Certolizumab pegol for treatment of plaque psoriasis: pooled efficacy outcomes across baseline Psoriasis Area and Severity Index subgroups (CIMPASI-1 and CIMPASI-2)

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Objectives

To assess the clinical outcomes of certolizumab pegol across baseline absolute Psoriasis Area and Severity Index subgroups, in patients with moderate to severe plaque psoriasis.

Background

- Certolizumab pegol (CZP) is an Fc-free PEGylated tumour necrosis factor inhibitor (TNFi) that has demonstrated long-term efficacy in moderate to severe plaque psoriasis (PSO).[1,2]
- High baseline Psoriasis Area and Severity Index (PASI) has been noted as a predictor of a meaningful clinical response to CZP.[3]
- Here, we report the clinical outcomes of CZP across baseline absolute PASI subgroups (<15/≥15) over 144 weeks.

Methods

- Data were pooled from the CIMPASI-1 (NCT02326298) and CIMPASI-2 (NCT02326272) phase 3 clinical trials, which had identical study designs **(Figure 1)**.[1,2]
- Adults with moderate to severe PSO (defined as PASI ≥12, body surface area ≥10% affected, and Physician's Global Assessment [PGA] ≥3 on a 5-point scale) of ≥6 months duration were enrolled.
- Clinical outcomes reported from Weeks 0–144 for patients with baseline PASI <15/≥15 included: PASI 75 (a 75% improvement from baseline PASI score), PASI 90 (a 90% improvement from baseline PASI score), PASI ≤2, PGA 0/1, and Dermatology Life Quality Index (DLQI) 0/1.
- Responder rates were based on a logistic regression model and reported according to the patients' respective randomised treatment groups.
- For patients not achieving a PASI 50 response at Week 16 (escape arm entry criterion) or at Week 32 onwards (mandatory withdrawal), non-responder imputation was used at subsequent timepoints. Other missing data were imputed with multiple imputation using the Markov Chain Monte Carlo methodology.

Results

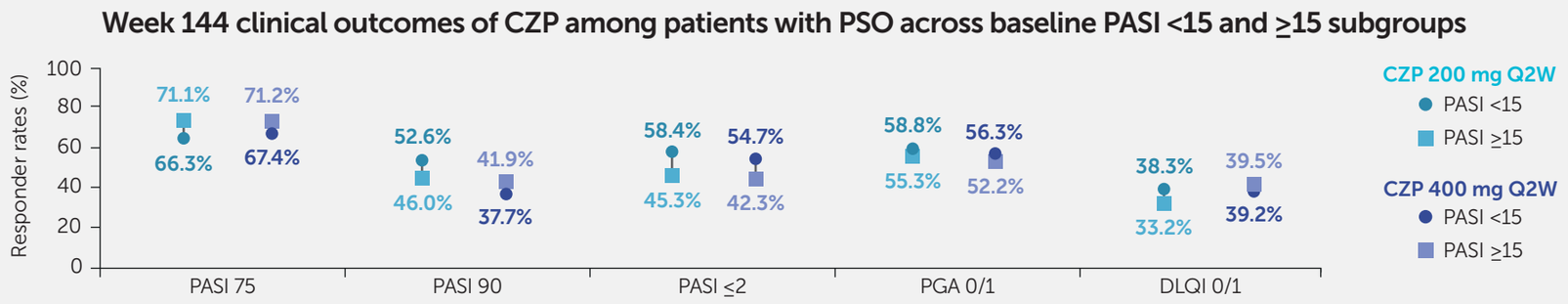
- At baseline, 186 patients were randomised to CZP 200 mg every 2 weeks (Q2W) and 175 patients to CZP 400 mg Q2W.
- Baseline demographics for all patients, stratified by baseline absolute PASI <15/≥15, are shown in **Table 1**.
- At Week 144, responder rates for PASI 75, PASI 90, PASI ≤2, PGA 0/1, and DLQI 0/1 were similar between baseline PASI <15 and ≥15 subgroups, for both CZP 200 mg Q2W- and CZP 400 mg Q2W-randomised patients **(Figure 2)**.

Conclusions

CZP treatment resulted in similar clinical efficacy outcomes across baseline absolute PASI <15 and PASI ≥15 subgroups over 144 weeks, regardless of CZP randomisation arm.

