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CERTOLIZUMAB PEGOL IN PATIENTS WITH RHEUMATOID ARTHRITIS: POOLED EFFICACY ANALYSIS OF PHASE 3 CLINICAL TRIALS ACROSS BASELINE RHEUMATOID FACTOR QUARTILES

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BACKGROUND

Elevated rheumatoid factor (RF) in patients with rheumatoid arthritis (RA) is considered a risk factor for disease progression¹ and is associated with reduced response to antiTNFs.^{2–3} Certolizumab pegol (CZP), a PEGylated, Fc-free anti-TNF, showed rapid and sustained reduction in signs and symptoms of moderate to severe RA, inhibition of radiographic progression and improvements in physical function in patients with an inadequate response to methotrexate (MTX).^{4–7} We assess the efficacy of CZP plus MTX in patients with established, active RA across baseline RF levels.

MATERIALS AND METHODS

Patients with active RA ≥ 6 months (defined by ACR 1987 criteria) received CZP 200 mg every two weeks (Q2W, CZP 400 mg at weeks 0/2/4) or placebo (PBO) Q2W plus MTX, over 24 weeks. Study design and results were reported previously (RAPID 1 [NCT00152386], RAPID 2 [NCT00175877], J-RAPID [NCT00791999] and RAPID-C [NCT02151851]).^{4–7} Rheumatoid factor titers were measured by validated assays; patients were classified into: < 25.0 , $\geq 25.0 - < 78.5$, $\geq 78.5 - < 207.0$ and ≥ 207.0 IU/mL. Disease activity score 28 - erythrocyte sedimentation rate [DAS28(ESR)] categories were adopted to classify patients: remission, < 2.6 ; low disease activity, ≤ 3.2 . Missing values were imputed using LOCF.

RESULTS

Data were pooled from 1,017 CZP+MTX and 504 PBO+MTX-treated patients. Baseline mean (SD) DAS28(ESR) was similar between groups, across RF quartiles (PBO+MTX: 6.5 [0.9]–7.0 [0.9]; CZP+MTX: 6.6 [0.9]–7.0 [0.9]). Numerically higher response was observed for CZP+MTX vs PBO+MTX at week 24, across RF quartiles (Fig. 1A). CZP+MTX response increased to week 24 (Fig. 1B); the response was generally similar across RF quartiles at all timepoints.

Figure 1. Pooled DAS28(ESR) LA and remission rates for CZP+MTX.

CONCLUSION

Over 24 weeks, CZP+MTX efficacy was consistent and independent of RF levels; results may be related to the unique molecular structure of CZP. CZP+MTX may be a feasible treatment option in RA irrespective of patients' baseline RF status.

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