Updated Dose Escalation Results From RESOLVE, An Ongoing Phase 1b/2a Study of EP-104GI (Long-Acting Fluticasone Propionate Injectable Suspension) For Eosinophilic Esophagitis

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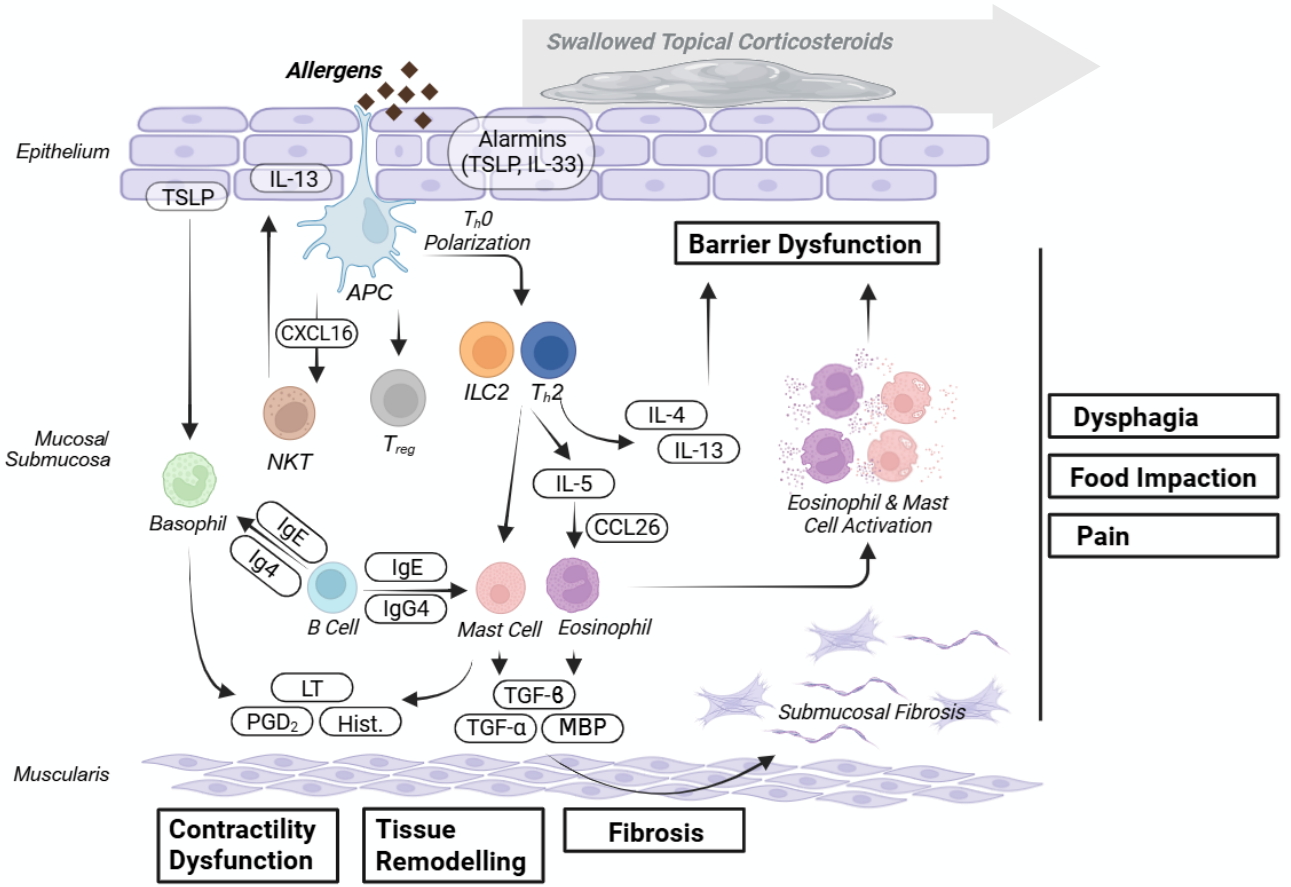
Potential of EP-104GI In Eosinophilic Esophagitis

