Multicenter, randomized, double-blind, placebo-controlled phase 2 trial.

Patients with active CD were randomized to 10, 40 or 160mg of mongersen or placebo per day for 2 weeks.

<u>Primary endpoint</u>: clinical remission at day 15 and safety.

Results: N=166

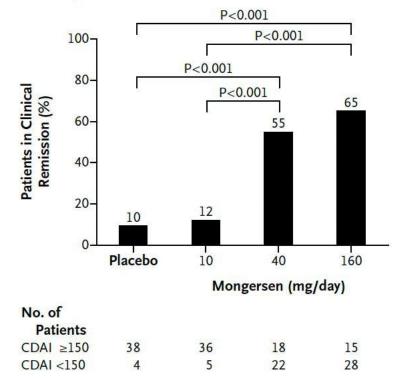
- Clinical remission at d15: 55% vs 65% for 40 and 160mg mongersen vs 10% placebo, p<0.001.
- Clinical response was 37%, 58% and 72% in the 10, 40 and 160mg mongersen vs 17% placebo, p<0.05 for all comparisons vs placebo.

Conclusion:

We found that study participants with Crohn's disease who received mongersen had significantly higher rates of remission and clinical response than those who received placebo.

*CD inflammation is characterized by reduced activity of TGF-beta1 due to high levels of SMAD7, an inhibitor of TGF-beta1

A Primary End Point



H