2021. UNISTAR

Phase 1/ UST/ pediaCD/Pharm/Safety

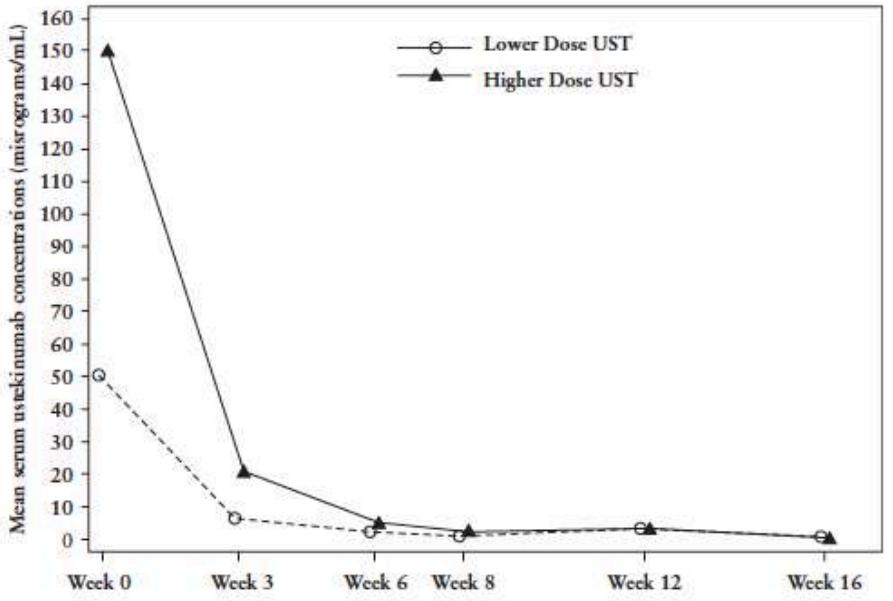
Ustekinumab in Paediatric Patients with Moderately to Severely Active CD: Pharmacokinetics, Safety, And Efficacy Results from UniStar, A Phase 1 Study

Phase 1, double-blind, induction dose-ranging study.
Paediatric CD moderately-to-severely active were randomised to:
One of two weight range-based IV doses: 130mg vs 390mg in patients >40kg and 3mg/kg vs 9mg/kg in patients <40Kg.
At w8 all patients received SC UST at 90mg in patients >40Kg or 2mg/kg <40kg.

Outcome:
To evaluate the pharmacokinetics, safety/tolerability, and efficacy.

Results:
- Pharmacokinetics were similar to those in adults with Crohn's disease.
- However, serum UST concentrations were lower among those with body weight <40 kg compared with patients ≥40 kg and the reference Phase 3 adult population.

Conclusion:
The pharmacokinetics/safety profiles were generally consistent with those observed in adults with Crohn's disease. These results suggest a different dosing regimen may be required for patients <40 kg from that employed in this study; additional pharmacokinetic analyses may be needed in this population



	Week 0	Week 3	Week 6	Week 8	Week 12	Week 16
Lower Dose UST	22	20	22	21	20	17
Higher Dose UST	20	20	19	18	17	13

Figure 2. Line plot of mean serum UST concentrations [μg/mL] through Week 16. BW, body weight; IV, intravenous; UST, ustekinumab; lower dose, 3 mg/kg IV for patients <40 kg BW or 130 mg IV for patients ≥40 kg BW; higher dose, 9 mg/kg IV for patients <40 kg BW or 390 mg IV for patients ≥40 kg BW.

Rosh JR et al. J Crohns Colitis. 2021.1931-1942