Long-Term Safety of Certolizumab Pegol in Plaque Psoriasis: Pooled Analysis over 3 Years from Three Phase 3, Randomized, Placebo-Controlled Studies


METHODS

Patients and Study Design

- Pooled safety data are presented for patients who received ≥1 dose of CZP during the 144 weeks of the CIMPASI-1 (NCT02526398), CIMPASI-2 (NCT02526272), or CIMPACT (NCT02544240) phase 3 studies (Figure 1).
- Only 11 placebo-randomized patients continued on placebo after Week 16, placebo data are presented to Week 16 only.
- Patient inclusion criteria:
  - ≥18 years of age with PSO for ≥6 months;
  - ADL: Physician’s global assessment (PGA) ≥3 on a 0–4 scale.
- Exclusion criteria: previous treatment with CZP or ≥2 biologics; previous treatment with etanercept (ETN) (CIMPACT only); treatment with ETN within the first 12 weeks of enrolment (CIMPASI-1 and CIMPASI-2 only).
- History of primary failure to any biologic or secondary failure to >1 biologic; erythrodermatitis, guttate or generalized Pso types; history of or current, chronic or recurrent viral, bacterial or fungal infections.

Safety Assessments

- Safety data were analyzed for the dose–combined CZP–treated group (All CZP) and separately for each CZP dose.
- For patients exposed to both doses of CZP over the course of the studies, treatment-emergent adverse events (TEAEs) were assigned to the dose being received at the time of onset, but each patient was counted in the All CZP group only.
- TEAEs and serious TEAEs were classified using MedDRA version 18.1.
- Serious TEAEs were defined as those meeting one or more of the following criteria: life-threatening, leading to death, hospitalization, congenital anomalies/birth defects, medically significant (based upon medical judgement), infections requiring intravenous antibiotics, or leading to persistent or significant disability.
- Incidence rates (IR) were calculated as the number of new cases per 100 patient-years (PY).