

2023. DIVERGENCE 1

RCT/Filgotinib/SB CD/Induction

Filgotinib for the Treatment of Small Bowel Crohn's Disease: the DIVERGENCE 1 Trial

Phase 2, double-blind, placebo-controlled multicenter trial. Patients with moderate to severe small bowel Crohn's disease were randomized to filgotinib 100 mg/d, 200 mg/d or placebo

Primary endpoints: Clinical remission at week 24

Results: N=78 but 43 (55.1%) completed the study.

- Clinical remission at week 24: 16.7% placebo, 25.0% filgo100 and 25.0% filgo200 (p=ns)
- W24 SB MaRIA (MRI score) remission: 0% placebo, 6.3% FILGO100; 8% FILGO 200
- Adverse events were experienced by 13/18 (72.2%) patients receiving placebo, 84.4% filgo100 and 89.3% filgo200

Conclusion:

In this unique, proof-of-concept study in SBCD, 24 weeks of treatment with filgotinib did not result in statistically significant differences versus placebo in the proportion of patients who achieved clinical remission, SB MaRIA remission, or MaRIA remission in any of the SB segments.

