2017.FITZROY

Phase 2/ Filgotinib/CD / Induction

Clinical remission in patients with moderate-severe CD treated with filgotinib (the FITZROY study): results phase 2, double blind RCT

Randomized control trial, patients with moderate-severe CD.
Part 1, randomly assigned (3:1) to receive filgotinib 200 mg once/day or placebo.
Part 2: After the first 10 w of treatment, patients were assigned based on CDAI clinical responder status as assessed by the investigator to receive either filgotinib 200 mg once a day, filgotinib 100 mg once a day, or placebo in part 2 for an additional 10 weeks.

Primary endpoint: clinical remission, defined as CDAI <150 at w10.

Results:
- In the ITT population, 60 (47%) of 128 patients treated with filgotinib 200 mg achieved clinical remission at w10 vs ten (23%) of 44 patients treated with placebo (p=0.0077).

Conclusions:
Filgotinib induced clinical remission in significantly more patients with active Crohn's disease compared with placebo, and had an acceptable safety profile.

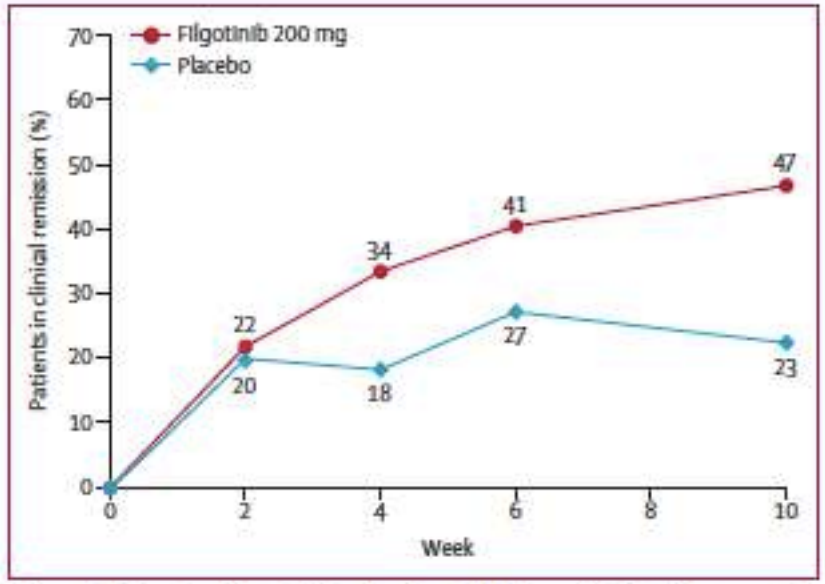

Figure 2: Clinical remission (defined as Crohn's Disease Activity Index <150) over time in response to filgotinib and placebo

Vermeire S et al.Lancet 2017.389;266-275