

IBD

PHASE II RESULTS
FOR IBD DRUGS

Current treatment guidelines do not recommend the use of antibiotics in patients with Crohn's disease. However, evidence suggests that an altered immune response to commensal gut bacteria might have a role in the development and persistence of intestinal inflammation in these patients. Thus, antibiotics might have a role in treatment.

Rifaximin is an oral, minimally absorbed antibiotic that has demonstrated efficacy in patients with intestinal bacterial infections, IBS and hepatic encephalopathy. Cosimo Prantera and colleagues performed a multicenter, randomized, double-blind trial of 400, 800 and 1,200 mg rifaximin given twice daily for 12 weeks to patients with moderately active Crohn's disease. 402 patients were included in the trial and the primary end point was remission. The researchers found that 800 mg rifaximin was associated with higher rates of remission than placebo and the 400 mg and 1,200 mg rifaximin doses. These findings now need to be confirmed in pivotal studies.

A separate study assessed the safety, efficacy, pharmacokinetics and tolerability of a new formulation of vedolizumab in patients with ulcerative colitis. Previous proof-of-concept studies demonstrated that an earlier version of vedolizumab had anti-inflammatory activity in patients with Crohn's disease and ulcerative colitis. However, some of these patients developed clinically relevant titers of human antihuman antibodies, which were associated with reduced efficacy. Hence, a new version of the agent has been developed.

In this study, 46 patients were randomly allocated to receive the new formulation of vedolizumab (2, 6 or 10 mg/kg) or placebo on days 1, 15, 29 and 85. Evaluations of safety, pharmacokinetics and immunogenicity were carried out at various time points.

Vedolizumab was well tolerated and during follow-up more patients treated with vedolizumab had a clinical response than those who received placebo. Phase III trials are currently ongoing to further evaluate the potential of vedolizumab.

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Original articles Prantera, C. *et al.* Rifaximin-extended intestinal release induces remission of patients with moderately active Crohn's disease. *Gastroenterology* doi:10.1053/j.gastro.2011.11.032 | Parikh, A. *et al.* Vedolizumab for the treatment of active ulcerative colitis: a randomized controlled phase 2 dose-ranging study. *Inflamm. Bowel Dis.* doi:10.1002/ibd.21896