

Efficacy and safety of mirikizumab in paediatric participants with moderately-to-severely active ulcerative colitis (SHINE-1): a multicentre, open-label, non-randomised phase 2 trial

Multicenter open-label, non-randomised phase 2 study. Paediatric patients with mod-severe active UC with inadequate or loss of response/intolerance to corticosteroids, immunomodulators, biologics or JAK inhibitors were included. Patients were given IV mirikizumab 5mg/kg or 10mg/kg (for body weight $\leq 40\text{Kg}$ or 300mg (if $>40\text{Kg}$) at weeks 0,4,8.

Primary endpoint: Pharmacokinetics. Secondary outcomes included clinical response at week 12 and week 52.

Results: N=26

- At 12w, 18/26 had clinical response (69.2%, 95% CI 50.0–83.5) and 10/26 (38.5%, 95% CI 22.4–57.5) were in clinical remission, both measured by mMS
- At week 52, 14/26 (53.8%, 35.5–71.2) achieved clinical response and 10/26 (38.5%, 95% CI 22.4–57.5)

Conclusion:

Mirikizumab exhibited safety and efficacy in paediatric participants with mod-severely active UC.

Efficacy at week 12 and 52

