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Summary

EFFICACY OF GUSELKUMAB FOR SMALL BOWEL LESIONS USING BALLOON ASSISTED ENTEROSCOPY: A PHASE 3, OPEN-LABEL, MULTICENTER STUDY

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A Phase 3 Japanese open-label study evaluated guselkumab safety and efficacy in 38 patients with moderately to severely active Crohn's disease, with exploratory assessment of small bowel lesions using balloon-assisted enteroscopy in 15 patients.

KEY POINTS

- Guselkumab 200 mg was administered intravenously at weeks 0, 4, and 8, then subcutaneously every 4 weeks from week 12 to week 44.
- Among 15 patients evaluated for small bowel lesions, median partial modified SES-CD decreased from 8.0 at baseline to 5.0 at week 48.
- Endoscopic response (50% or greater reduction in pmSES-CD) was achieved in 46.7% of small bowel patients, ulcer-free status in 26.7%, and complete mucosal healing in 13.3%.
- No CD-related hospitalizations or surgeries occurred, and no adverse events of strictures were reported; 86.8% of patients experienced an adverse event and 7.9% experienced a serious adverse event.
- The study concluded that guselkumab is well-tolerated and effective for moderately to severely active Crohn's disease, with results suggesting effectiveness in small bowel lesions.

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