# 2019. ANDANTE I&II

RCT/PF-04236921/ CD/Induction

**Randomised trial and open-label extension study of an anti interleukin-6 antibody in Crohn's disease (ANDANTE I and II)**

Double-blind, placebo controlled, dose ranging trial.
Patients with moderately-severely active CD with inadequate response to antiTNF were randomised to:
- Induction: PF-04236921 10, 50 or 200mg SC on day 1 and 28 or placebo.
- OLE study: PF-04236921 50mg q8w up to week 28

Primary endpoint: Clinical response (≥70-point reduction in CDAI score) w8 or 12.

Results: N=247
- Clinical response w8: PF-04236921 50mg 49.3% vs 30.6% placebo
- Clinical remission w12: PF-04236921 50mg 27.9% vs 10.9% placebo, p<0.05

Conclusion:
PF-04236921 50 mg induced clinical response and remission in refractory patients with moderate-to-severe CD following failure of anti-TNF therapy. GI abscess and perforation were observed, a specific focus of attention during future clinical development.

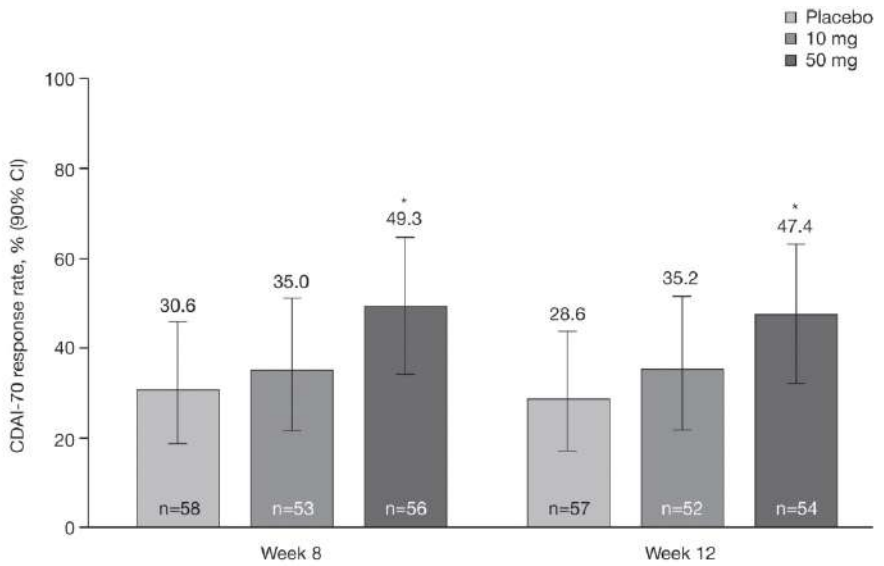


**Figure 2** Primary end point: CDAI-70 response rates at weeks 8 and 12 (generalised linear mixed model; modified intention-to-treat population). *P<0.05 versus placebo. CDAI, Crohn's Disease Activity Index; CDAI-70, proportion of patients who achieved a ≥70-point reduction in CDAI score.

*PF-04236921: Anti interleukin-6
**200mg was discontinued due to safety findings in NCT01405196 a trial in lupus and was not included in primary analysis. This other trial discontinued the dose based upon an assessment of fatalities due to serious infections and thromboembolic events,.

Danese S et al. Gut. 2019; *68:40–48.*