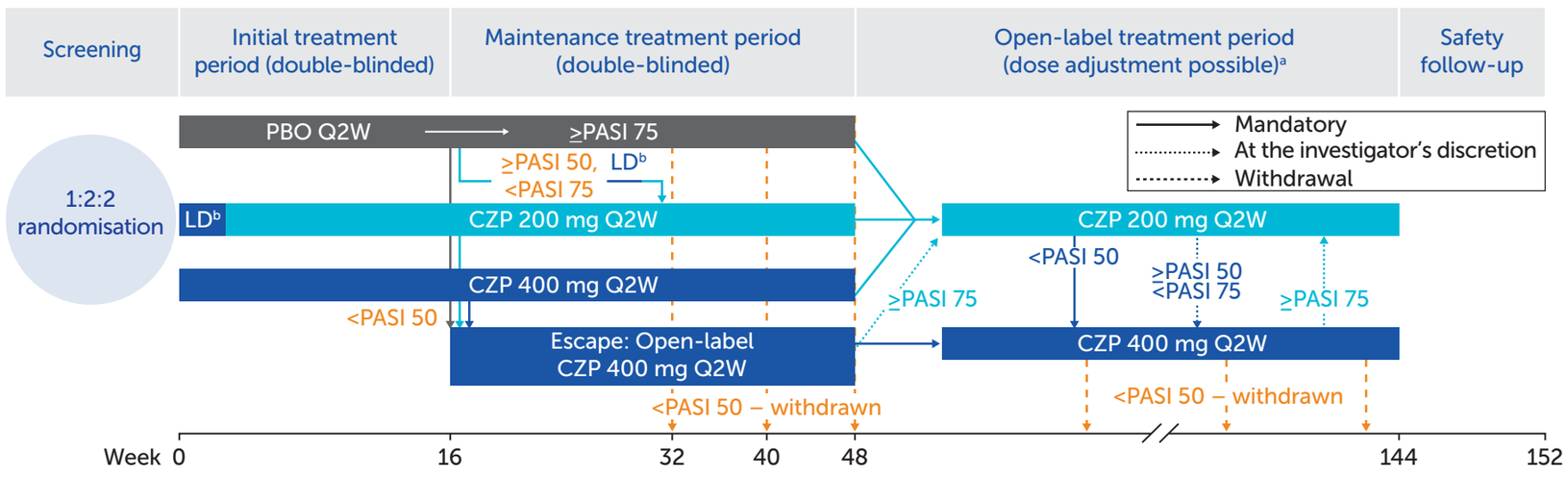
These results support the suitability of CZP as a long-term treatment in patients with PSO, regardless of baseline PASI.

Summary



CZP treatment resulted in largely similar long-term clinical efficacy outcomes, regardless of baseline PASI.

Figure 1 Study design



[a]Dose adjustments were mandatory or at the investigator's discretion, based on PASI response; [b]Loading dose of CZP 400 mg Q2W at Weeks 0, 2 and 4, or Weeks 16, 18 and 20.

