2017. OCTAVE 1&2

Phase 3/ TOFA/ UC/ Induct/Maintain

Tofacitinib as Induction and Maintenance Therapy for Ulcerative Colitis

Randomized double-blind, placebo-controlled trial.
Patients with moderate-to-severe UC randomised to:
OCTAVE Induction 1 and 2: TOFA 10 mg/BD vs placebo for 8w.

Primary endpoint: remission w8.
OCTAVE sustain: those on remission randomized to 5mg BD or 10mg BD or placebo
Primary endpoint: remission w52

Results:
-Induction 1: remission w8, 18.5% Tofa vs 8.2% pbo; p=0.007
-Induction 2: remission w8, 16.6% Tofa vs 3,6% pbo; p<0.001
- Sustain: 34.3% (5mg) vs 40.6% (10mg) vs 11.1% pbo; p<0.001 for both comparisons.
- Increased risk of infection and higher cholesterol levels in Tofacitinib than placebo.

Conclusions:
In moderate-severe UC tofacitinib is more effective as induction and maintenance than placebo.

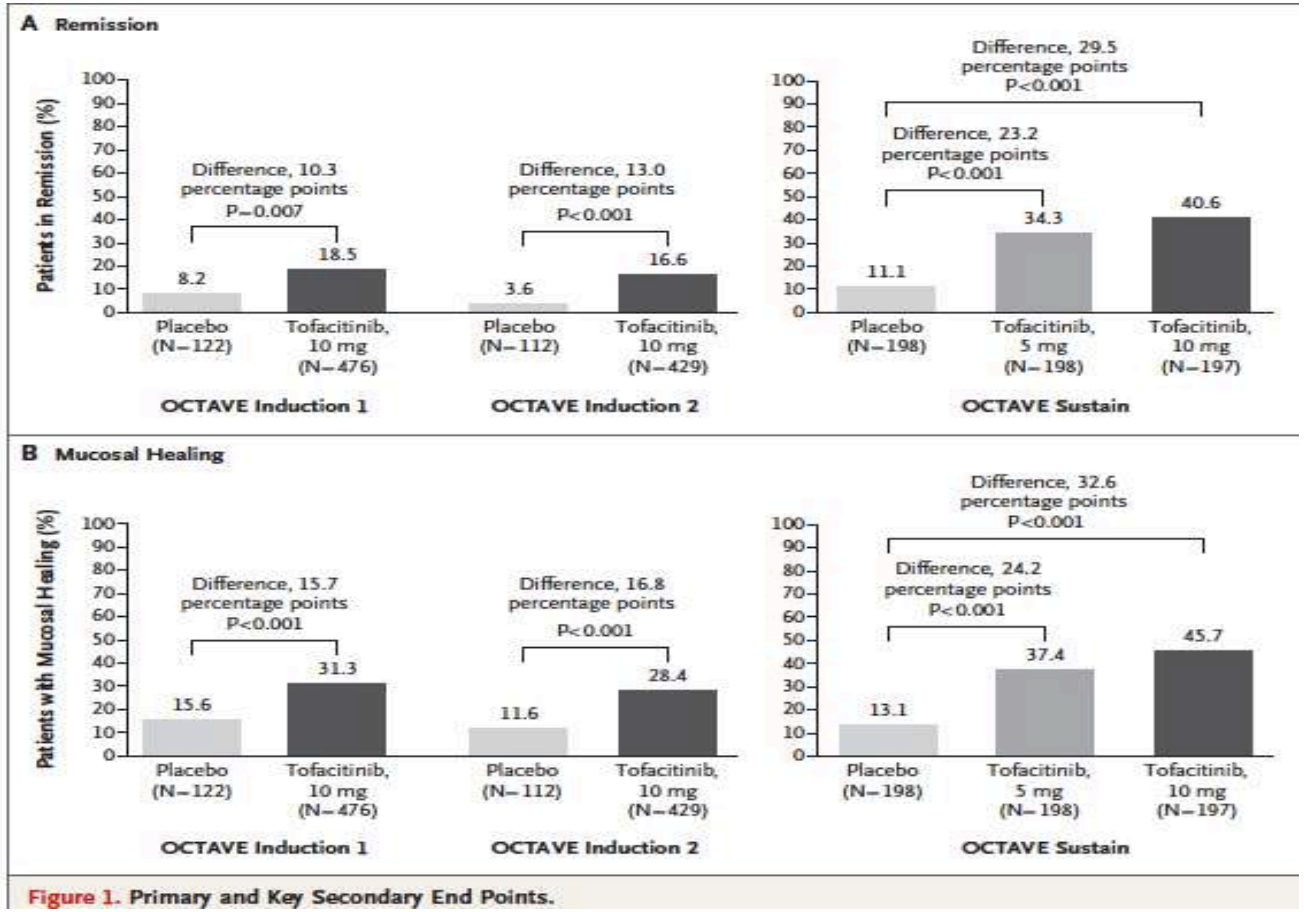

Figure 1. Primary and Key Secondary End Points.

Sandborn WJ et al. N Engl Med 2017;376: 1723-36