Results from RESOLVE, An Ongoing Phase 1b/2a Study of EP-104GI (Long-Acting Fluticasone Propionate Injectable Suspension) For Eosinophilic Esophagitis: Dose Escalation Cohorts 3 Through 6

Malone A.[1], Helliwell J.[1], Kowalski M. M.[1], Nguyen N[2], Ko H. H.[3], Afif W[4], Holtmann G[5], Dobek C[1], Dellon E. S.[6], Bredenoord A. J.[7]

1.Eupraxia Pharmaceuticals Inc. Victoria, Canada 2.Royal Adelaide Hospital, Adelaide, Australia 3.G.I. Research Institute, Vancouver, Canada 4. McGill University Health Center, Montreal, Canada 5.Princess Alexandra Hospital, Woolloongabba, Australia 6.UNC School of Medicine, NC, USA 7.Amsterdam UMC, Netherlands

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BACKGROUND

- Local inflammation in eosinophilic esophagitis (EoE) leads to burdensome symptoms such as dysphagia, but treatment options remain limited[1]
- The broad anti-inflammatory action of topical corticosteroids enables them to address EoE's complex pathogenesis[2]
  - Transient and indirect contact of swallowed topical corticosteroids with the mucosa may limit efficacy
- EP-104GI is as a submucosal, long-acting formulation of fluticasone propionate microparticles, engineered to provide controlled, localized drug release at a consistent rate.
  - It presents the potential to locally address esophageal inflammation[3]

METHODS

- RESOLVE part 1 (NCT05608681) is a Phase 1b, multicenter, open-label, dose-escalation trial to evaluate the safety, tolerability and feasibility of EP-104GI injection in adults with EoE (Fig 1)

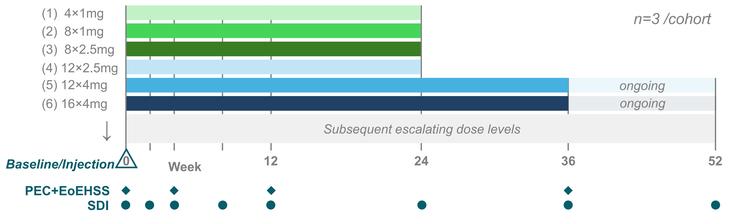

Figure 1. RESOLVE-I Dose Escalation Study Design

- EP-104GI was injected in esophageal layers in alternating quadrants during endoscopy in escalating dose levels (number of sites and dose per site)
- Participants are followed for up to 24 (4×1mg to 12×2.5mg) or 52 weeks (12×4mg, 16×4mg and subsequent dose levels)

REFERENCES

1. Dellon et al. (2025) AJG 120(1):31-59. 2. Schoepfer et al. (2024) Inflamm Intest Dis. 9(1):199–209 3. Malone et al. (2025) Gastroenterology, 169:1 S-402. 4. 1. Schoepfer et al. (2016) Dis Esophagus. 29(8):959-966.

RESULTS

Inflammation

- Inflammation markers and histological scores show an escalating response for doses reported
- Week 36: Improvements **>30%** in Esophageal Biopsies With Peak Eosinophil Count (PEC) ≤6/hpf (Fig. 2a)
- Week 36: Improvements **>45%** in EoE Histology Scoring System (EoEHSS) grade and stage scores (Fig. 2b&c)

