2021. IFX IV/SC

RCT/IFX IV or SC/IBD/Maintenance

# Randomized Controlled Trial: Subcutaneous vs Intravenous Infliximab CT-P13 Maintenance in Inflammatory Bowel Disease

Randomized, multicenter, open-label, parallel-group, phase 1 trial. Patients with IBD with active disease who received CT-P13 IV induction at w0 and w2 were randomized to receive CT-P13 120 mg (<80kg) or 240mg (>80kg) SC q2w or CT-P13 IV (5mg/kg). At week 30, all patients on IV switched to CT-P13 SC until week 54

Primary endpoint: pharmacokinetic endpoint of non-inferiority of SC to IV observed predose concentration at w22

*The study was finally not powered for secondary endpoints.

Results:

- IFX concentrations at week 22 were higher in the SC arm than IV 21.45µgr/mL vs 2.93µgr/mL
- Secondary outcomes underpowered: No differences in clinical response by partial Mayo in UC or clinical remission. No differences in CD patients in clinical response or remission

Conclusion:

The pharmacokinetic non-inferiority of CT-P13 SC to CT-P13 IV, and the comparable efficacy, safety, and immunogenicity profiles, support the potential suitability of CTP13 SC treatment in IBD.

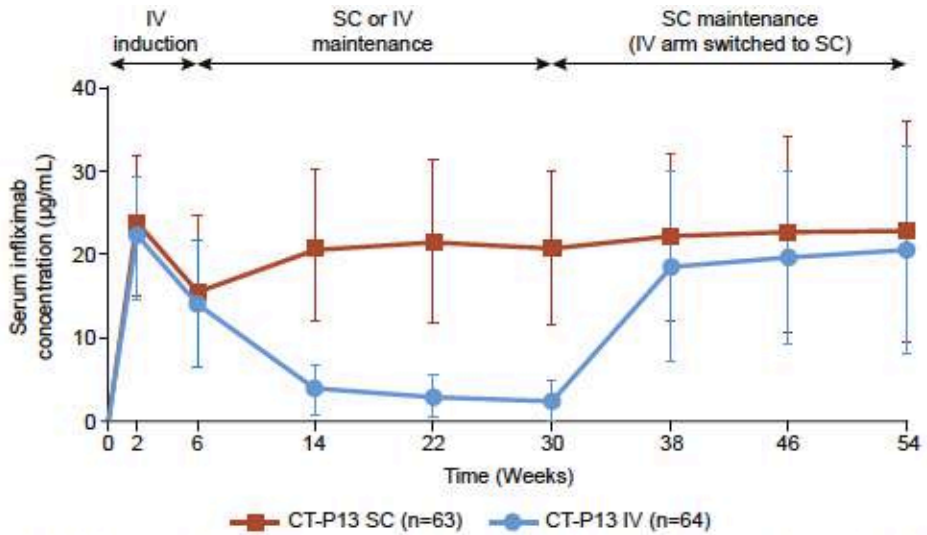


**Figure 2.** Mean (±SD) predose serum infliximab concentration[a] for CT-P13 SC and CT-P13 IV arms (PK population). PK, pharmacokinetic; SD, standard deviation. [a]Concentrations below the lower limit of quantification (BLQ) before W0 were set to zero; other concentrations BLQ were set to the lower limit of quantification.

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