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Summary

EFFICACY OF RISANKIZUMAB BY CROHN'S DISEASE LOCATION: RESULTS FROM 144 WEEKS OF THE FORTIFY OPEN-LABEL EXTENSION STUDY

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Long-term risankizumab treatment in the FORTIFY open-label extension demonstrated sustained or improved clinical and endoscopic outcomes across all Crohn's disease locations through 144 weeks in a refractory patient population.

KEY POINTS

- In 1112 patients with moderately to severely active Crohn's disease who completed 52 weeks of risankizumab maintenance, treatment continued with subcutaneous risankizumab 180 mg or 360 mg every 8 weeks through the FORTIFY open-label extension.
- As-observed analyses showed clinical remission rates generally improved across all disease locations through week 96 and 144, with CDAI remission at week 144 reaching 86.6% for colonic, 82.6% for ileocolonic, and 73.6% for ileal disease.
- Endoscopic response at week 96 in as-observed analyses reached 80.1% for colonic, 75.9% for ileocolonic, and 51.3% for ileal disease, with endoscopic remission achieved in 63.8%, 56.0%, and 53.8%, respectively.
- Modified nonresponder imputation analyses showed improvements over time in endoscopic response, endoscopic remission, and ulcer-free endoscopy for colonic and ileocolonic disease, while ileal disease showed consistency over time.
- There were no new safety signals through week 144, with the safety profile consistent with previous reports of risankizumab.

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