Durable Efficacy of Certolizumab Pegol Dosed at 400 mg Every Two Weeks Over 128 Weeks in Patients with Plaque Psoriasis Enrolled in Three Phase 3 Trials (CIMPASI-1, CIMPASI-2 and CIMPACT)

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OBJECTIVE

- To assess the long-term efficacy of and durability of response to certolizumab pegol dosed at 400 mg every two weeks in patients with moderate to severe plaque psoriasis who achieve PASI 75 after an initial 16 weeks of treatment.

BACKGROUND

- Certolizumab pegol (CZP), an Fc-free, PEGylated anti-tumor necrosis factor (anti-TNF), has demonstrated efficacy and safety in moderate to severe plaque psoriasis (PSO).[1,2]

METHODS

Study Design

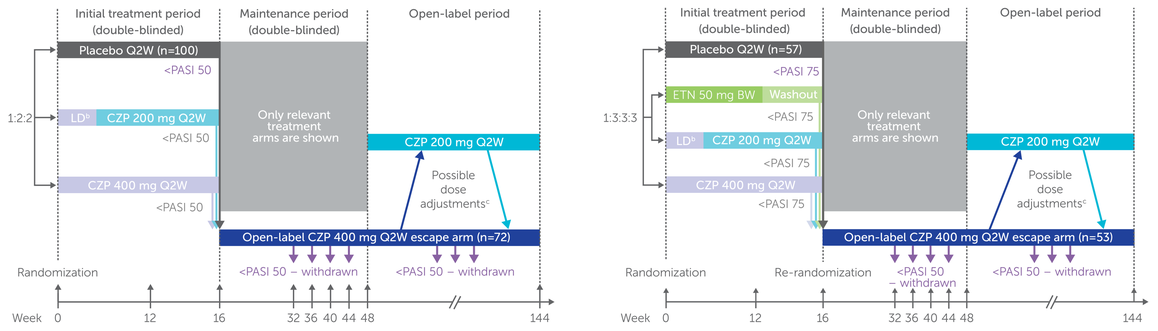
- Pooled data from the CIMPASI-1 (NCT02326298), CIMPASI-2 (NCT02326272), or CIMPACT (NCT02346240) phase 3 studies are reported **(Figure 1)**.
- Patient inclusion criteria:
  - ≥18 years of age with PSO for ≥6 months;
  - Psoriasis Area and Severity Index (PASI) ≥12;
  - ≥10% body surface area (BSA) affected;
  - Physician's Global Assessment (PGA) ≥3 on a 5-point scale;
  - Candidates for systemic PSO therapy, phototherapy and/or photochemotherapy.

Table 1. Demographics and baseline characteristics of included patients

	Placebo → CZP 400 mg Q2W (N=116)
Age (years), mean ± SD	46.4 ± 12.6
Male, n (%)	76 (65.5)
Caucasian, n (%)	108 (93.1)
Weight (kg), mean ± SD	94.0 ± 26.1
Duration of PSO (years), mean ± SD	17.7 ± 12.1
Concomitant PsA,[a] n (%)	19 (16.4)
PASI, mean ± SD	18.8 ± 6.7
BSA (%), mean ± SD	23.2 ± 13.9
PGA score, n (%)	
3: moderate	81 (69.8)
4: severe	35 (30.2)
DLQI total score, mean (SD)	12.9 ± 7.4
Any prior systemic therapy use for PSO, n (%)	87 (75.0)
Prior biologic use, n (%)	33 (28.4)
anti-TNF	19 (16.4)
anti-IL-17	12 (10.3)
anti-IL-12/IL-23	6 (5.2)

