

Phase 2b/3 double-blind, randomised, placebo-controlled trial. Patients with moderate to severe UC were randomised to: Filgotinib 200 mg, Filgotinib 100 mg or placebo.

Primary outcome: clinical remission by Mayo endoscopic, rectal bleeding stool frequency subscore at w10 and w58;

Secondary: Clinical remission/response/endoscopic remission/response/biomarker response/PRO remission

Results:

Clinical remission w10:

- Bionäive: 15.3% pbo vs 19.1% FIL100 (p=ns) vs 26.1% FIL200; p=0.016
- No naïve: 4.2% pbo vs 9.5% FIL100 (p=ns) vs 11.5% FIL200; p=0.01

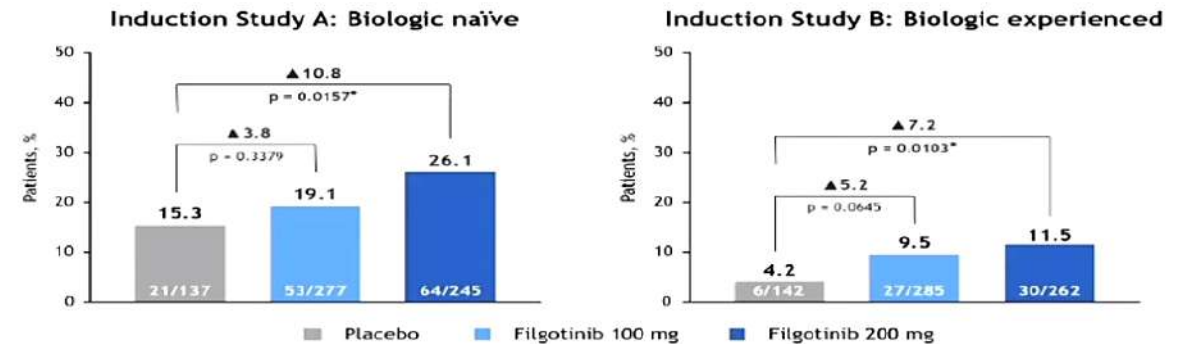
Clinical remission w58:

- 13.5% pbo vs 23.8% FIL100; p=0.042
- 11.2% pbo vs 37.2% FIL200; p<0.0001

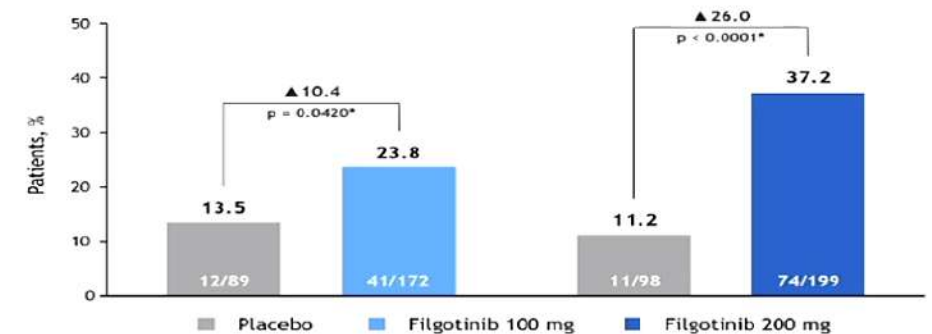
Conclusions:

Filgotinib 200 mg was efficacious inducing and maintaining clinical remission in patients with moderate-severe UC compared to placebo.

Phase 2b/3 RCT Filgotinib (100 or 200 mg) in mod-severe Ulcerative Colitis vs placebo



Clinical remission: Mayo endoscopic subscore=0 or 1, rectal bleeding subscore=0, and ≥1-point decrease in stool frequency from baseline to achieve a subscore=0 or 1



Clinical remission: Mayo endoscopic subscore=0 or 1, rectal bleeding subscore=0, and ≥1-point decrease in stool frequency from baseline to achieve a subscore=0 or 1

