Certolizumab Pegol for Treatment of Plaque Psoriasis: Pooled Three-Year Efficacy Outcomes from Two Phase 3 Trials (CIMPASI-1 and CIMPASI-2)

K. Gordon,1 R. B. Warren,2 A. B. Gottlieb,3 A. Blauvelt,4 D. Thaçi,5 C. Leonardi,6 Y. Poulin,7 M. Boehnlein,8 S. Kavanagh,9 C. Arendt,10 K. Reich11

OBJECTIVE
- To present pooled, three-year efficacy data from two phase three trials of certolizumab pegol in moderate to severe plaque psoriasis.

BACKGROUND
- Psoriasis (PsO) is an inflammatory disease that affects around 3% of adults in the United States.1,2
- Treatment options for PsO include phototherapy/phototherapies, topical treatments, systemic agents and biologics.3,4,5
- Given the chronic nature of PsO, sustained treatment efficacy over the long-term is highly important. However, loss of response over time has previously been associated with biologics in PsO.6,7
- Certolizumab pegol (CZP) is an Fc-free, PEGylated anti-tumor necrosis factor (TNF) which has led to durable clinical improvements in patients with PsO over two years of treatment.8,9
- Here, we report the clinical responses of PsO patients over three years of CZP treatment, using data from the CIMPASI-1 (NCT01326298) and CIMPASI-2 (NCT01236272) phase 3 trials.

METHODS

Study Design
- Data were pooled for patients enrolled in two phase 3 trials, CIMPASI-1 (NCT01326298) and CIMPASI-2 (NCT01236272).
- This analysis includes all patients who were randomized to CZP 400 mg every two weeks (Q2W) or CZP 200 mg Q2W at Week 0 (intent-to-treat population).
- On entry to the open-label phase, all patients were initially treated with CZP 400 mg Q2W; subsequent dosing adjustment based on Psoriasis Area Severity Index (PASI) response was either mandatory or at the discretion of the Investigator (Figure 3).

Patients
- >18 years of age with moderate to severe PsO, >6 months with PASI >12, >10% body surface area (BSA) affected, and Physician’s Global Assessment (PGA) ≥3 on a 5-point scale.
- Candidates for systemic PsO therapy, phototherapy and/or phototherapy.
- Exclusion criteria: previous treatment with CZP or >2 biologics; 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.

Study Assessments and Statistical Analyses
- Patients were assessed through Weeks 0–144 for:
  - Study Assessments and Statistical Analyses
  - Initial week 16 responder rates were durable through to Week 48

RESULTS

Patient Population
- At Week 0, 175 patients were randomized to CZP 400 mg Q2W and 186 patients to CZP 200 mg Q2W.
- Baseline characteristics were balanced across treatment groups (Table 1).

Clinical Response to Week 144
- Week 16 responder rates were durable through to Week 48 for both CZP 400 mg Q2W and CZP 200 mg Q2W (Figure 4).
- In patients initially randomized to CZP 200 mg Q2W, PASI 75, PASI 90 and DLQI 0/1 responder rates were sustained for a further two years to Week 144 (Figure 4).
- In patients initially randomized to CZP 400 mg Q2W, clinical response gradually decreased following dose reduction to CZP 200 mg Q2W at Week 48 (Figure 4).

CONCLUSIONS
- In patients randomized to CZP 400 mg Q2W, responder rates were greater than or equal to Week 48 and were higher than the CZP 200 mg Q2W group. These rates then gradually decreased following dose reduction, indicating that continued treatment at 400 mg CZP Q2W may be needed to maintain optimal response.
- Long-term efficacy over three years was durable in patients who received CZP 200 mg Q2W.

Table 1. Demographics and baseline characteristics for all patients randomized to CZP 400 mg Q2W and CZP 200 mg Q2W

<table>
<thead>
<tr>
<th>Age, years, mean (SD)</th>
<th>45.0 (12.9)</th>
<th>45.6 (13.2)</th>
<th>45.3 (13.0)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male, n (%)</td>
<td>103 (58.9)</td>
<td>125 (67.2)</td>
<td>228 (65.2)</td>
</tr>
<tr>
<td>BMI, kg/m², mean (SD)</td>
<td>31.2 (7.9)</td>
<td>32.0 (7.8)</td>
<td>31.6 (7.8)</td>
</tr>
<tr>
<td>PASI disease duration, years, mean (SD)</td>
<td>18.5 (12.6)</td>
<td>17.7 (12.9)</td>
<td>18.1 (12.7)</td>
</tr>
<tr>
<td>Prior anti-TNF therapy, n (%)</td>
<td>39 (22.2)</td>
<td>44 (23.7)</td>
<td>83 (25.0)</td>
</tr>
<tr>
<td>BSA affected, %, mean (SD)</td>
<td>23.6 (14.3)</td>
<td>23.5 (14.4)</td>
<td>23.5 (14.6)</td>
</tr>
<tr>
<td>PASI, mean (SD)</td>
<td>19.6 (7.2)</td>
<td>19.2 (7.2)</td>
<td>19.4 (7.3)</td>
</tr>
<tr>
<td>PGA Score, n (%)</td>
<td>3 (24.3)</td>
<td>4 (27.3)</td>
<td>3 (2.7)</td>
</tr>
<tr>
<td>PASI 75</td>
<td>80.9</td>
<td>80.9</td>
<td>80.9</td>
</tr>
<tr>
<td>PASI 90</td>
<td>66.5</td>
<td>66.5</td>
<td>66.5</td>
</tr>
<tr>
<td>DLQI 0/1</td>
<td>13.7 (6.9)</td>
<td>14.2 (7.4)</td>
<td>14.0 (7.1)</td>
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</tbody>
</table>

Patients with responses to ≥2 biologics (including anti-TNFs) on the day to baseline, or history of chronic or recurrent viral, bacterial or fungal infections.

References

Author Contributions
- Substantial contributions to study concept, design, acquisition of data, or analysis and interpretation of data: KG, AB, AT, CF, MB, CA, KF. Drafting of the manuscript: KG. Obtained critical input for important intellectual content: KG, AB, AT, CF, MB, CA, KF. Final approval of the publication: KG, AB, AT, CF, MB, CA, KF.

AuthorDisclosures
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- AbbVie; Amgen; Biogen; Celgene; Genentech; Janssen; Lilly; Medac; Merck; Novartis; Pfizer; Regeneron; Sanofi Genzyme; Samsung Bioepis, Sanofi, Takeda, UCB Pharma, Valeant, Xenoport.
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