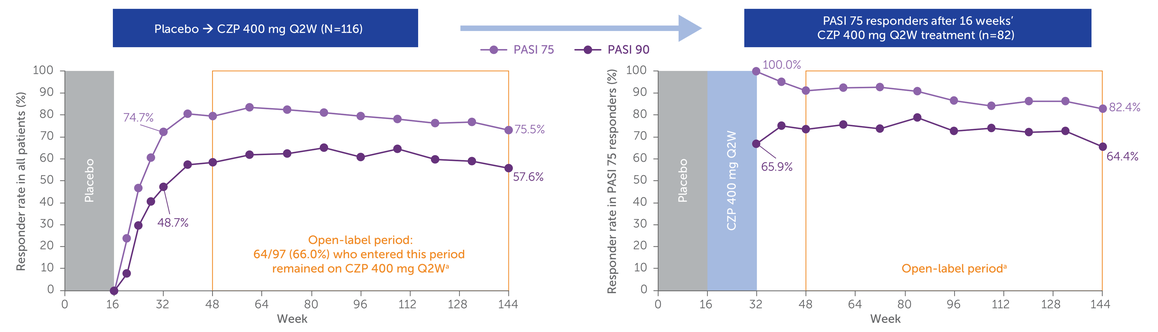
[a]Presence of concurrent PsA was self-reported. BSA: body surface area; CZP: certolizumab pegol; DLQI: Dermatology Life Quality Index; IL: interleukin; PASI: Psoriasis Area Severity Index; PGA: physician's Global Assessment; PsA: psoriatic arthritis; PSO: plaque psoriasis; Q2W: every two weeks; SD: standard deviation; TNF: tumor necrosis factor.

Figure 1. Study design of CIMPASI-1 and 2 and CIMPACT



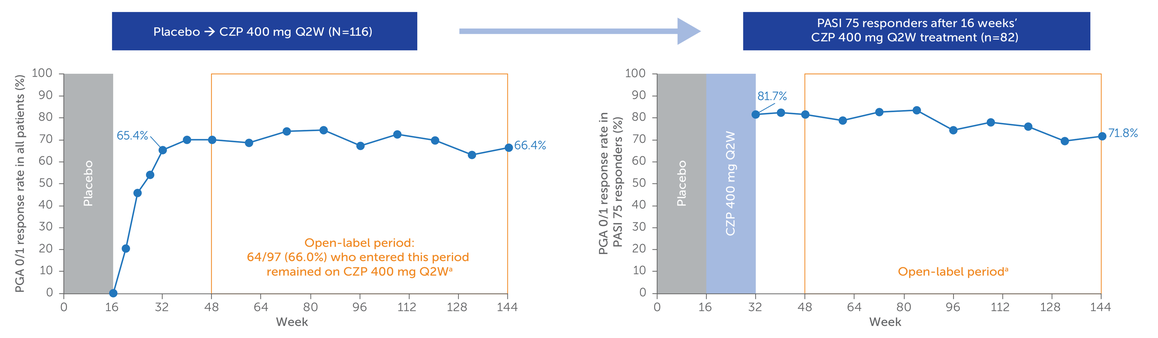
[a]CIMPASI-1: NCT02326298; CIMPASI-2: NCT02326272; CIMPACT: NCT02346240; [b]Loading dose of CZP 400 mg Q2W at Week 0, 2, and 4; [c]Depending on PASI response, any dose adjustments were either mandatory or at the investigators discretion: BW: twice per week; CZP: certolizumab pegol; ETN: etanercept; LD: loading dose; PASI 50/75: 50%/75% improvement from Baseline in Psoriasis Area Severity Index; Q2W: every two weeks.

