Nail Outcome Improvements with Certolizumab Pegol in Moderate to Severe Plaque Psoriasis: Results from Phase 3 Trials

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OBJECTIVE
• To report the impact of 48 weeks’ certolizumab pegol treatment on nail disease outcomes in patients with moderate to severe plaque psoriasis.

BACKGROUND
• Plaque psoriasis (PSO) is an immune-mediated, inflammatory disease, treatment options include systemic medication, phototherapy and biologic agents.
• Certolizumab pegol (CZP) is a unique, Fc-free, PEGylated, anti-tumor necrosis factor (TNF) biologic approved for the treatment of adults with moderate to severe PSO by the FDA and EMA.1,2
• CZP has demonstrated sustained improvements in the skin disease of adults with moderate to severe PSO in phase 3 trials.3,4
• In the RAPID-PsA phase 3 trial of CZP in psoriatic arthritis (PsA), 54% of patients achieved total resolution of their nail disease after 48 weeks’ CZP treatment, increasing to 71% after 4 years.5 However, nail disease outcomes from the CZP in PSO phase 3 trials have not yet been reported.
• Here, nail disease outcomes in patients with PSO who received double-blind CZP over 48 weeks in three phase 3 trials are presented.

METHODS
Study Design
• Patients with PSO were enrolled in three phase 3, placebo-controlled, double-blind trials of CZP in adults with moderate to severe PSO: CIMPASI-1 (NCT02326298), CIMPASI-2 (NCT02326272) and CIMPACT (NCT02346240) (Figure 1).1,4

Patients
• Inclusion criteria: ≥18 years of age with PSO for ≥6 months with Psoriasis Area Severity Index (PASI) ≥12, ≥10% body surface area affected, Physician’s Global Assessment ≤3 on a 5-point scale. Candidates for systemic PSO therapy, phototherapy and/or photochemotherapy.
• Exclusion criteria: previous treatment with 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; erythrodermic, guttate or generalized Pso types; current or history of chronic or recurrent viral, bacterial or fungal infections.
• Presence or absence of concomitant PsA (>PsA and → PsA respectively) was self-reported by patients at baseline.
• This analysis includes patients with nail disease at baseline (defined as a modified Nai Psoriasis Severity Index mNAPSI score ≥0) who received the same dose of CZP through 48 weeks.

Study Assessments and Statistical Analyses
• mNAPSI 75 (>75% improvement from baseline), total resolution of nail disease (mNAPSI=0) and change from baseline in mNAPSI are reported at Week 48 (post-baseline mNAPSI was not measured prior to Week 48).
• Observed data are reported for patients who received CZP 200 mg every 2 weeks (Q2W) and CZP 400 mg Q2W, stratified by self-reported PsA at baseline.
• Data are pooled for CIMPASI-1 and CIMPASI-2.

RESULTS
• 154 patients in CIMPASI-1/2 and 71 patients in CIMPACT had nail disease at baseline and were randomized to CZP treatment at Week 0.
• Patient baseline characteristics are shown in Table 1.
• Patients completing 48 weeks of CZP treatment in CIMPASI-1/2 or CIMPACT demonstrated considerable improvement in their nail disease (Figure 2A) and of these:
  – Over 70% patients achieved mNAPSI ≥75 (Figure 2B)
  – Over 65% demonstrated total resolution of their nail disease (Figure 2C).
• Similar results were observed between patients with and without self-reported concomitant PsA (Figure 2).

CONCLUSIONS
• Substantial proportions of patients with PSO treated with CZP over 48 weeks showed improved nail disease, with more than 6 in every 10 patients achieving total resolution.
• CZP demonstrated similar efficacy in treating nail disease in PSO patients with and without concomitant PsA.
• The efficacy of CZP treatment on nail disease outcomes observed in patients with PSO is comparable with previously reported efficacy in patients with PsA.

Table 1. Demographics and baseline characteristics of CZP-treated patients with nail disease in CIMPASI-1/CIMPASI-2 and CIMPACT

| Age, years, mean ± SD | 41.9 ± 13.2 | 42.0 ± 12.9 | 44.1 ± 13.0 | 44.9 ± 13.0 | 42.7 ± 13.0 | 42.8 ± 13.1 |
| Age, years, median | 37.5 | 38.0 | 38.0 | 38.0 | 38.0 | 38.0 |
| Male, n (%) | 122 (72.7) | 47 (66.2) | 23 (62.2) | 6 (50) | 89 (75.9) | 41 (69.5) |
| BMI, kg/m², mean ± SD | 30.4 ± 6.5 | 26.5 ± 7.5 | 30.3 ± 6.5 | 26.0 ± 6.5 | 30.2 ± 8.0 | 28.5 ± 4.8 |
| Prior biologic use, n (%) | 61 (59.6) | 18 (24.1) | 16 (43.2) | 6 (50) | 45 (56.8) | 20 (30) |
| Anti-TNF | 39 (37.3) | 12 (16.2) | 3 (8.1) | 0 (50) | 27 (32.5) | 0 (30) |
| Anti-IL-12/23 | 11 (10.7) | 4 (5.4) | 4 (11.1) | 0 (50) | 9 (10.6) | 8 (12.3) |
| PASI duration, years, mean ± SD | 15.8 ± 13.9 | 15.6 ± 14.1 | 10.2 ± 14.5 | 21.7 ± 11.1 | 16.6 ± 9.9 | 18.2 ± 6.9 |
| BSA, %, mean ± SD | 198.9 ± 8.1 | 21.0 ± 7.5 | 19.4 ± 9.9 | 17.9 ± 16 | 19.8 ± 7.5 | 21.6 ± 7.8 |
| CSA, %, mean ± SD | 96.7 ± 1.5 | 20.8 ± 16.8 | 22.7 ± 14.7 | 22.6 ± 12.2 | 24.6 ± 14.2 | 29.1 ± 17.5 |
| Dox, %, mean ± SD | 55.0 ± 16.7 | 46.7 ± 27.7 | 59.1 ± 21.8 | 57.2 ± 21.8 | 56.8 ± 24.9 | 44.4 ± 28.9 |

References

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

Author Disclosures
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