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Summary

EFFICACY AND SAFETY OF RISANKIZUMAB SUBCUTANEOUS INDUCTION IN PATIENTS WITH MODERATELY TO SEVERELY ACTIVE CROHN'S DISEASE: WEEK 12 RESULTS FROM THE PHASE 3 AFFIRM STUDY

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AFFIRM demonstrated that subcutaneous risankizumab 720 mg induction (weeks 0, 2, 4, 8) achieved significantly higher clinical remission (55.0% vs 29.6%, P<0.0001) and endoscopic response (44.0% vs 14.3%, P<0.0001) than placebo at week 12 in patients with moderately to severely active Crohn's disease.

KEY POINTS

- The study enrolled 289 patients with moderately to severely active Crohn's disease (CDAI 220–450, SES-CD ≥6 or ≥4 for isolated ileal disease) who had prior inadequate response or intolerance to conventional and/or advanced therapies; 64.9% of risankizumab and 66.3% of placebo patients were advanced-therapy inadequate responders.
- Both co-primary endpoints were met: CDAI clinical remission was achieved by 55.0% on risankizumab versus 29.6% on placebo (treatment difference 26.6%, P<0.0001), and endoscopic response by 44.0% versus 14.3% (treatment difference 29.4%, P<0.0001).
- In the advanced-therapy-naïve subpopulation, risankizumab achieved clinical remission in 73.1% versus 27.3% on placebo (difference 45.9%) and endoscopic response in 61.2% versus 15.2% (difference 46.0%).
- In the advanced-therapy-exposed subpopulation (including ustekinumab- and JAK-inhibitor-experienced patients), risankizumab achieved clinical remission in 45.2% versus 30.8% on placebo (difference 14.4%) and endoscopic response in 34.7% versus 13.8% (difference 20.8%).

- Treatment-emergent adverse events occurred in 42.4% of risankizumab patients versus 59.2% of placebo patients; no deaths, serious infections, major adverse cardiovascular events, malignancies, anaphylaxis, active tuberculosis, opportunistic infections, or herpes zoster were reported, and injection-site reactions occurred in 2.1% of risankizumab patients.
- Safety results were consistent with the known safety profile of risankizumab from prior intravenous induction studies.

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