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

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OBJECTIVE

• To present pooled, three-year efficacy data from two phase 3 trials of certolizumab pegol in moderate to severe plaque psoriasis.

BACKGROUND

• Plaque psoriasis (PSO) is an inflammatory disease that affects around 3% of adults in the United States.1,2
• Treatment options for PSO include phototherapy/photopheresis, topical treatments, systemic agents and biologics.1,3
• 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.4
• 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.1
• Here, we report the clinical responses of PSO patients over three years of CZP treatment, using data from the CIMPASI-1 and CIMPASI-2 phase 3 trials.

METHODS

Study Design

• Data were pooled for patients enrolled in two phase 3 trials, CIMPASI-1 (NCT02326298) and CIMPASI-2 (NCT02326272) (Figure 1).
• 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 200 mg Q2W; subsequent dosing adjustment based on Psoriasis Area Severity Index (PASI) response was either mandatory or at the discretion of the Investigator (Figure 1).

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

• Initial Week 16 responder rates were durable through to Week 48 for both CZP 400 mg Q2W and CZP 200 mg Q2W (Figure 2).
• 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 2).
• In patients initially randomized to CZP 400 mg Q2W, clinical response gradually declined following dose reduction to CZP 200 mg Q2W at Week 48 (Figure 2).

CONCLUSIONS

• In patients randomized to CZP 400 mg Q2W, responder rates increased to Week 48 and were higher than in the CZP 200 mg Q2W group. These rates then gradually decreased following dose reduction, indicating that continued treatment at 400 mg Q2W may be needed to maintain optimal response.
• Long-term efficacy over three years was durable in those 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></th>
<th>CZP 400 mg Q2W (n=175)</th>
<th>CZP 200 mg Q2W (n=186)</th>
<th>All CZP (N=361)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years, mean (SD)</td>
<td>45.0 (12.9)</td>
<td>45.6 (13.2)</td>
<td>45.3 (13.0)</td>
</tr>
<tr>
<td>Male, n (%)</td>
<td>103 (58.9)</td>
<td>125 (67.2)</td>
<td>228 (63.2)</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>PASO 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>40 (22.9)</td>
<td>44 (23.7)</td>
<td>84 (23.3)</td>
</tr>
<tr>
<td>BSA affected, %, mean (SD)</td>
<td>23.6 (14.3)</td>
<td>23.5 (14.9)</td>
<td>23.5 (14.6)</td>
</tr>
<tr>
<td>PASI, mean (SD)</td>
<td>19.6 (7.5)</td>
<td>19.2 (7.2)</td>
<td>19.4 (7.3)</td>
</tr>
<tr>
<td>PGA Score, n (%)</td>
<td>3 (moderate)</td>
<td>126 (72.0)</td>
<td>254 (70.4)</td>
</tr>
<tr>
<td>4 (severe)</td>
<td>49 (28.0)</td>
<td>58 (31.2)</td>
<td>107 (29.6)</td>
</tr>
<tr>
<td>DLQI total score, mean (SD)</td>
<td>13.7 (6.9)</td>
<td>14.3 (7.4)</td>
<td>14.0 (7.1)</td>
</tr>
</tbody>
</table>

1Patients with exposure to ≥2 biologics including anti-TNF for PSO or RA prior to baseline, or primary diagnosis of RA at baseline. All previous biologic exposure was included in the study. BSA, body surface area; BMI, body mass index; CZP, certolizumab pegol; DLQI, Dermatology Life Quality Index; PASO, Psoriasis Area Severity Index; PGA, Psoriasis Global Assessment; PASI, Psoriasis Area and Severity Index; Q2W, every 2 weeks; SD, standard deviation; TNF, tumor necrosis factor.

REFERENCES

5. Gottlieb AB.

AUTHOR CONTRIBUTIONS

Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: KG, RBW, ABG, AB, DT, CL, YP, MB, SK, CA, KR.

Manuscript writing: KG, RBW, ABG, AB, DT, CL, YP, MB, SK, CA, KR.

All authors had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.

The authors thank the patients and their caregivers in addition to the investigators and their teams who contributed to this study. The authors acknowledge Bartosz Łukowski, MSc, UCB Pharma, Brussels for publication coordination and Amelia Frizell-Armitage, Costello Centre of Excellence, AbbVie, Chicago, for editorial assistance.

Acknowledgements

The authors declare no use of conflict of interest. The authors are thankful for the support of UCB Pharma. UCB Pharma provided editorial and statistical support for this manuscript.

Presented at the 5th Annual 2020 PA & NP Fall Clinical Dermatology Conference, Orlando, Florida, November 13–15, 2020

Previously presented at 28th EADV Congress 2019