Efficacy of Certolizumab Pegol for Psoriasis of the Head and Neck in Two Phase 3 Clinical Trials: CIMPASI-1 and CIMPASI-2

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OBJECTIVE
• To report the efficacy of certolizumab pegol for psoriasis of the head and neck region in two phase 3 clinical trials.

BACKGROUND
• Plaque psoriasis (PsO) is an immune-mediated, inflammatory disease that is associated with significant physical and emotional burden.1
• Psoriatic lesions located on visible areas of the body can have a major impact on patients’ quality of life (QoL).2 Psoriasis of the head and neck region in particular can cause a high degree of emotional distress, despite only representing 10% of the body surface area (BSA), and the greatest impact on QoL is reported by female patients.3,4
• 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.1,5
• In phase 3 trials, CZP has demonstrated significant improvements in the signs and symptoms of PsO.6

Study Design
- Patients achieving a 75% and 90% improvement in psoriasis of the head and neck region, and the mean percentage change from baseline in head and neck PASI are reported, through Weeks 0–48.
- Calculation of change from baseline included only patients with head and neck involvement. Calculation of PASI 75 and PASI 90 responder rates included all randomized patients (patients with and without head and neck involvement were considered non-responders).
• For patients missing one or two severity measures (redness, thickness, or scaling) for the head and neck region at a given study visit, values were substituted with the mean of the measures available for that region at that visit.
• Patients who did not achieve PASI 50 at Week 16 had their Week 16 value carried forwards. Patients who should have been mandatorily withdrawn from study treatment at Week 31 or Week 40 due to not achieving PASI 50 were treated as non-responders for subsequent visits with missing data.

METHODS
Study Design
- Data were pooled from the CIMPASI-1 (NCT02326298) and CIMPASI-2 (NCT02326278) phase 3 trials in adults with moderate to severe PsO (Figure 1). Full study designs have been reported previously.6
- Patients were randomized 2:2:1 to receive CZP 400 mg every 2 weeks (Q2W), CZP 200 mg Q2W (400 mg loading dose at Weeks 0, 2, and 4) or placebo.
- At Week 16, patients receiving CZP who achieved ≥50% improvement from baseline in PASI (PASI 50) continued to receive the same CZP dose to Week 48.

RESULTS
Patient Demographics and Baseline Characteristics
- 175, 186, and 100 patients were randomized to CZP 400 mg Q2W, CZP 200 mg Q2W and placebo, respectively, at Week 0. Patient baseline characteristics are shown in Table 1.
- Baseline PASI of the head and neck region was comparable across CZP 400 mg Q2W, CZP 200 mg Q2W and placebo treatment groups (Table 1).

PASI of the Head and Neck Region
- At Week 16, a higher proportion of patients receiving CZP treatment achieved 75% and 90% improvements in PASI of the head and neck region compared with placebo (Figure 2).
- Week 16 responder rates were maintained to Week 48 for patients receiving both CZP doses (Figure 2).
- Mean percentage change from baseline in PASI of the head and neck region was also greater for CZP-treated patients compared with placebo at Week 16, and maintained to Week 48 (Figure 3).
- Although improvements were seen for both CZP doses, responder rates were higher in patients receiving CZP 400 mg Q2W.

CONCLUSIONS
• Rapid improvements in psoriasis of the head and neck region were seen as early as Week 2 of CZP treatment.
• A higher proportion of patients treated with CZP demonstrated a 75% or 90% improvement in PASI of the head and neck region at Week 16 compared with placebo. Improvements in CZP-treated patients were maintained to Week 48, indicating a durable clinical response in this hard-to-treat area.
• The greatest improvements were observed for patients receiving CZP 400 mg Q2W.
• This novel subset of CZP may be a suitable treatment option for patients with moderate to severe PsO affecting the head and neck, a known detractor from patients’ QoL.

REFERENCES
5. Author Disclosures
- PvdK: Received fees for consultancy service or lectureships from Celgene, Centocor, Amgen, Pfizer, AbbVie, Eli Lilly, Galderma, Novartis, Janssen, UCB Pharma, Sanofi, Boehringer Ingelheim, Sandoz, and PPD.
- AP: Received research or travel grants from AbbVie, Amgen, Celgene, Lilly, UCB Pharma, and Janssen.
- JJC: Received fees for consultancy service or lectureships from Celgene, Centocor, Amgen, PPD, Abbott, Eli Lilly, Galderma, Novartis, Janssen, UCB Pharma, Sanofi, Boehringer Ingelheim, Sandoz, and PPD.
- SF: Received fees for consultancy service or lectureships from Celgene, Centocor, Amgen, PPD, Abbott, and Eli Lilly.
- LS: Received fees for consultancy service or lectureships from Celgene, Centocor, Amgen, PPD, Abbott, and Eli Lilly.
- RE: Received research or travel grants from AbbVie, Amgen, Celgene, Lilly, UCB Pharma, and Janssen.

Author Contributions
- Substantial contributions to study conception or design, acquisition of data, or analysis and interpretation of data: JJC, SF, KR, JU, LS.

Acknowledgements
- The authors would like to thank the patients and their caregivers who contributed to this study. The authors acknowledge Dr. Delphine Fournier for the statistical analysis, Dr. Marcella Pizzocroco for the preparation of the manuscript, and Dr. Carmen Patruno for the expert medical editorial assistance.

Presented at Fall Clinical Dermatology Conference 2019 | Las Vegas, NV, USA | 17–20 October 2019

Previously presented at 28th EADV Congress 2019