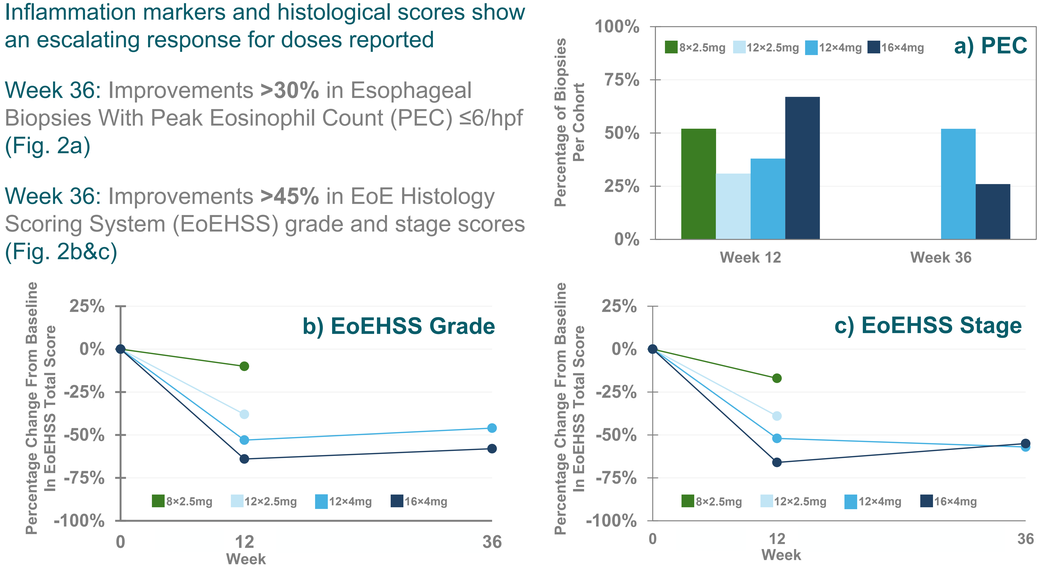

Figure 2. Changes In Inflammation Markers Following EP-104GI Administration a) Mean Percentage of Esophageal Biopsies With Peak Eosinophil Count ≤6/hpf b & c) Mean Relative Change In EoEHSS

Dysphagia

- Persistent, long-term improvements in patient-reported dysphagia following single administration of EP-104GI
- Week 24: Most cohorts demonstrate a response in Straumann Dysphagia Index ≥3[4] (Fig. 3)
- Week 36: Doses of 12×4mg and 16×4mg maintained mean improvements >2.5 (Fig. 3); relative change from baseline between –42% and –65% at week 36. (*data not shown*)

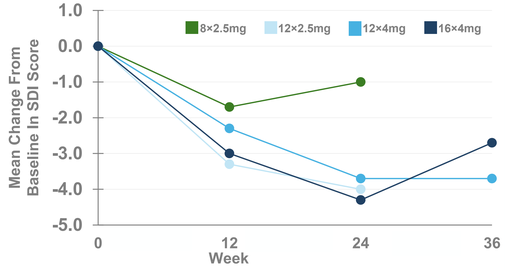

Figure 3. Mean Change In Straumann Dysphagia Index (SDI) Following EP-104GI Administration

Safety

- No Dose-Limiting Toxicity Observed to Date
- Serum concentrations of glucose and cortisol were stable following EP-104GI administration (Fig. 4)
- No serious treatment-emergent adverse events were reported to date*

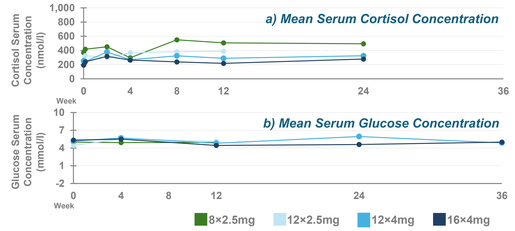

Figure 4. Glucose And Cortisol Serum Concentrations Following Single Administration of EP-104GI

** Treatment-emergent adverse events related to EP-104GI administration for doses reported included chest pain, nausea, throat tightness, pressure sensation and esophageal sensitivity*

CONCLUSIONS

- EP-104GI administration has been feasible, safe and well tolerated to date, with no gastrointestinal candidiasis, signs of adrenal suppression, or other dose-limiting toxicity reported
- Escalating improvements in inflammation and long-term improvements in dysphagia support the investigation of escalating dose levels over a 52-week post-dose period