Maintenance of Response With Certolizumab Pegol for the Treatment of Chronic Plaque Psoriasis: 48-Week Results From Two Ongoing Phase 3, Multicenter, Randomized, Placebo-Controlled Studies (CIMPASI-1 and CIMPASI-2)

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INTRODUCTION

Patient demographics, demographics, and baseline disease characteristics in both studies, at least 80% of patients in each treatment arm were enrolled, and the final planned study populations were in CIMPASI-1 and CIMPASI-2. The studies were conducted at 231 sites in North America and Europe. By adjusting for treatment, region, and prior biologic exposure and placebo response, patients were randomized in a 2:1 ratio to receive CZP 200 mg Q2W (N=87) or placebo (N=51) for 16 weeks (Fig 1).

METHODS

Study Design

CIMPASI-1 and CIMPASI-2 are replicate phase 3, multicenter studies conducted in North America and Europe, including 231 sites, and placebo controlled to placebo for the first 16 weeks followed by 52 weeks of open-label extension. Patients were randomized to CZP 200 mg Q2W (N=87) or placebo (N=51) for 16 weeks, followed by open-label extension for up to 52 additional weeks. Patients in the escape arm of the study (not part of this report) continued to receive their blinded treatment (CIMPASI-1 and CIMPASI-2 are replicate, phase 3, multicenter studies conducted in North America and Europe, consisting of controlled, double-blind, placebo-controlled parallel studies for the first 16 weeks followed by 52 weeks of open-label extension).

RESULTS

Patient Disposition, Demographics, and Baseline Disease Characteristics

In both studies, at least 80% of patients in each treatment arm were enrolled, and the final planned study populations were in CIMPASI-1 and CIMPASI-2. The studies were conducted at 231 sites in North America and Europe. By adjusting for treatment, region, and prior biologic exposure and placebo response, patients were randomized in a 2:1 ratio to receive CZP 200 mg Q2W (N=87) or placebo (N=51) for 16 weeks (Fig 1).

Safety

For patients who entered the blinded maintenance period in CIMPASI-2, 200 mg CZP was considered as a follow-up to the blinded treatment period. In CIMPASI-2, patients continued about 16 48 weeks, 52 weeks with CIMPASI and 48 weeks with CIMPASI-2. Patients who entered the blinded maintenance period in CIMPASI-2, the difference between the two studies was presented here.

Figure 1. Study Design

Figure 2. Patient Disposition

Figure 3. PASI 75 Responder Rates From Baseline to Week 48

Figure 4. PGA 01 Responder Rates From Baseline to Week 48

Figure 5. PASI 90 Responder Rates From Baseline to Week 48

Table 1. Patient Demographics and Baseline Disease Characteristics

Table 2. Adverse Events From Baseline to Week 48

Table 3. Most Frequently Reported TEAEs (≥25% in Any Group) Baseline to Week 48

CONCLUSIONS

Maintenance of response with certolizumab pegol for the treatment of chronic plaque psoriasis: 48-week results from two ongoing phase 3, multicenter, randomized, placebo-controlled studies (CIMPASI-1 and CIMPASI-2)

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Author Disclosures

References

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[Table 1. Patient Demographics and Baseline Disease Characteristics]

[Table 2. Adverse Events From Baseline to Week 48]

[Table 3. Most Frequently Reported TEAEs (≥25% in Any Group) Baseline to Week 48]