

Durability of Response in Patients with Chronic Plaque Psoriasis Treated with Certolizumab Pegol over 48 Weeks: Pooled Results from Ongoing Phase 3, Multicenter, Randomized, Placebo-Controlled Studies (CIMPASI-1, CIMPASI-2 and CIMPACT)

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OBJECTIVE

- To assess the durability of the initial clinical response to certolizumab pegol in patients with moderate to severe plaque psoriasis over 48 weeks in phase 3 trials.

BACKGROUND

- Plaque psoriasis (PSO) is an immune-mediated, inflammatory disease.
- Treatment options include topicals, phototherapy or systemic medications (including biologics). However, loss of response can occur over time.¹
- Certolizumab pegol (CZP) is a unique Fc-free, PEGylated, anti-tumor necrosis factor biologic, approved by both the FDA and EMA for the treatment of moderate to severe PSO.^{2,3}
- In phase 3 trials, CZP has demonstrated significant improvements in the signs and symptoms of PSO, and a safety profile consistent with the class.^{4,5}
- We assessed durability of the initial Week 16 response to CZP over a further 32 weeks of treatment.

METHODS

Study Design

- Data were pooled from three ongoing CZP phase 3 trials in adults with PSO: CIMPASI-1 (NCT02326298), CIMPASI-2 (NCT02326272) and CIMPACT (NCT02346240) (Figure 1).
- This analysis includes only patients who achieved a $\geq 75\%$ reduction from baseline in Psoriasis Area Severity Index (PASI 75) at Week 16, and continued on the same CZP dose during the maintenance period.

Patients

- ≥ 18 years of age with PSO for ≥ 6 months with PASI ≥ 12 , $\geq 10\%$ body surface area affected and physician's global assessment ≥ 3 on a 5-point scale.
- Candidates for systemic PSO therapy, phototherapy and/or photochemotherapy.
- Exclusion criteria: previous treatment with CZP or >2 biologics; history of primary failure to any biologic or secondary failure to >1 biologic; erythrodermic, guttate or generalized PSO types; history of current, chronic or recurrent viral, bacterial or fungal infections.

Study Assessments

- PASI 75 and PASI 90 ($\geq 90\%$ reduction) responder rates were assessed through Weeks 16–48 in patients who achieved PASI 75 at Week 16.
- PASI 90 responder rates were additionally assessed through Weeks 16–48 in patients who achieved PASI 90 at Week 16.

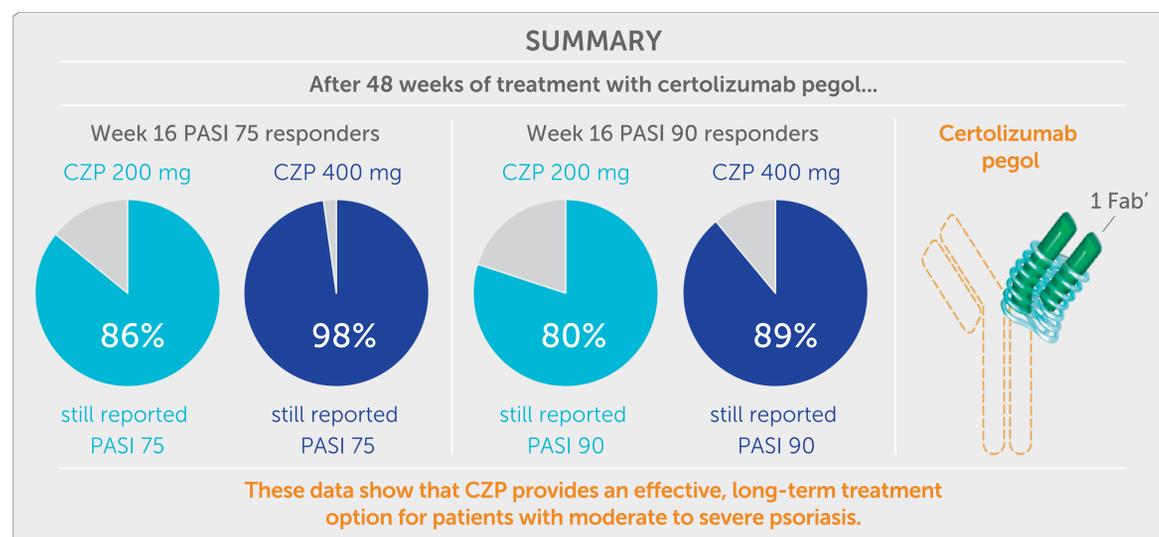
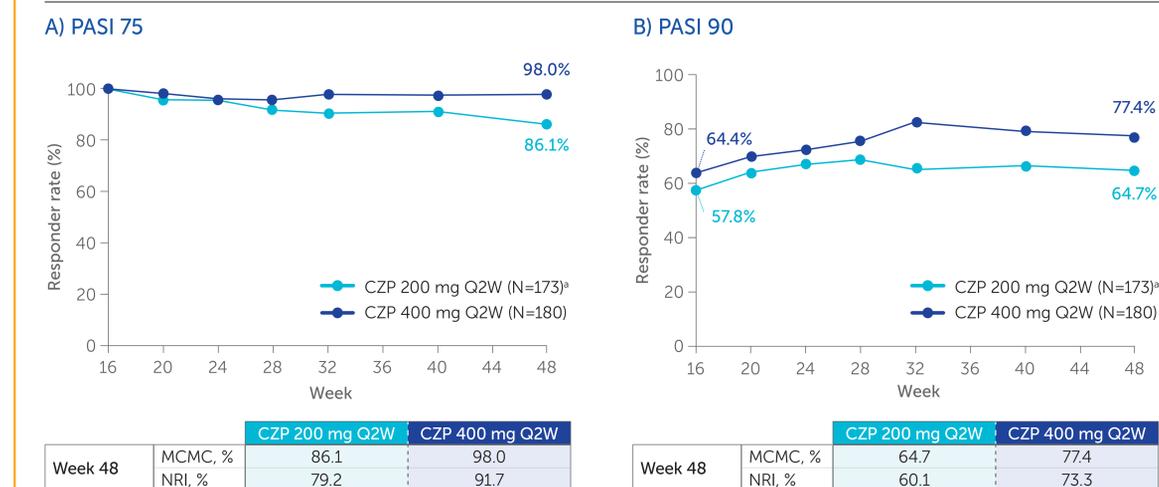


