
PASI ≤10, n (%)	139 (34.8)	44 (34.6)	95 (34.9)	65 (33.7)
Missing PASI, n (%)	10 (2.5)	3 (2.4)	7 (2.6)	6 (3.1)
DLQI score, mean±SD	12.3±7.5	10.8 ± 7.6	13.1±7.3	13.2 ± 7.3
DLQI ≤10, n (%)	164 (41.1)	64 (50.4)	100 (36.8)	65 (33.7)
Missing DLQI, n (%)	23 (5.8)	3 (2.4)	20 (7.4)	19 (9.8)
Any plaque psoriasis medication history, n (%)	369 (92.5)	113 (89.0)	256 (94.1)	190 (98.4)
Prior systemic treatment with a non-biologic, n (%)	272 (68.2)	83 (65.4)	189 (69.5)	139 (72.0)
Prior biologic treatment[b], n (%)	144 (36.1)	52 (40.1)	92 (33.8)	59 (30.6)
1	85 (59.0)[c]	32 (61.5)[c]	53 (57.6)[c]	33 (55.9)[c]
≥2	59 (41.0)[c]	20 (38.5)[c]	39 (42.4)[c]	26 (44.1)[c]
Comorbidities, n (%)	186 (46.6)	61 (48.0)	125 (46.0)	81 (42.0)
Vascular disorders, n (%)	53 (13.3)	27 (21.3)	26 (9.6)	6 (3.1)
Musculoskeletal and connective tissue disorders, n (%)	58 (14.5)	21 (16.5)	37 (13.6)	23 (11.9)
Metabolism and nutrition disorders, n (%)	59 (14.8)	29 (22.8)	30 (11.0)	9 (4.7)
Psychiatric disorders, n (%)	35 (8.8)	8 (6.3)	27 (9.9)	16 (8.3)

[a]WoCBP is a subgroup of the overall population in this study. [b]Only biologic agents with potential impact on plaque psoriasis. [c]Percentages are computed based on patients with 'prior biologic treatment'.

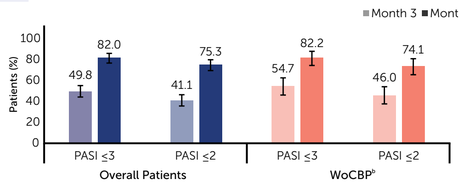
Figure 2 Patients achieving PASI 75 and PASI 90 response and DLQI remission (0/1) at Month 3 and 12 – FAS (OC)[a]



Month 3, n/N	150/333	78/333	92/322	49/110	23/110	37/108	101/223	55/223	55/214	74/150	41/150	40/143
Month 12, n/N	218/283	160/283	161/271	70/92	47/92	62/91	148/191	113/191	99/180	104/135	81/135	70/125

[a]Error bars represent the 95% confidence interval. [b]WoCBP is a subgroup of the overall population in this study.

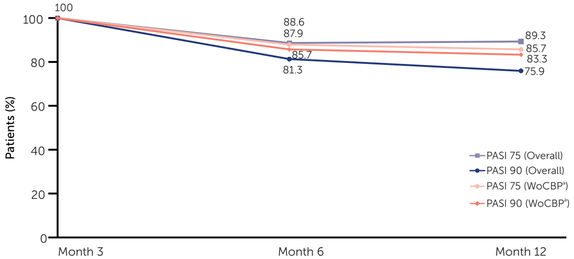
Figure 3 Patients achieving PASI ≤3 and PASI ≤2 – FAS (OC)[a]



Month 3, n/N	166/333	137/333	82/150	69/150
Month 12, n/N	232/283	213/283	111/135	100/135

[a]Error bars represent the 95% confidence interval. [b]WoCBP is a subgroup of the overall population in this study.

Figure 4 Patients maintaining PASI 75 and PASI 90 response over time – FAS (OC)



[a]WoCBP is a subgroup of the overall population in this study.

Table 2 Incidence of AEs at Month 12 in overall and WoCBP patients[a] – SAS

Variable	Overall Patients n=399 n (%)	WoCBP Patients n=193[a] n (%)
Any TEAEs	122 (30.6)	70 (36.3)
Serious TEAEs	37 (9.3)	25 (13.0)
Treatment-emergent ADRs	36 (9.0)	17 (8.8)
Serious treatment-emergent ADRs	9 (2.3)	6 (3.1)
Deaths (TEAEs leading to death)	1 (0.3)	1 (0.5)

[a]WoCBP is a subgroup of the overall population in this study.

