

Double-blind, placebo-controlled phase 2 randomized trial.
Moderate to severe UC randomised to 3 arms:
Ozanimod 0.5 mg/d; Ozanimod 1 mg/d or placebo up to 32 weeks.

Primary endpoint: clinical remission w8.

Results:

- Remission w8: 6% pbo vs 14% OZA-0.5 vs 16% OZA-1, $p=0.14/p=0.048$.
- Response w8: 57% OZA-1; 54% OZA-0.5, 37% placebo, $p=0.02, p=0.06$
- Clinical remission w32: 21% OZA-1; 26% OZA-0.5; 6% placebo
- At w8 absolute lymphocyte counts declined 49% from baseline in OZA-1 vs 32% in OZA-0.5

Conclusions:

Ozanimod at a daily dose of 1 mg resulted in a slightly higher rate of clinical remission of ulcerative colitis than placebo. The trial was not large enough or of sufficiently long duration to establish clinical efficacy or assess safety.

Ozanimod Induction and Maintenance Treatment for Ulcerative Colitis

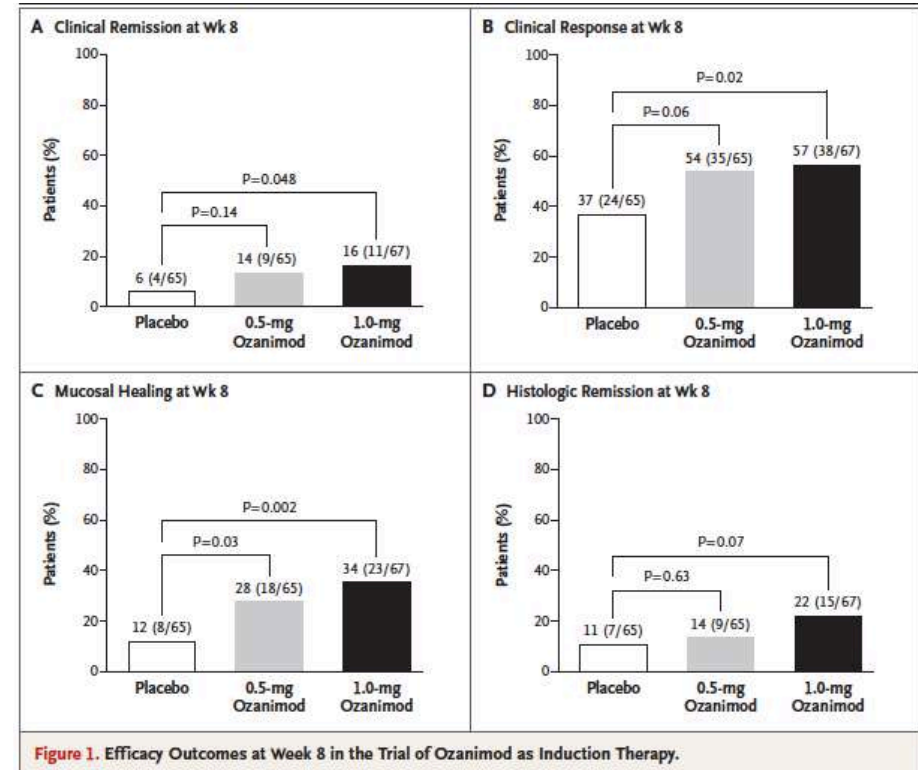


Figure 1. Efficacy Outcomes at Week 8 in the Trial of Ozanimod as Induction Therapy.

