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Summary

EFFICACY AND SAFETY OF RISANKIZUMAB RESCUE TREATMENT IN PATIENTS WITH MODERATE-TO-SEVERE CROHN'S DISEASE: RESULTS FROM PATIENTS WHO DEMONSTRATED INADEQUATE RESPONSE DURING THE 4-YEAR FORTIFY OPEN-LABEL LONG-TERM EXTENSION

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In patients with moderate-to-severe Crohn's disease who developed inadequate response to risankizumab maintenance therapy, rescue treatment with 1200 mg IV followed by 360 mg SC resulted in durable clinical and endoscopic improvements through at least two years.

KEY POINTS

- Among 287 patients (25% of the FORTIFY open-label extension cohort) who received risankizumab rescue therapy for inadequate response, CDAI clinical response rates increased from 41.5% at rescue to 94.6% at week 192, and CDAI clinical remission rates increased from 14.3% to 67.6%.
- Stool frequency/abdominal pain clinical remission rates improved from 1.0% at rescue to 65.9% at week 192.
- Endoscopic response and endoscopic remission rates at week 96 post-rescue were 50.0% and 34.3%, respectively, representing substantial increases from baseline rescue values of 26.0% and 6.7%.
- Most rescued patients (79.8%) required only one rescue dose; 15.3% received two rescues and 4.9% received three rescues during the study period.
- Exposure-adjusted rates of serious adverse events (19.1 per 100 patient-years) and adverse events leading to discontinuation (4.5 per 100 patient-years) were low and consistent with risankizumab's known safety profile, with worsening Crohn's disease the most common serious adverse event and one death unrelated to treatment.

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