Conclusions

- **Treatment with CZP improved skin clearance and quality of life in both overall and WoCBP study population up to 1-year.**
- **The safety profile was consistent with that known for CZP.**
- **This study in a real world setting suggests that CZP might be a valuable option for disease control in WoCBP.**

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 patient's life); **FAS**: full analysis set; **Fc**: fragment crystallisable; **MI**: multiple imputation; **OC**: observed cases; **OP**: observation point; **PASI**: Psoriasis Area and Severity Index; **Q2W**: every 2 weeks; **SAS**: safety analysis set; **SD**: standard deviation; **TEAE**: treatment-emergent adverse event; **TNFα**: tumour necrosis factor alpha; **WoCBP**: women of child-bearing potential.

Institutions: [1]Department of Dermatology, Charité Universitätsmedizin Berlin, Berlin, Germany; [2]Dermatology Potsdam, MVZ, Potsdam, Germany; [3]Dermatology, Department of Biotechnological and Applied Clinical Science, University of L'Aquila, L'Aquila, Italy; [4]Institute of Dermatology, Fondazione Policlinico Universitario A. Gemelli IRCCS, Università del Sacro Cuore, Rome, Italy; [5]HIA, Hôpital Sainte Anne, Toulon, France; [6]Department of Dermatology, University Hospitals Leuven, Leuven, Belgium; [7]Department of Dermatovenerology, University Hospital Motol, Prague, Czech Republic; [8]West Glasgow Ambulatory Care Hospital, Dalnair Street, Yorkhill, Glasgow, UK; [9]Probity Medical Research and Alliance Clinical Trials, Waterloo, and University of Toronto, Toronto, ON, Canada; [10]Department of Dermatology, Pontevedra University Hospital, Pontevedra, Spain; [11]UCB Pharma, Morrisville, NC, USA; [12]UCB Pharma, Madrid, Spain; [13]UCB Pharma, Slough, UK; [14]UCB Pharma, Brussels, Belgium; [15]Department of Dermatology, National and Kapodistrian University of Athens Medical School, Athens, Greece

References: 1. EMA. June 2022. Summary of Product Characteristics, available at: https://www.ema.europa.eu/documents/product-information/cimzia-epar-productinformation_en.pdf. Accessed March 2023; 2. Mariette X, et al. Annals of the rheumatic diseases. 2018;77(2):228-233; 3. Clowse ME, et al. *Annals of the rheumatic diseases*. 2017;76(11):1890-1896; 4. ClinicalTrials.gov Identifier: NCT04053881. Available at: https://classic.clinicaltrials.gov/ct2/show/NCT04053881. Last accessed: September 2023.

