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Summary

MIRIKIZUMAB, THE FIRST IL-23P19 INHIBITOR TO DEMONSTRATE SUSTAINED EFFICACY THROUGH 1 YEAR IN PEDIATRIC MODERATELY-TO-SEVERELY ACTIVE ULCERATIVE COLITIS: EFFICACY AND SAFETY FINDINGS FROM SHINE-2

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Standards & Guidelines | Paediatrics | Mechanisms & Personalised Medicine | Immunology | IBD | Endoscopy

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SHINE-2, the first Phase 3 pediatric trial of mirikizumab (anti-IL23p19), demonstrated that 50.0% of Week 12 responders with moderately to severely active ulcerative colitis achieved clinical remission at Week 52, comparable to adult rates and exceeding adult placebo.

KEY POINTS

- Among 63 children and adolescents aged 2 to <18 years (mean age 13.2 years, 54% with previous biologic failure), 81% responded to weight-based intravenous mirikizumab induction (300 mg for >40 kg; 5 mg/kg for ≤40 kg, every 4 weeks for 3 doses).
- The primary endpoint was met: 50.0% of Week 12 responders achieved modified Mayo score clinical remission at Week 52, matching the adult mirikizumab rate (50.7%) and significantly exceeding adult placebo (26.6%).
- Corticosteroid-free remission without surgery was achieved by 50.0% of Week 12 responders at Week 52, compared to 22.5% for adult placebo.
- Endoscopic remission (endoscopic subscore = 0) was achieved by 44.2% of Week 12 responders at Week 52, double the adult placebo rate of 13.6%.
- Most adverse events were mild or moderate; 2 patients discontinued due to UC flare, 4 (6.3%) had serious adverse events (none deemed drug-related), and there were no deaths, malignancies, opportunistic infections, or growth-related safety concerns.

– Pharmacokinetic exposures after weight-based dosing were generally comparable across pediatric subgroups and with adults, though sample size limited assessment of smaller weight categories through Week 12.

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