Figure 2. PASI response through Weeks 16–48 in Week 16 PASI 75 responders



MCMC imputation. ^aCZP 200 mg Q2W patients received loading dose of CZP 400 mg at Weeks 0, 2 and 4. CZP: certolizumab pegol; MCMC: Markov Chain Monte Carlo; NRI: non-responder imputation; PASI: Psoriasis Area Severity Index; Q2W: every two weeks.

Statistical Analyses

- Patients who did not achieve PASI 50 ($\geq 50\%$ reduction) at Week 32 or later were treated as non-responders at subsequent time points.
- Missing data and patients withdrawn during Weeks 16–48 were imputed using multiple imputation (Markov Chain Monte Carlo [MCMC] method).
- Sensitivity analyses were conducted using non-responder imputation (NRI) for all missing data.

RESULTS

- 173 patients receiving CZP 200 mg every two weeks (Q2W) and 180 patients receiving CZP 400 mg Q2W achieved a PASI 75 response at Week 16 and entered the maintenance period. Patient baseline characteristics are shown in Table 1.
- Of patients who achieved a Week 16 PASI 75 response:
 - A high proportion achieved PASI 75 at Week 48 (Figure 2A)
- The proportion of patients who also demonstrated a PASI 90 response was maintained or further increased to Week 48 (Figure 2B).
- PASI 90 responder rates for Week 16 PASI 90 responders remained high to Week 48 (Figure 3).

