Certolizumab Pegol for the Treatment of Chronic Plaque Psoriasis: DLQI and WPAI Patient-Reported Outcomes From an Ongoing Phase 3, Multicenter, Randomized, Active- and Placebo-Controlled Study (CIMPACT)

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INTRODUCTION

Psoriasis is a chronic, inflammatory disease of the skin and immune system that affects 12% of adults and 3% of children worldwide. It is a complex disease characterized by chronic inflammation with increasing comorbidities, including cardiovascular, metabolic, and psychiatric diseases. Despite the availability of many biologics, the disease remains difficult to treat, and up to 50% of patients are nonresponders to currently approved treatments (1,2).

The design of certolizumab pegol (CZP) CIMPACT (NCT02346240) is designed to assess the efficacy and safety of treatment in patients with chronic plaque psoriasis (cPP) who have failed or been intolerant to ≥2 systemic treatments (1,3). Previous work has demonstrated that patients with cPP undergoing biologic therapy are at risk of developing comorbidities and may become more reliant on societal and economic resources to meet their disease burden (4).

METHODS

Study Design

• CIMPACT is a 24-week, double-blind, multicenter, placebo-controlled, parallel-group study (4).
• Patients were randomized 3:3:1:3 to CZP 400 mg Q2W (N=167), CZP 200 mg Q2W (N=165), ETN 50 mg BW Q2W (N=57), or Placebo Q2W (N=53).
• Patients initially treated with CZP and re-randomized to the same or different dose of CZP.
• Patients completing 24 weeks of baseline therapy were randomized to the 200 mg Q2W or 400 mg Q2W CZP dose for 12 weeks following baseline in a 2:1 ratio.
• Patients completing 8 weeks of baseline therapy were randomized to the 400 mg Q2W or 200 mg Q2W CZP dose for 12 weeks following baseline in a 1:1 ratio.

RESULTS

Patient Disposition, Demographics, and Baseline Disease Characteristics

A total of 167, 165, and 57 patients were randomized to CZP 400 mg Q2W, CZP 200 mg Q2W, ETN 50 mg BW Q2W, and Placebo Q2W, respectively, at Week 0. The majority of patients were male (55.5%), the mean age was 53.8 years, and mean PASI 75 nonresponders entered an Escape Arm for treatment with CZP in patients who did not achieve DLQI MCID and/or DLQI 0/1 compared with placebo.

Statistical Analysis

• Effectiveness analysis of Week 16 was performed on the full analysis set (FAS).
• Analysis of DLQI and WPAI scores at Baseline and Week 16 was performed on the FAS with last observation carried forward (LOCF).

CONCLUSIONS

CZP has the potential to be an important new treatment option for patients with moderate to severe chronic plaque psoriasis; results of patient-reported outcomes (PROs) support this conclusion. The CIMPACT study is ongoing and further analysis of PROs will be reported.

References


Author Contributions

Janice Drew, Janine Finstuen, Gayla A. Tumlin, Yvonne F. Johnson, Maria A. Pina, Maria G. Eneroth, Carole M. Revilla, Karen Ray, Nadine C. D’Souza, and Andrew Blauvelt contributed to the conception and design of the study, and Andrew Blauvelt drafted the manuscript. All authors critically reviewed the manuscript. Partial financial disclosure may be found here.

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