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Summary

RESULTS FROM DOSE ESCALATION IN RESOLVE, AN ONGOING PHASE 1B/2A DOSE-ESCALATION STUDY OF EP-104GI (EXTENDED-RELEASE FLUTICASONE PROPIONATE INTRA-ESOPHAGEAL INJECTION) FOR EOSINOPHILIC ESOPHAGITIS

Albert J. Bredenoord

UEG Week Vienna 2024 | Poster

Oesophagus

October 13, 2024

RESOLVE is a Phase 1b dose-escalation study evaluating EP-104GI, an extended-release fluticasone propionate intra-esophageal injection, for safety, tolerability, and efficacy in adults with active eosinophilic esophagitis.

KEY POINTS

- EP-104GI consists of polymer-coated fluticasone propionate crystals that release drug locally via diffusion at a pre-defined rate; preclinical data in pigs showed the drug remains at injection sites for at least 6 weeks.
- Four dose cohorts were studied: 4 mg (1 mg at 4 sites), 8 mg (1 mg at 8 sites), 20 mg (2.5 mg at 8 sites), and 30 mg (2.5 mg at 12 sites) total dose, with assessment up to 24 weeks after single administration.
- Safety observations in Cohorts 1-3 included mild-moderate adverse events, mostly unrelated to EP-104GI; procedure-related events included chest pain, throat tightness, and nausea; glucose remained stable, cortisol stayed within normal range, and no adrenal insufficiency or candidiasis occurred.
- In Cohort 2 (8 mg), mean peak eosinophil count decreased by 26% at Week 4 and 44% at Week 12, with reductions observed in all patients; Cohort 1 (4 mg) showed no reduction in peak eosinophil count.

– Both cohorts showed decreases from baseline in Straumann Dysphagia Index and patient-reported dysphagia and odynophagia scores at Weeks 12 and 24; the authors suggest findings support potential for at least 6-month intervals between injections, and recruitment is ongoing.

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