OL/ GOLI/paediatric UC / Induction

Subcutaneous Golimumab in Pediatric Ulcerative Colitis: Pharmacokinetics and Clinical Benefit

Phase 1 open label study.
Paediatric patients with UC naïve to antiTNF.
Golimumab w0 and 2, dose 90/45mg/m2 if <45kg or 200/100mg if >45 kg. Responders at w6 continued q4w

Primary endpoint: to assess pharmacokinetic of induction with GOLI in paediatric UC.

Results:
- Median GOLI levels comparable to reference in UC adults at w2,w4 and w6.
- At w 6, 60%, 34% and 54% achieved Mayo clinical response, PUCAI remission and mucosal healing (Mayo 0/1).

Conclusions:
Pediatric and adult golimumab pharmacokinetics are similar. Clinical benefit and safety shows promise in biologically naive pediatric patients with UC.

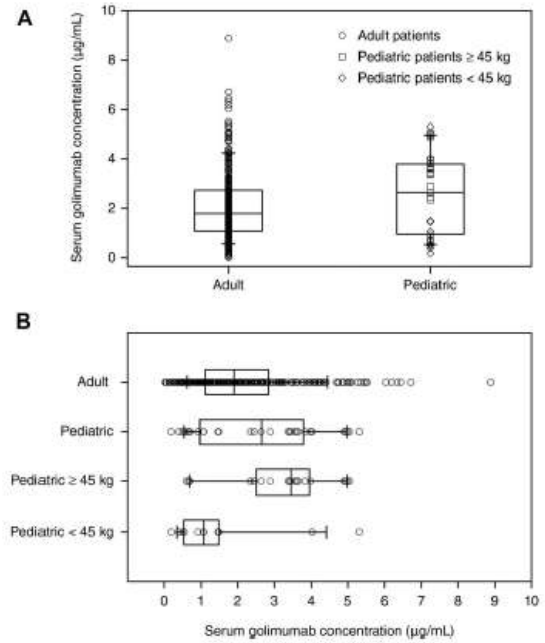
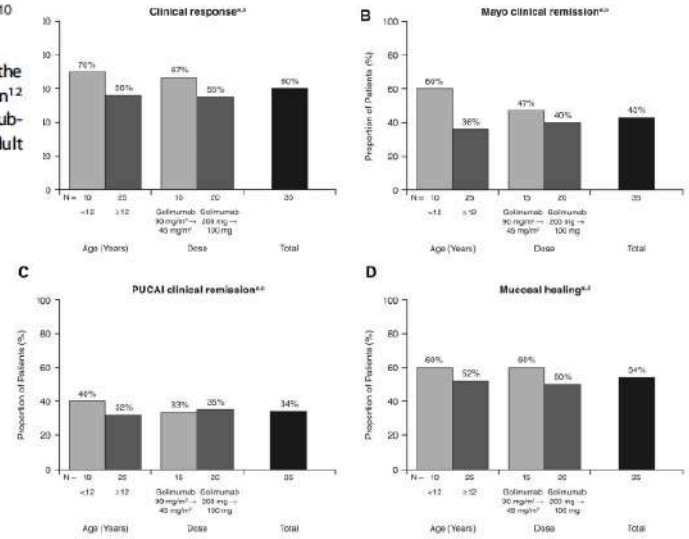


FIGURE 2. Serum golimumab concentrations through week 6 in the pediatric study population and the historical adult study population[12] (A) and at week 6 in the pediatric study population (including subgroups by baseline weight/dose regimen) and the historical adult study population[12] (B).



Hyams JS et al. Inflamm Bowel Dis 2017;23:2227–2237)