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Summary

PHARMACOKINETICS, EFFICACY AND SAFETY OF MIRIKIZUMAB AS INDUCTION THERAPY IN PAEDIATRIC PATIENTS WITH MODERATELY TO SEVERELY ACTIVE ULCERATIVE COLITIS: RESULTS FROM THE PHASE 2 SHINE-1 STUDY

Amy Larkin

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Phase 2 SHINE-1 study reports the first efficacy and safety data for mirikizumab, a p19 IL-23 inhibitor, in 26 pediatric patients aged 2 to <18 years with moderately to severely active ulcerative colitis after 12 weeks of induction therapy.

KEY POINTS

- At Week 12, MMS clinical response was achieved in 69.2% of pediatric patients, clinical remission in 38.5%, and endoscopic remission in 53.8%, with PUCAI response in 76.9% and PUCAI remission in 38.5%.
- These efficacy rates were consistent with or numerically higher than those observed in adults treated with 300 mg mirikizumab in the Phase 3 LUCENT-1 study (adult MMS clinical response 63.5%, clinical remission 25.6%, endoscopic remission 36.3%).
- Pharmacokinetic analysis confirmed that dosing of 300 mg IV for patients >40 kg and 5 mg/kg IV for patients ≤40 kg achieved exposures similar to adult levels, while 10 mg/kg yielded approximately 2-fold higher exposure.
- Safety findings in pediatric patients were consistent with the acceptable safety profile observed in the adult LUCENT-1 induction study.
- This material is relevant for pediatric gastroenterologists and researchers interested in novel biologics for pediatric inflammatory bowel disease and the development pathway for mirikizumab in children with ulcerative colitis.

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