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Summary

STENOVA TRIAL UPDATE: OPEN-LABEL EXTENSION OF ONTUNISERTIB IN FIBROSTENOSING CROHN'S DISEASE WITH OBJECTIVE IMAGING EFFICACY ASSESSMENTS

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STENOVA trial demonstrates that ontunisertib, an oral GI-restricted ALK5 inhibitor, was generally well tolerated for up to 36 weeks in patients with fibrostenosing Crohn's disease, with positive trends in endoscopic and MRE stricture outcomes.

KEY POINTS

- In the 12-week Part A, the 200mg BID group showed improvement in SES-CD with higher endoscopic response and remission rates, and a higher proportion of participants with non-passable strictures at baseline had passable strictures at Week 12.
- Treatment was generally well tolerated through 36 weeks with no new safety signals; the data safety monitoring board identified no safety concerns, and no signals of cardiac injury, pro-inflammatory effects, vasculitis, or liver toxicity were observed.
- Over the first 24 weeks of open-label extension, participants originally randomized to ontunisertib showed continued trends for improvement in MRE stricture length, while those transitioning from placebo showed stabilization after prior worsening.
- Stricture length demonstrated the highest reliability and strongest correlation with overall disease severity among MRE items, with the most evident improvement trends compared to placebo in the 200mg BID and 100mg QD groups.
- The outcomes contribute to advancing validation of objective endpoints in fibrostenosing Crohn's disease, a condition with significant unmet need and lack of validated endpoints.

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