2013. IFX kids

Phase 3/ IFX/paediatric UC/ Maintain

Pharmacokinetics of Infliximab in Children with Mod-Severe UC: Results from a Randomized, Multicenter, Open-label, Phase 3 Study

Open Label, paediatric moderate to severe UC.
All 5mg/kg induction at 0,2,6w.
Clinical responders at w8 were randomized to:
IFX 5mg/kg q8w or 5mg/kg q12w.
Patients losing response, eligible to dose increase.

Primary outcome:
Clinical response w8.

Results:
- w8, higher serum concentrations better efficacy endpoints.
- W30 higher serum levels in q8w than q12w

Conclusion:
IFX pharmacokinetics/exposure–response relationship in patients with UC aged 6 to 17 years comparable with those in adult UC, supporting using IFX 5 mg/kg at weeks 0, 2, and 6 followed by maintenance dosing with 5 mg/kg q8w in these patients. A positive relationship was noted between serum infliximab level and clinical effect following induction therapy similar to adults.

TABLE 3. Proportions of Pediatric Patients with UC Achieving Efficacy Endpoints at Week 8 by Serum Infliximab Concentration Quartile

	Infliximab Serum Concentration (μg/mL) Quartile			
Week 8 Response	<18.1 (N = 13), %	≥18.1 to <28.9 (N = 14), %	≥28.9 to <41.1 (N = 14), %	≥41.1 (N = 14), %
Clinical response[a]	53.9	78.6	92.9	92.9
Mucosal healing[b]	53.9	71.4	78.6	92.9
Clinical remission[c]	30.8	42.9	35.7	64.3

[a]Decrease from baseline in the Mayo score by ≥30% and ≥3 points, with a decrease in the rectal bleeding subscore of ≥1 or a rectal bleeding subscore of 0 or 1.
[b]Endoscopy subscore of the Mayo score of 0 or 1.
[c]Mayo score ≤2 points with no individual subscore >1.

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