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Summary

ABBV-466, A NOVEL DUAL-TARGETING THERAPY, LEADS TO ENDOSCOPIC REMISSION IN MODERATE-TO-SEVERE CROHN'S DISEASE: PRIMARY RESULTS AND MOLECULAR PROFILING FROM THE PHASE 2A TARGET-CD STUDY

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ABBV-466, a novel dual-targeting therapy combining risankizumab (anti-IL-23 p19) and trosunilimab (anti-α4β7), achieved 40.5% endoscopic remission at Week 24 in moderate-to-severe Crohn's disease, nearly double the rate of risankizumab monotherapy (22.4%) in a phase 2a study of highly treatment-refractory patients.

KEY POINTS

- At Week 24, endoscopic remission (SES-CD ≤4) was achieved by 40.5% of patients receiving ABBV-466 versus 22.4% with risankizumab alone (adjusted difference 17.8%) and 20.0% with trosunilimab alone (adjusted difference 20.1%).
- The study enrolled 300 patients with mean SES-CD 14.0 and high treatment refractoriness: 75% had failed prior targeted advanced therapies, including 24% who had failed 3 or more, and the majority had failed same or similar drug classes (p19, p40, or α4β7 inhibitors).
- All efficacy endpoints were steroid-free; mandatory steroid tapering began at Week 2.
- Endoscopic response at Week 24 was 52.4% with ABBV-466 versus 40.8% with risankizumab and 28.8% with trosunilimab; mucosal healing (ulcerated subscore of 0) was 33.3% versus 23.7% and 15.2%, respectively.
- Transcriptomic analyses showed ABBV-466 promoted colonic epithelial repair and barrier restoration at Week 12, followed by tissue remodeling and metabolic changes at Week 24 not observed with either monotherapy; 54% of partial responders at Week 12 progressed to complete response by Week 24.

– Safety profiles were comparable across all three treatment groups; serious adverse events occurred in 10.4% of ABBV-466 patients versus 9.6% with risankizumab and 9.0% with trosunilimab, with low and similar rates of serious infection (2.1–3.0%) across all groups.

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