Figure 3. PASI 90 response through Weeks 16–48 in Week 16 PASI 90 responders

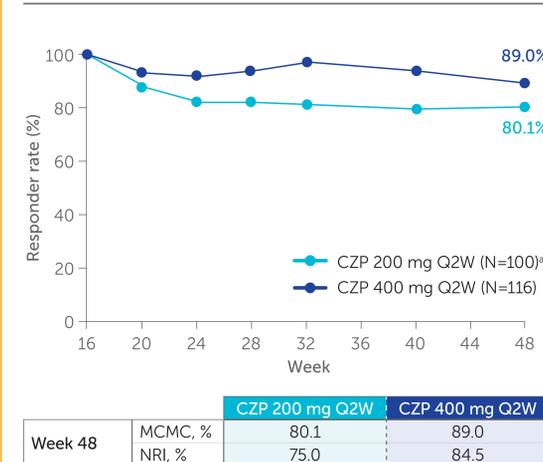
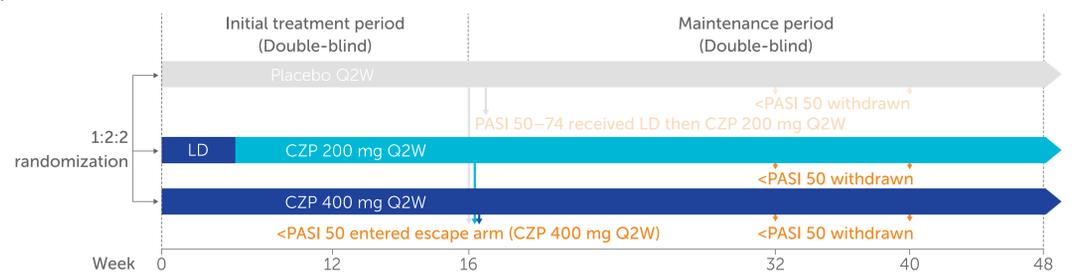
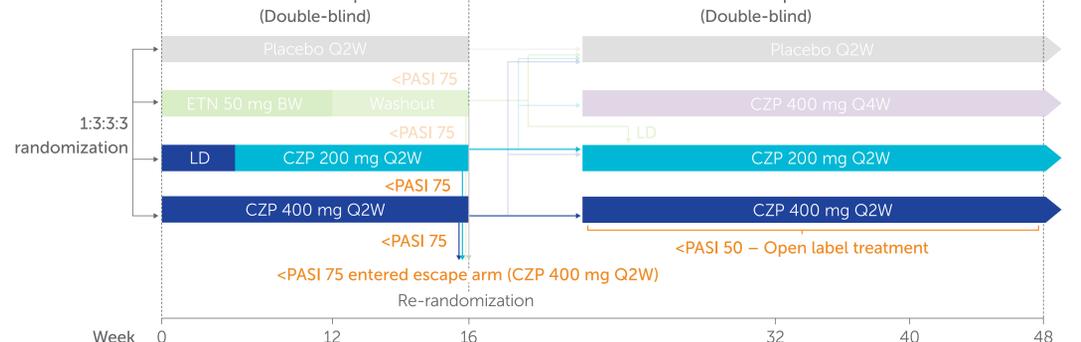


Figure 1. Study design for CZP in PSO phase 3 trials

A) CIMPASI-1 and CIMPASI-2



B) CIMPACT



BW: twice per week; CZP: certolizumab pegol; ETN: etanercept; LD: CZP 400 mg loading dose at Weeks 0, 2 and 4 or Weeks 16, 18 and 20; PASI: Psoriasis Area Severity Index; Q2W: every two weeks; Q4W: every four weeks.

Table 1. Demographics and baseline characteristics

	CZP 200 mg Q2W ^a (N=173)	CZP 400 mg Q2W (N=180)
Age, years, mean (SD)	44.8 (13.0)	44.7 (13.0)
Male, n (%)	117 (67.6)	114 (63.3)
BMI, kg/m ² , mean (SD)	30.9 (7.7)	29.6 (6.5)
Prior biologic use, n (%)	52 (30.1)	55 (30.6)
Anti-TNF	32 (18.5)	27 (15.0)
Anti-IL-17	17 (9.8)	14 (7.8)
Anti-IL-12/IL-23	1 (0.6)	11 (6.1)
PSO duration, years, mean (SD)	18.1 (12.7)	17.7 (11.9)
PASI, mean (SD)	19.9 (7.9)	19.8 (6.8)
BSA affected, %, mean (SD)	24.3 (16.0)	24.4 (13.4)
PGA score, n (%)		
3 (moderate)	121 (69.9)	128 (71.1)
4 (severe)	52 (30.1)	52 (28.9)

^aCZP 200 mg Q2W patients received CZP 400 mg at Weeks 0, 2 and 4. BMI: body mass index; BSA: body surface area; CZP: certolizumab pegol; IL: interleukin; PASI: Psoriasis Area Severity Index; PGA: physician's global assessment; SD: standard deviation; TNF: tumor necrosis factor.

CONCLUSIONS

- The response to CZP was durable, with high response rates maintained through Week 48.
- CZP provides an effective, long-term treatment option for patients with moderate to severe PSO.

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Author Contributions: Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: MA, JW, ML, CP, VP, HS, AB, LP, RR, KR, DT, CL, YP, CA, ABG; Drafting of the publication, or revising it critically for important intellectual content: MA, JW, ML, CP, VP, HS, AB, LP, RR, KR, DT, CL, YP, CA, ABG; Final approval of the publication: MA, JW, ML, CP, VP, HS, AB, LP, RR, KR, DT, CL, YP, CA, ABG.

