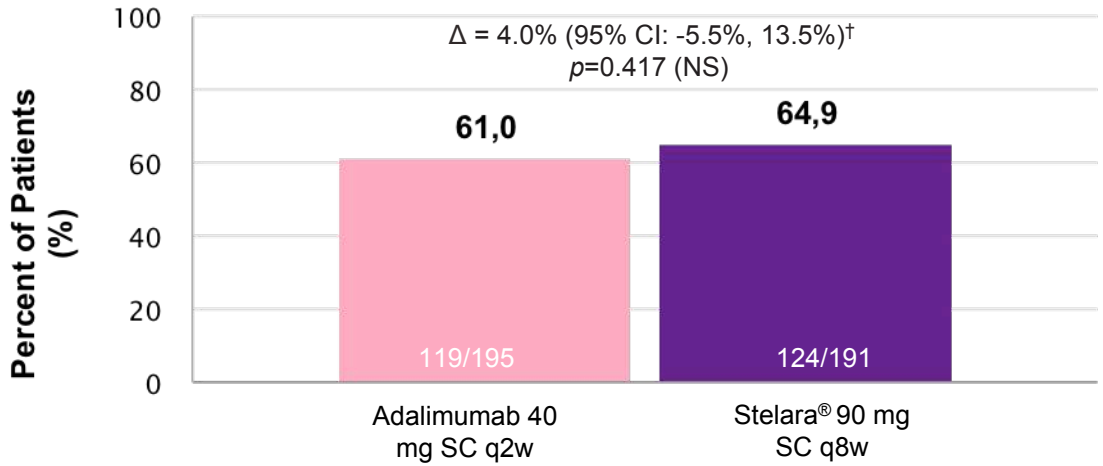
2022. SEAVUE

Phase 3b/ ADA vs UST/ CD/ Maintain

Safety and Efficacy of Adalimumab Versus Ustekinumab for One Year (SEAVUE)

Randomised, double-blind, parallel-group, active comparator, phase 3b trial. Moderate-severe CD patients randomised to:

- ADA 160/80 mg sc then 40mg sc/q2w vs UST 6mg/kg IV baseline UST then 90 mg sc q8w
- Primary endpoint: clinical remission w52
- Secondary endpoints: SES-CD score w52; SES-CD improvement; steroid-free remission; clinical response, PRO-2; clinical remission w16;



Results:

- Primary outcome: Clinical remission w52 (CDAI<150): 64.9% UST vs 61% ADA p=ns.
- Secondary outcomes: Clinical remission w16: 57.1% UST vs 60% ADA p=ns
- Endoscopic remission w52 : 28.5% UST vs 30.7% ADA, p=Ns Steroid free remission: 60.7% UST vs 57.4 % ADA p=ns Clinical response: 72.3% UST vs 66.2% ADA, p=ns
- PRO remission: 65.5% UST vs 55.4% ADA, p=ns

Conclusions:
No difference in terms of efficacy regarding ADA vs UST at w52.

Sands BE et al. Lancet.2022; 399(10342):2200-2211