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Summary

# IMPACT OF OZANIMOD (OZA) ON C-REACTIVE PROTEIN (CRP) LEVELS AND THE ASSOCIATION WITH OZA EFFICACY IN PATIENTS (PTS) WITH MODERATELY TO SEVERELY ACTIVE ULCERATIVE COLITIS (UC): RESULTS FROM THE PHASE 3 TRUE NORTH (TN) STUDY

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UEG Week Copenhagen 2023 | Poster

IBD

October 15, 2023

**In a phase 3 study of 645 patients with moderately to severely active ulcerative colitis, ozanimod treatment resulted in significant reductions in C-reactive protein levels at 10 weeks compared to placebo, and baseline CRP levels and early CRP changes were prognostic for clinical outcomes independent of treatment.**

KEY POINTS

- Patients randomized to ozanimod 0.92 mg showed mean CRP reductions of 26.8% (Cohort 1) and 25.7% (Cohort 2) at Week 10 versus a 1.2% reduction with placebo (P<0.001 for both cohorts).
- CRP reductions were significantly greater in patients achieving clinical response versus nonresponders at Week 10 across all treatment groups (P<0.001), and CRP reductions were maintained through Week 52 in responders.
- Higher baseline CRP levels were associated with lower rates of endoscopic improvement, mucosal healing, and histologic remission at Week 10, while greater CRP reductions at Week 5 were associated with better clinical response at Week 10, independent of treatment assignment.
- Baseline CRP levels correlated significantly with most baseline disease activity scores (Spearman's rho 0.2-0.3, P<0.05) except rectal bleeding subscore, and Week 10 CRP changes correlated with changes in most disease activity scores.

– The findings support CRP as a prognostic biomarker in ulcerative colitis; this analysis is relevant for clinicians managing moderately to severely active UC and considering inflammatory biomarkers in treatment monitoring.

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