Author Disclosures: MA: AbbVie, Almirall, Amgen, Biogen, Boehringer Ingelheim, Celgene, Centocor, Eli Lilly, GlaxoSmithKline, Hexal, Janssen, LEO Pharma, Medac, Merck, MSD, Mundipharma, Novartis, Pfizer, Sandoz, UCB Pharma, Xenoport; JW: Amgen, Celgene, Coherus, Dermira Inc., Eli Lilly, Galderma, Janssen, LEO Pharma, Merck, Pfizer, Regeneron, Sandoz, UCB Pharma; ML: Allergan, Aqua LEO Pharma, Promius. Employee of Mount Sinai which receives research funds from AbbVie, Amgen, Boehringer Ingelheim, Celgene, Eli Lilly, Janssen/Johanson & Johnson, Kadmon, MedImmune/AstraZeneca, Novartis, Pfizer, Valeant, VIDac; CP: AbbVie, Almirall, Amgen, Boehringer Ingelheim, Celgene, GlaxoSmithKline, Janssen-Cilag, LEO Pharma, Eli Lilly, Novartis, Pierre Fabre, Pfizer, Sanofi Regeneron, UCB Pharma; VP: AbbVie, Amgen, Boehringer Ingelheim, Celgene, Dermira Inc., Janssen, Eli Lilly, MedImmune, Novartis, Pfizer, Sun Pharma, UCB Pharma, Valeant; HS: AbbVie, Amgen, Boehringer Ingelheim, Celgene, Dermira Inc., Janssen, Eli Lilly, MedImmune, Novartis, Pfizer, Sun Pharma, UCB Pharma, Valeant; AB: AbbVie, Aclaris, Almirall, Amgen, Boehringer Ingelheim, Celgene, Dermavant, Dermira Inc., Eli Lilly, Genentech/Roche, GlaxoSmithKline, Janssen, LEO Pharma, Meiji, Merck, Novartis, Pfizer, Purdue Pharma, Regeneron, Sandoz, Sanofi Genzyme, Sierra Pharmaceuticals, Sun Pharma, UCB Pharma, Valeant, Vidac; KR: AbbVie, Affibody, Amgen, Biogen, Boehringer Ingelheim, Celgene, Centocor, Covagen, Forward Pharma, GlaxoSmithKline, Janssen-Cilag, Kyowa Kirin, LEO Pharma, Eli Lilly, Medac, Merck Sharp & Dohme Corp., Novartis, Ocean Pharma, Pfizer, Regeneron, Samsung Bioepis, Sanofi, Takeda, UCB Pharma, Valeant, Xenoport; DT: AbbVie, Almirall, Amgen, Boehringer-Ingelheim, Celgene, Dignity, Dr. Reddy, Galapagos, GlaxoSmithKline, Janssen, LEO Pharma, Morphosis, MSD, Eli Lilly, Novartis, Pfizer, Sandoz-Hexal, Regeneron/Sanofi, UCB Pharma; CL: AbbVie, Actavis, Amgen, Boehringer Ingelheim Pharma, Celgene, Coherus, Corrona, Dermira Inc., Eli Lilly, Galderma, Glenmark, Janssen, LEO Pharma, Merck, Novartis, Novella, Pfizer, Sandoz, Stiefel, Wyeth, UCB Pharma, Vitea. Treasurer of the International Psoriasis Council. Fellow of the American Academy of Dermatology. Member of the American Dermatological Association. Adjunct Professor of Dermatology at St. Louis University School of Medicine. Private practice in St. Louis, MO; YP: AbbVie, Baxter, Boehringer Ingelheim Pharma, Celgene, Centocor/Janssen, Eli Lilly, EMD Serono, GlaxoSmithKline, LEO Pharma, MedImmune, Merck, Novartis, Pfizer, Regeneron, Sanofi Genzyme, Takeda, UCB Pharma; ABG: AbbVie, Allergan, Beiersdorf Inc., Bristol Myers Squibb, Celgene, Dermira Inc., Eli Lilly, Janssen, Incyte, LEO Pharma, Novartis, Reddy Labs, Sun Pharmaceutical Industries, UCB Pharma, Valeant; LP, RR, CA: Employees of UCB Pharma.

Acknowledgements: The studies were funded by Dermira Inc. in collaboration with UCB Pharma. UCB is the regulatory sponsor of certolizumab pegol in psoriasis. We thank the patients and their caregivers in addition to the investigators and their teams who contributed to this study. The authors acknowledge Bartosz Lukowski, MSc, UCB Pharma, Brussels, Belgium for publication coordination and Amelia Frizell-Armitage, PhD, Costello Medical, Cambridge, UK for medical writing and editorial assistance. All costs associated with development of this poster were funded by UCB Pharma.