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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Objectives
To assess the long-term efficacy of CZP dosed at 400 mg every two weeks (Q2W), in addition to the durability of response in patients who achieve PASI 75 after an initial 16 weeks of treatment.

Background
- Plaque psoriasis (PSO) is an immune-mediated, inflammatory disease that affects around 2–4% of the population in Western countries.
- Certolizumab pegol (CZP) is a unique Fc-free, PEGylated, anti-tumor necrosis factor approved by the FDA and EMA for the treatment of moderate to severe PSO.

- In phase 3 trials, patients with moderate to severe PSO received unblinded CZP 400 mg Q2W for 16 weeks.
- Patients who failed to achieve a 50% improvement from baseline in Psoriasis Area and Severity Index (PASI 50) at Week 16 were randomized to placebo or CZP 400 mg Q2W in an open-label period to Week 32.

Methods
Study Design
- Data were pooled from three phase 3 trials in adults with PSO: CIMPASI-1 (NCT03263101), CIMPASI-2 (NCT03326727), and CIMPACT (NCT03824690).
- Full study designs have been reported previously.

- At Week 0, patients were randomized to receive CZP 200 mg Q2W (400 mg loading dose at Weeks 0/1), CZP 400 mg Q2W, or placebo.

- Patients included in the analysis were:
  - Randomized to placebo at Week 0
  - Failed to achieve a 50% improvement from baseline in Psoriasis Area and Severity Index (PASI 50) at Week 16
  - Entered the open-label escape arm where they received unblinded CZP 400 mg Q2W for 16 weeks.

- Patients who did not achieve PASI 50 at any visit after receiving unblinded CZP 400 mg Q2W for 16 weeks were withdrawn from the study.

Patients
- Patient inclusion and exclusion criteria have been reported.

Synopsis
Patients with moderate to severe plaque psoriasis were treated with certolizumab pegol dosed at 400 mg every two weeks for up to 128 weeks. Patients demonstrated a rapid response in the first 16 weeks of treatment, with a high proportion achieving PASI 75, PASI 90, PGA 0/1, and PGA DI-1 responses, which were durable to Week 128 of treatment.

Statistical Analysis
- Proportions of patients who achieved a 75% or 90% improvement from baseline in PASI (PASI 75 or PASI 90), a Physician’s Global Assessment score of 0 or 1 (PGA 0/1), Dermatology Life Quality Index (DLQI) 0/1 through 128 weeks of treatment with CZP 400 mg Q2W (Weeks 16–144 of the study) are reported.

- Responder rates in the subset of patients who achieved a PASI 75 response following 16 weeks of treatment with CZP 400 mg Q2W in the escape arm are also reported.

- Estimates of responder rates were based on the simplified average response. Patients mandatorily withdrawn from the study were treated as non-responders at subsequent timepoints; all other missing data were imputed using Markov Chain Monte Carlo (MCMC) methodology.

Results
Patient Population and Baseline Characteristics
- 116 patients did not achieve PASI 50 after 16 weeks of placebo treatment and entered the open-label CZP 400 mg Q2W escape arm. Baseline demographics of these patients are shown in Table 1.

Response to CZP Treatment
- Patients demonstrated a rapid response during the first 16 weeks of CZP 400 mg Q2W treatment; 74.7% of patients achieved PASI 75 at Week 32, 48.7% achieved PASI 90, and 65.4% achieved PGA 0/1 (Figure 1A).

- Initial responder rates were sustained to Week 144 (Figure 1B).

- Similar trends were observed for DLQI 0/1 (Figure 2).

Maintenance of Response
- Of the 82 patients who achieved PASI 75 after 16 weeks of CZP 400 mg Q2W treatment (Week 32):
  - The majority (82.4%) maintained PASI 75 over a further 112 weeks of treatment (Figure 2A).
  - 65.5% achieved PGA 0/1 through 128 weeks of treatment (Figure 1B).

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