



Tofacitinib effective in ulcerative colitis

Current treatment options for ulcerative colitis are limited, and many patients do not respond to existing medications. Published in *The New England Journal of Medicine*, the findings from three phase III trials now indicate that tofacitinib — an oral Janus kinase (JAK) inhibitor — is more effective than placebo for the induction and maintenance of remission in individuals with active ulcerative colitis.

To evaluate the efficacy of tofacitinib as an induction and maintenance therapy, the investigators conducted three randomized, double-blind phase III trials; the primary endpoint was remission and the key secondary endpoint was mucosal healing. In the OCTAVE Induction 1 and 2 trials, which

comprised 598 and 541 patients with moderately to severely active ulcerative colitis, respectively, participants were randomly assigned to tofacitinib (10 mg twice daily) or placebo for 8 weeks. In OCTAVE Sustain, 593 patients who responded during the two induction trials were re-randomized to receive maintenance therapy with tofacitinib (twice-daily doses of 5 mg or 10 mg or placebo for 52 weeks).

In OCTAVE Induction 1, clinical remission was achieved in 18.5% of individuals in the tofacitinib group versus 8.2% of individuals in the placebo group ($P=0.007$); in OCTAVE Induction 2, remission occurred in 16.6% versus 3.6% of individuals in the respective groups ($P<0.001$). In OCTAVE

Sustain, remission occurred in 34.3% and 40.6% of patients in the 5 mg and 10 mg tofacitinib groups, respectively, compared with 11.1% in the placebo group ($P<0.001$ for both tests). In all three trials, the occurrence of mucosal healing was significantly higher in the tofacitinib groups than in the placebo groups ($P<0.001$).

“Tofacitinib is potentially a new treatment option for patients with moderate to severe ulcerative colitis, pending review by the FDA, EMEA and other international regulatory bodies,” concludes author William Sandborn.

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