Figure 2 CZP responder rates by baseline PASI

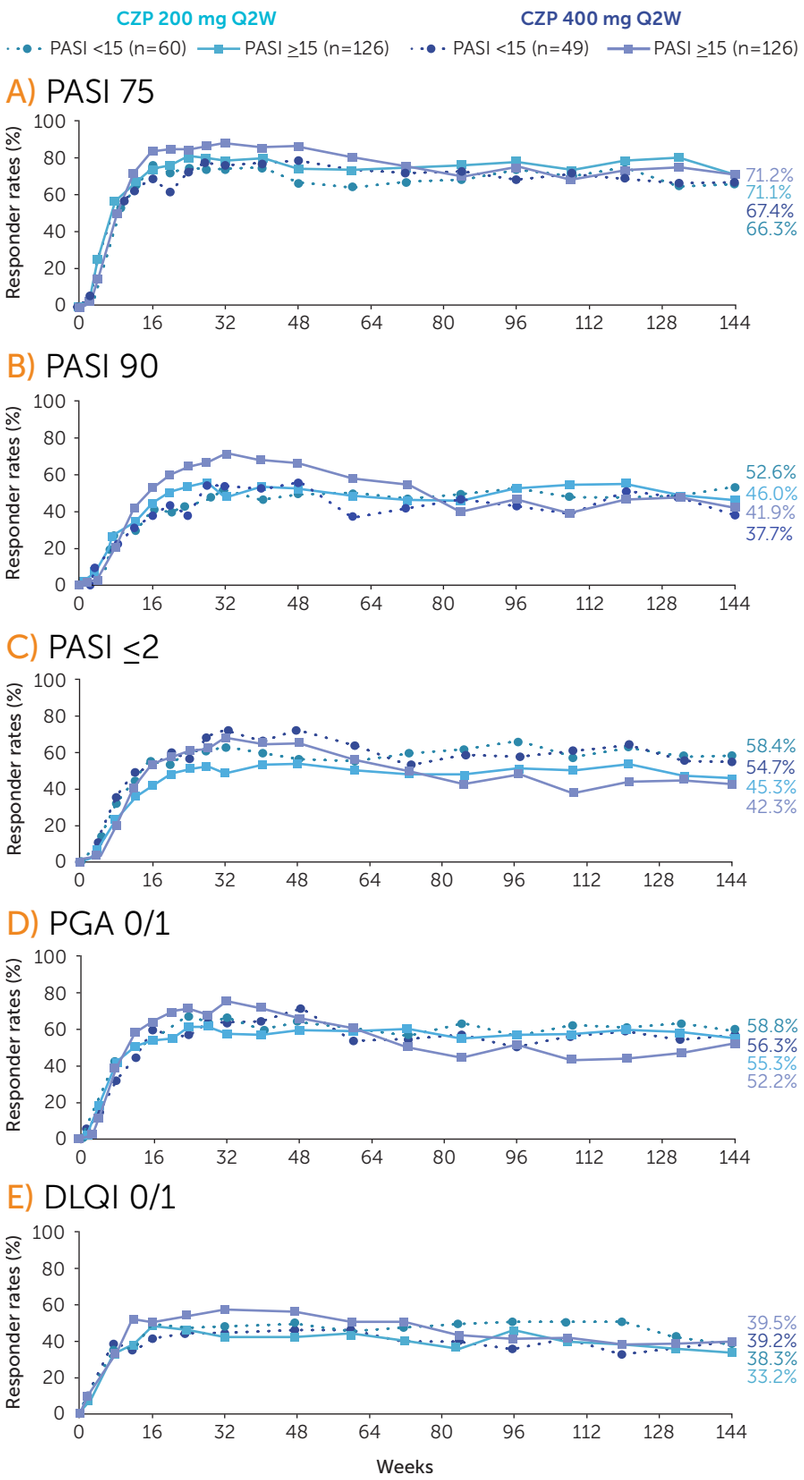


Table 1 Patient demographics and baseline disease characteristics

	CZP 200 mg Q2W (N=186)		CZP 400 mg Q2W (N=175)	
	PASI <15 (n=60)	PASI ≥15 (n=126)	PASI <15 (n=49)	PASI ≥15 (n=126)
Demographics				
Age, years, mean (SD)	46.4 (13.9)	45.2 (12.9)	42.9 (14.6)	45.8 (12.1)
Male, n (%)	40 (66.7)	85 (67.5)	23 (46.9)	80 (63.5)
White, n (%)	58 (96.7)	115 (91.3)	47 (95.9)	113 (89.7)
Geographical region, n (%)				
North America	35 (58.3)	75 (59.5)	31 (63.3)	75 (59.5)
Europe	25 (41.7)	51 (40.5)	18 (36.7)	51 (40.5)
Weight, kg, mean (SD)	93.6 (22.3)	95.9 (24.0)	90.7 (21.1)	92.5 (26.2)
BMI (kg/m^2), mean (SD)	31.4 (7.4)	32.2 (8.0)	31.3 (8.0)	31.1 (7.9)
Baseline disease characteristics				
Disease duration, years, mean (SD)	20.1 (13.9)	16.6 (12.3)	19.0 (13.8)	18.3 (12.1)
Concurrent PsA (self-reported), n (%)	15 (25.0)	17 (13.5)	11 (22.4)	30 (23.8)
PASI, mean (SD)	13.6 (0.9)	21.9 (7.4)	13.4 (0.8)	22.0 (7.3)
DLQI, mean (SD)	12.6 (7.7)	15.0 (7.1)	11.3 (6.9)	14.6 (6.7)
BSA affected (%), mean (SD)	14.8 (5.2)	27.6 (16.2)	15.0 (5.0)	26.9 (15.4)
PGA, n (%)				
3: moderate	56 (93.3)	72 (57.1)	47 (95.9)	79 (62.7)
4: severe	4 (6.7)	54 (42.9)	2 (4.1)	47 (37.3)
Prior treatment, n (%)				
Any systemic psoriasis treatment	41 (68.3)	90 (71.4)	34 (69.4)	90 (71.4)
Biologic therapy				
0	42 (70.0)	82 (65.1)	34 (69.4)	82 (65.1)
1	13 (21.7)	31 (24.6)	10 (20.4)	33 (26.2)
2	5 (8.3)	13 (10.3)	5 (10.2)	10 (7.9)
≥3	0	0	0	1 (0.8)
Anti-TNF	12 (20.0)	32 (25.4)	8 (16.3)	32 (25.4)
Anti-IL-17A	6 (10.0)	10 (7.9)	2 (4.1)	6 (4.8)
Anti-IL-12/IL-23	2 (3.3)	1 (0.8)	4 (8.2)	6 (4.8)

BMI: body mass index; BSA: body surface area; CZP: certolizumab pegol; DLQI: Dermatology Life Quality Index; IL: interleukin; LD: loading dose; PASI: Psoriasis Area and Severity Index; PBO: placebo; PGA: Physician's Global Assessment; PsA: psoriatic arthritis; Q2W: every 2 weeks; SD: standard deviation; TNF: tumour necrosis factor.

