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Summary

EFFICACY AND SAFETY OF RISANKIZUMAB AFTER 4 YEARS OF TREATMENT IN PATIENTS WITH MODERATE TO SEVERE CROHN'S DISEASE: RESULTS FROM THE FORTIFY OPEN-LABEL LONG-TERM EXTENSION

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UEG Week Berlin 2025 | Presentation

IBD | Mechanisms & Personalised Medicine

October 5, 2025

Four-year data from the FORTIFY open-label extension show that risankizumab maintained durable clinical and endoscopic efficacy in patients with moderate to severe Crohn's disease, with no new safety signals identified.

KEY POINTS

- At week 144 of the open-label extension (4 years total treatment), clinical remission by SF/APS was achieved in 75.8% (as observed) and endoscopic remission in 58.8% of patients continuing risankizumab 180mg or 360mg every 8 weeks without rescue.
- Among 278 patients who required rescue therapy during the extension, clinical remission rates improved from 1.1% at rescue initiation to 53.0% at 48 weeks post-rescue, and endoscopic response improved from 35.8% to 54.0% at 96 weeks.
- The overall safety profile remained consistent with prior risankizumab data, with serious adverse event rates of 12.2 events per 100 patient-years in the full population and 20.0 events per 100 patient-years in the rescue group, where most events were attributed to active Crohn's disease.
- Patients requiring rescue therapy had longer disease duration, higher rates of prior biologic failure, and higher baseline endoscopic scores compared to those who did not require rescue.
- The study was sponsored by AbbVie, and several authors are AbbVie employees; the presenting author has consulting relationships with multiple pharmaceutical companies including AbbVie.

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