

EFFICACY AND SAFETY OF MIRIKIZUMAB IN PATIENTS WITH CROHN'S DISEASE: 104-WEEK EXTENSION RESULTS FROM A PHASE 2 RANDOMIZED CONTROLLED TRIAL

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A Phase 2 extension study found that mirikizumab (anti-IL-23p19 antibody) maintained clinical and symptom remission through Week 104 in patients with moderately-to-severely active Crohn's disease who achieved early endoscopic improvement.

KEY POINTS

- Among 127 patients randomized to mirikizumab induction, 68.5% achieved endoscopic improvement at Week 12 and were rerandomized to maintenance therapy with either continued IV dosing or subcutaneous dosing.
- CDAI remission rates at Week 104 were 66.7% for IV continuation and 61.0% for subcutaneous dosing among Week 12 endoscopic improvers who entered the extension period.
- PRO remission rates at Week 104 were 63.6% for IV continuation and 46.3% for subcutaneous dosing among the same population.
- Among all patients receiving mirikizumab from Week 52 to Week 104, 79.4% experienced at least one treatment-emergent adverse event, with no unexpected safety signals reported.
- The authors concluded that no differences in remission rates were observed between IV continuation and subcutaneous maintenance regimens through the extension period.

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