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Summary

FIRST IN HUMAN TRIAL OF IMU-856, AN ORALLY AVAILABLE EPIGENETIC MODULATOR OF BARRIER REGENERATION FOR THE TREATMENT OF CELIAC DISEASE

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A phase 1/1b trial of IMU-856, an oral SIRT6 modulator, demonstrated safety, tolerability, and proof-of-concept signals for improving intestinal barrier function in celiac disease patients undergoing gluten challenge.

KEY POINTS

- IMU-856 is an orally available small molecule targeting SIRT6, a transcriptional regulator of intestinal barrier function and bowel epithelium regeneration.
- The first-in-human, double-blind, randomized, placebo-controlled trial evaluated single and multiple ascending doses in healthy volunteers and two dose levels in celiac disease patients during gluten-free diet and 15-day gluten challenge.
- IMU-856 was safe and well-tolerated with a benign adverse event profile, no systematic clinically relevant safety findings, and pharmacokinetics supporting once-daily dosing.
- Treatment with IMU-856 led to amelioration of gluten-induced biomarker increases, signs and symptoms of acute and chronic inflammation, and histological deterioration from the 15-day gluten challenge.
- This material is most relevant for researchers and clinicians interested in novel non-immunosuppressive therapeutic approaches for celiac disease and intestinal barrier dysfunction.

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