2019. UNIFI

Phase 3/ UST/UC/ Induction/Maintain

Ustekinumab as Induction and Maintenance Therapy for Ulcerative Colitis

8-w induction therapy and 44-week maintenance in mod-severe UC. Both double-blind, placebo controlled trials. UST IV induction vs placebo.

Responders re-randomized to: UST sc 90 mg q12w or 18w or placebo.

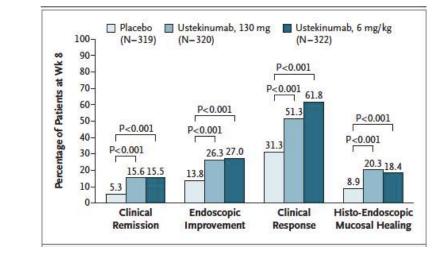
<u>Primary endpoint</u> for induction trial and maintenance trial: clinical remission w 8 and w44

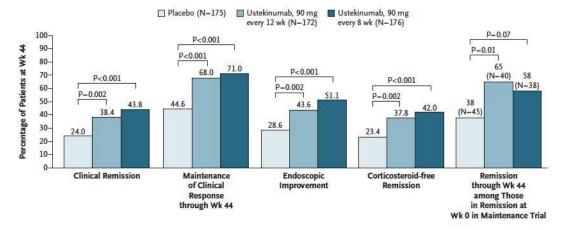
<u>Results:</u>

- Clinical remission w8 after UST IV superior than placebo (15.6% vs 5.3%, p<0.001.
- Among responders with second randomization, clinical remission w44: UST 90mg q12w (38.2%) vs UST q8w (43.8%) vs placebo (24%), p=0.002 and p>0.001 respectively.

Conclusions:

Ustekinumab was more effective than placebo for inducing and maintaining remission in patients with moderate-to-severe UC.





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