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References: [1]Gordon KB. Br J Dermatol 2021;184(4):652–662; [2]Gottlieb AB. J Am Acad Dermatol 2018;79(2):302–314.e6; [3]Warren RB. Br J Dermatol 2019;180(5):1069–1076. **Author Contributions:** Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: **LS, PF, CB, NT, TM, AL, PF-P**; Drafting of the publication, or revising it critically for important intellectual content: **LS, PF, CB, NT, TM, AL, PF-P**; Final approval of the publication: **LS, PF, CB, NT, TM, AL, PF-P**. **Author Disclosures:** **LS**: Consultant, and/or scientific adviser, and/or investigator, and/or scientific officer, and/or speaker for Amgen, Anacor, AbbVie, Ascend, Astellas, AstraZeneca, Blaze Bioscience, Bristol Myers Squibb, Boehringer Ingelheim, Botanix, Celgene, Dermira Inc., Eli Lilly, Galderma, Genentech, GSK, Hexima, Janssen, LEO Pharma, Mayne, Medimmune, Merck (MSD), Merck-Serono, Novartis, Otsuka, Pfizer, Phosphagenics, Photon MD, Regeneron, Roche, Samumed, Sanofi/Genzyme, SHR, Sun Pharma ANZ, Trius, UCB Pharma, and Zai Lab; **PF**: Received grant support from AbbVie, Amgen, Bristol Myers Squibb, Celgene, Eli Lilly, Galderma, Janssen, LEO Pharma, Merck, Novartis, Pfizer, Sanofi, and Sun Pharma; investigator for AbbVie, Akaal, Amgen, Arcutis, Argenx, Aslan, AstraZeneca, Bristol Myers Squibb, Boehringer Ingelheim, Botanix, Celgene, Celtaxsys, CSL, Cutanea, Dermira Inc., Eli Lilly, Evelo, Galderma, Genentech, Geneseq, GenesisCare, GSK, Hexima, Janssen, Kymab, LEO Pharma, MedImmune, Merck, Novartis, Pfizer, Regeneron, Reistone, Roche, Sanofi, Sun Pharma, Teva, UCB Pharma, and Valeant; served on the advisory board for AbbVie, Amgen, Aslan, Bristol Myers Squibb, Boehringer Ingelheim, Celgene, Eli Lilly, Galderma, GSK, Hexima, Janssen, LEO Pharma, Mayne Pharma, MedImmune, Novartis, Pfizer, Roche, UCB Pharma and Wintermute; received travel grants from AbbVie, Eli Lilly, Galderma, Janssen, LEO Pharma, Merck, Novartis, Pfizer, Roche, Sanofi, and Sun Pharma; speaker for or received honoraria from AbbVie, Amgen, Celgene, Eli Lilly, Galderma, GSK, Janssen, LEO Pharma, Merck, Novartis, Pfizer, Roche, Sanofi, Sun Pharma, UCB Pharma, and Valeant; **CB**: Advisory committee and/or educational lectures and/or clinical investigator for: Abbvie, Eli Lilly, Janssen, LEO Pharma, Novartis, Pfizer, and UCB Pharma; **NT and TM**: Employees of UCB Pharma; **AL**: Employee of UCB Pharma and participant in the UCB Stock Award Plan; **PF-P**: Advisory committee for: AbbVie, Amgen, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Eli Lilly, Janssen, LEO Pharma, Merck, MSD, Novartis, Roche, Sanofi, and Sun Pharma; educational lectures for: AbbVie, Amgen, Avene, Eli Lilly, Galderma, Janssen, La Roche Posay, LEO Pharma, Merck, Novartis, Pfizer, Roche, Sanofi, Schering Plough, Sun Pharma, and UCB Pharma; clinical trials for: AbbVie, Amgen, Arena, AstraZeneca, Boehringer Ingelheim, Bristol Myers Squibb, CSL, Dermira Inc., Eisai, Eli Lilly, Galderma, GSK, Janssen, Jiangsu Hengrui, Kyowa Hakko Kirin, LEO Pharma, miRagen, Novartis, OncoSec, Pfizer, Regeneron, Roche, Sun Pharma, UCB Pharma, and Xoma. **Acknowledgements:** These studies were funded by UCB Pharma. We thank the patients and their caregivers in addition to the investigators and their teams who contributed to this study. The authors acknowledge Susanne Wiegratz, UCB Pharma, Monheim, Germany, for publication coordination, Paige Foo, MPharm, and Yi Ling Teo, PhD, Costello Medical, Singapore, for medical writing and editorial assistance, and the Costello Medical Design Team for design support. All costs associated with development of this poster were funded by UCB Pharma.