AUTHOR CONTRIBUTIONS: Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: KA, MCF, CDS, TB, TH, AMac, AMak, KP, AF, PW, IDP, NH, FF, and EP; drafting of the publication, or revising it critically for important intellectual content: KA, MCF, CDS, TB, TH, AMac, AMak, KP, AF, PW, IDP, NH, FF, and EP; final approval of the publication: KA, MCF, CDS, TB, TH, AMac, AMak, KP, AF, PW, IDP, NH, FF, and EP; **Author Disclosures: KA** received honoraria for participation in advisory boards, consultation, clinical trials or as speaker from Abbvie, Almirall, Antabio, Bayer, Brand Murray Fuller, Bristol Myers Squibb, Emeritipharma, Emphasis, Euroimmune, Galderma, Janssen, La Roche-Posay, Leo, L'Oréal, Novartis, Parexel International, Pierre Fabre, RG Pharma, Roxall, Sanofi Genzyme, TFS Trial Form Support, UCB Pharma. **MCF** served on advisory boards and received honoraria for lectures and/or research grants from: Abbvie, Almirall, Amgen, Bristol Myers Squibb, Eli Lilly, Galderma, Janssen, Kyowa Hakko Kirin, Leo Pharma, MSD, Novartis, Pfizer, Pierre Fabre, Sanofi-Genzyme, Sun Pharma, UCB Pharma. **CDS** received fees as advisory board member or speaker from: Abbvie, Amgen, Eli Lilly, Janssen, Novartis, Sanofi, UCB Pharma. **TB** received consulting fees from Abbvie, Eli Lilly, Janssen, Leo Pharma, Novartis, Pfizer, UCB Pharma; was speaker for Abbvie, Amgen, Eli Lilly, Janssen, Leo Pharma, Novartis, Pfizer; participated in clinical studies for Abbvie, Amgen, Eli Lilly, Janssen, Leo Pharma, Novartis, UCB Pharma. **TH** received consultancy, speaker fees and/or research funding from AbbVie, Almirall, Amgen, Biogen, Bristol Myers Squibb, Celgene, Eli Lilly, Janssen, LEO Pharma, Novartis, Pfizer Inc, Roche, Sandoz, Sanofi. UCB Pharma. **AMac** was adviser, speaker and investigator for AbbVie, Amgen, Eli Lilly, Galderma, Leo Pharma, Novartis, Pfizer, Sanofi-Genzyme, UCB Pharma. **AMak** was speaker at sponsored events, participated in Advisory Board meetings, received honoraria, offered consultancy and received sponsorship to attend conferences from: AbbVie, Almirall, Celgene, Eli Lilly, Janssen, Novartis, and UCB Pharma. **KP** was consultant for AbbVie, Acelyrin, Akros, Amgen, Aralez Pharmaceuticals, Arcutis, Avillion, Bausch Health/Valeant, Boehringer Ingelheim, Bristol-Myers Squibb, Can-Fite Biopharma, Celgene, Celltrion, Coherus, Dermavant, Dermira, Dice Pharmaceuticals, Dow Pharma, Eli Lilly, Evelo, Forbion, Galderma, Incyte, Janssen, Kyowa Hakko Kirin, Leo, Meiji Seika Pharma, Merck (MSD), Mitsubishi Pharma, Novartis, Pfizer, Regeneron, Reistone, Roche, Sanofi-Aventis/Genzyme, Sandoz, Sun Pharma, Takeda, UCB, vTv Therapeutics, Xencor; received speakers bureau from AbbVie, Amgen, Bausch Health/Valeant, Celgene, Eli Lilly, Galderma, Incyte, Janssen, Kyowa Hakko Kirin, Leo, Merck (MSD), Novartis, Pfizer, Sanofi-Aventis/Genzyme; received clinical research grants from AbbVie, Akros, Amgen, Anacor, Arcutis, Avillion, Bausch Health/Valeant, Boehringer Ingelheim, Bristol-Myers Squibb, Can-Fite Biopharma, Celgene, Coherus, Dermavant, Dermira, Dow Pharma, Eli Lilly, Evelo, Galderma, Gilead, GSK, Incyte, Janssen, Kyowa Hakko Kirin, Leo, Merck (MSD), Novartis, Pfizer, Regeneron, Roche, Sanofi-Aventis/Genzyme, Sun Pharma, Takeda, UCB; received honoraria from AbbVie, Acelyrin, Akros, Amgen, Aralez Pharmaceuticals, Bausch Health/Valeant, Boehringer Ingelheim, Celgene, Celltrion, Coherus, Dermavant, Dice Pharmaceuticals, Eli Lilly, Forbion, Galderma, Janssen, Kyowa Hakko Kirin, Leo, Meiji Seika Pharma, Merck (MSD), Mitsubishi Pharma, Novartis, Pfizer, Reistone, Sanofi-Aventis/Genzyme, Sandoz, Sun Pharma, Takeda, UCB, vTv Therapeutics, Xencor, was scientific officer for Akros, Anacor, Arcutis, Dice Pharmaceuticals, Kyowa Hakko Kirin; was in steering committees for AbbVie, Amgen, Bausch Health/Valeant, Boehringer Ingelheim, Celgene, Eli Lilly, Janssen, Kyowa Hakko Kirin, Merck (MSD), Novartis, Pfizer, Regeneron, Reistone, Sanofi-Aventis/Genzyme; was in advisory boards for AbbVie, Amgen, Bausch Health/Valeant, Boehringer Ingelheim, Bristol-Myers Squibb, Celgene, Dice Pharmaceuticals, Dow Pharma, Eli Lilly, Galderma, Janssen, Merck (MSD), Novartis, Pfizer, Regeneron, Sanofi-Aventis/Genzyme, Sun Pharma, UCB. **AF** conducted clinical trials and acted as a speaker and consultant for Abbvie, Almirall, Amgen, Celgene, Eli Lilly, Janssen, Kyowa Hakko Kirin, Leo Pharma, Novartis, Pfizer, Roche Farma, Sanofi, Sun Pharma, Takeda and UCB Pharma. **PW**, **IDP**, **NH** and **FF** are employees of UCB Pharma. **EP**: None declared. **Acknowledgements:** This study was funded by UCB Pharma. Medical writing support was provided by Ensego Life Sciences.