Figure 2. PASI 75 and PASI 90 responses to Week 144



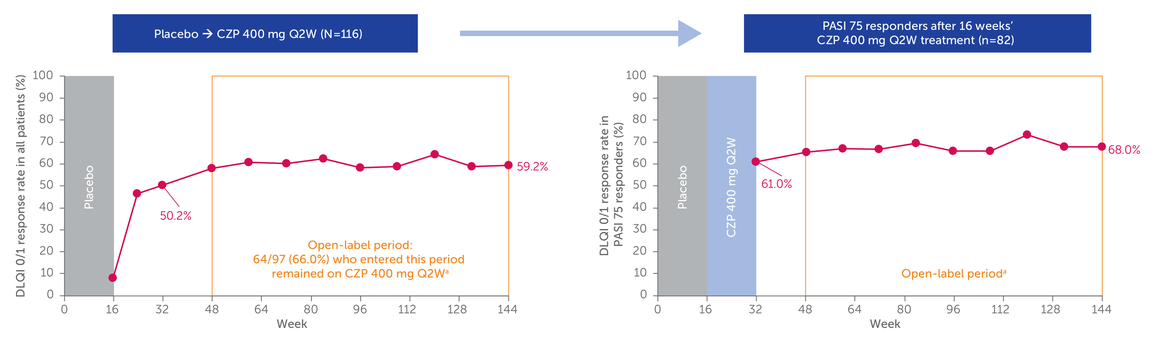
[a]Depending on PASI response, dose reductions to CZP 200 mg Q2W were permitted at the discretion of the investigator. CZP: certolizumab pegol; PASI 75/90: 75/90% improvement from Baseline in Psoriasis Area Severity Index; Q2W: every two weeks.

Figure 3. PGA 0/1 response to Week 144



[a]Depending on PASI response, dose reductions to CZP 200 mg Q2W were permitted at the discretion of the investigator. CZP: certolizumab pegol; PGA 0/1: Physician's Global Assessment score of 0 or 1 ("clear" or "almost clear") with ≥2-point improvement from baseline; Q2W: every two weeks.

Figure 4. DLQI 0/1 response to Week 144



[a]Depending on PASI response, dose reductions to CZP 200 mg Q2W were permitted at the discretion of the investigator. CZP: certolizumab pegol; DLQI 0/1: Dermatology Life Quality Index of 0 or 1; no effect of disease on quality of life; PASI 75: 75% improvement from baseline in Psoriasis Area Severity Index; Q2W: every two weeks.

Outcomes

- Outcomes are reported for Week 0 placebo-randomized patients who did not achieve PASI 50 at Week 16, and entered the CZP 400 mg Q2W escape arm (Weeks 16–144).
- We report PASI 75, PASI 90, PGA 0/1 and Dermatology Life Quality Index (DLQI) 0/1 responses to Week 144.
- Missing data were imputed using Markov Chain Monte Carlo (MCMC) methodology.
- Responder rates reflect the simple average response and include patients who did and did not dose adjust during the open-label period.

RESULTS

- 116 placebo-randomized patients had a PASI <50 at Week 16 and entered the CZP 400 mg Q2W escape arm.
- Baseline characteristics of included patients are shown in **Table 1**.
- Patients demonstrated a rapid response during the first 16 weeks of CZP 400 mg Q2W treatment, with 74.7% achieving a PASI 75 response and 48.7% a PASI 90 response.
  - These responses were durable over 128 weeks of treatment: PASI 75 and PASI 90 responses were 75.5% and 57.6%, respectively, at Week 144 **(Figure 2)**.
- Of the patients who achieved PASI 75 after 16 weeks' CZP treatment, 65.9% also achieved PASI 90.
  - After a further 128 weeks' CZP treatment, 82.4% of these patients maintained PASI 75 and 64.4% achieved PASI 90 **(Figure 2)**.
- Similar trends were reported for PGA 0/1 **(Figure 3)** and DLQI 0/1 **(Figure 4)**.

CONCLUSIONS

- CZP dosed at 400 mg Q2W offers a durable, long-term treatment option for patients with moderate to severe PSO.

References

1. Gottlieb A.B. *et al.* JAAD 2018;79:302–14.e6; **2.** Lebwohl M. *et al.* JAAD 2018;79:266–76.e5.

Author Contributions

Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: KG, RBW, ABG, AB, DT, YP, MB, FB, CA, KR; Drafting of the publication, or revising it critically for important intellectual content: KG, RBW, ABG, AB, DT, YP, MB, FB, CA, KR; Final approval of the publication: KG, RBW, ABG, AB, DT, YP, MB, FB, CA, KR.

Author Disclosures

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