INTRODUCTION

Maintenance of response with Certolizumab Pegol for the Treatment of Chronic Plaque Psoriasis: Results of a 32-Week Re-Randomized Maintenance Period from an Ongoing Phase 3, Multicenter, Randomized, Active- and Placebo-Controlled Study (CIMPACT)

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METHODS

Study Design

• Certolizumab pegol (CZP) plus placebo
• Certolizumab pegol (CZP) plus etanercept (ETN)
• Certolizumab pegol (CZP) plus golimumab (GOL) (Simponi®)

Patients

• Eligible patients were ≥18 years old with active severe chronic plaque psoriasis for ≥6 months with a Baseline psoriasis area and severity index (PASI) ≥12 and ≥60% of the body surface area affected

Statistical Analysis

• Week 12 and Week 48 PASI 75 responder rates were assessed via a logistic regression model for superiority to ETN
• Week 12 and Week 48 PASI 90 responder rates were assessed via a logistic regression model for non-inferiority of CZP to ETN

RESULTS

Table 1. Patient Demographics and Baseline Disease Characteristics

Demographics

Age (years), mean ± SD 40.5 ± 12.6 44.1 ± 12.6 44.7 ± 11.9 48.0 ± 12.6 Male (%) 55.0 52.7 51.6 57.6 52.3 54.5 50.3 54.5 54.5 54.5 54.5 Week (N) 37 (125) 50 (186) 50 (186) 50 (186) Geographic region (N) 145 (481) 146 (482) 146 (482) 146 (482) 146 (482) 146 (482) 146 (482) 146 (482) 146 (482) 146 (482) Weight (kg), mean ± SD 85.5 ± 15.6 88.6 ± 20.0 89.5 ± 20.0 89.3 ± 20.0 BMI (kg/m²), mean ± SD 31.2 ± 8.5 30.8 ± 7.7 31.1 ± 7.7 31.1 ± 7.7 31.0 ± 7.7 31.0 ± 7.7 31.0 ± 7.7 31.0 ± 7.7 31.0 ± 7.7 31.0 ± 7.7

Table 2. Adverse Events From Baseline to Week 48 by CZP Dose Taken at Time of TEAE

CZP 400 mg every 2 weeks (Q2W) CZP 200 mg every 2 weeks (Q2W) ETN 5 mg every 4 weeks (Q4W) Placebo

TEAEs, n (%) [incidence rate]

• Primary failure to any biologic or secondary failure to >1 biologic
• >2 biologics (including anti-TNF); or history of severe chronic plaque psoriasis; results through Week 48 for patients initially treated with CZP compared with placebo and etanercept (ETN) in adult patients with moderate-to-severe chronic plaque psoriasis

CONCLUSIONS

Pfizer, Regeneron, Sandoz.