- Local inflammation in eosinophilic esophagitis (EoE) leads to burdensome symptoms such as dysphagia[1]
- Novel treatments with improved efficacy or duration are needed.
- 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]

Sub-Epithelial Eosinophilic Esophagitis Pathogenesis



Adapted and modified from: Choi et al. (2025) Korean J Helicobacter Up Gastrointest Res., O'Shea et al. (2018) Gastroenterology, Racca et al. (2022) Front. Physiol., Underwood et al. (2023) Ann Allergy Asthma Immunol., Young et al. (2022) Dig. Dis Sci. Created using BioRender

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

RESOLVE Trial (NCT05608681)

Phase 1b/2, multicenter, open-label, dose-escalation and optimization trial to evaluate the safety, tolerability, feasibility, pharmacokinetics, and efficacy of EP-104GI in adults with EoE

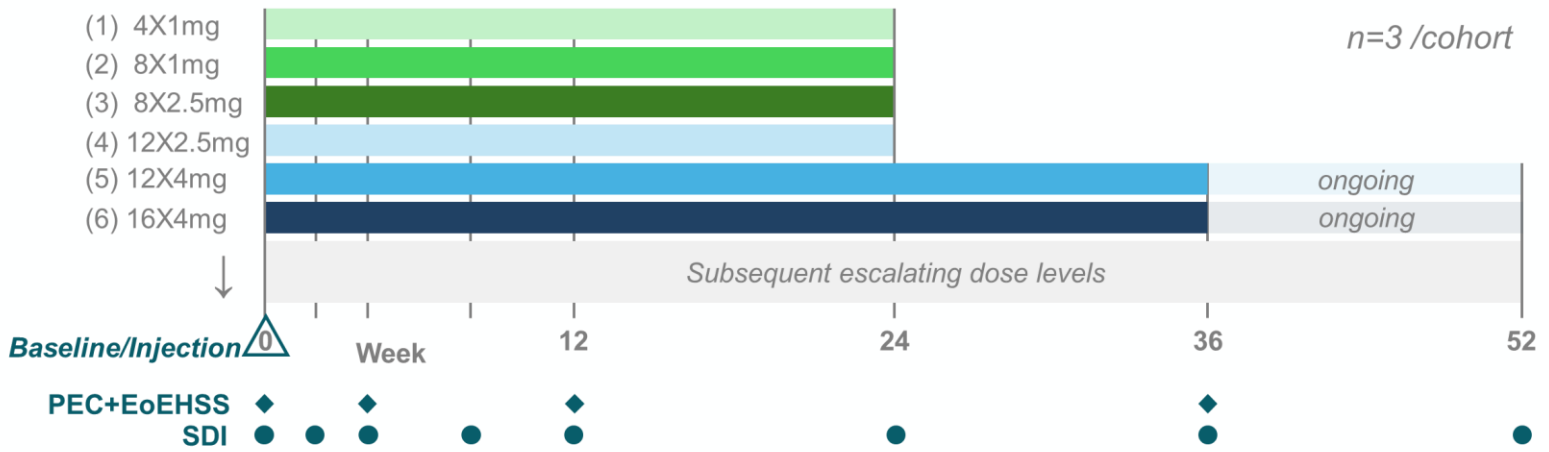
- EP-104GI is injected in the esophageal layers once, at baseline during endoscopy, in escalating dose levels (number of sites and dose per site).

Part I - Dose Escalation

- Participants are followed for up to
  - 24 weeks (4×1mg - 12×2.5mg)
  - 52 weeks (subsequent dose levels)

- Esophageal Inflammation assessed by Peak Eosinophil Counts (PEC) and EoE Histology Scoring System (EoEHSS)

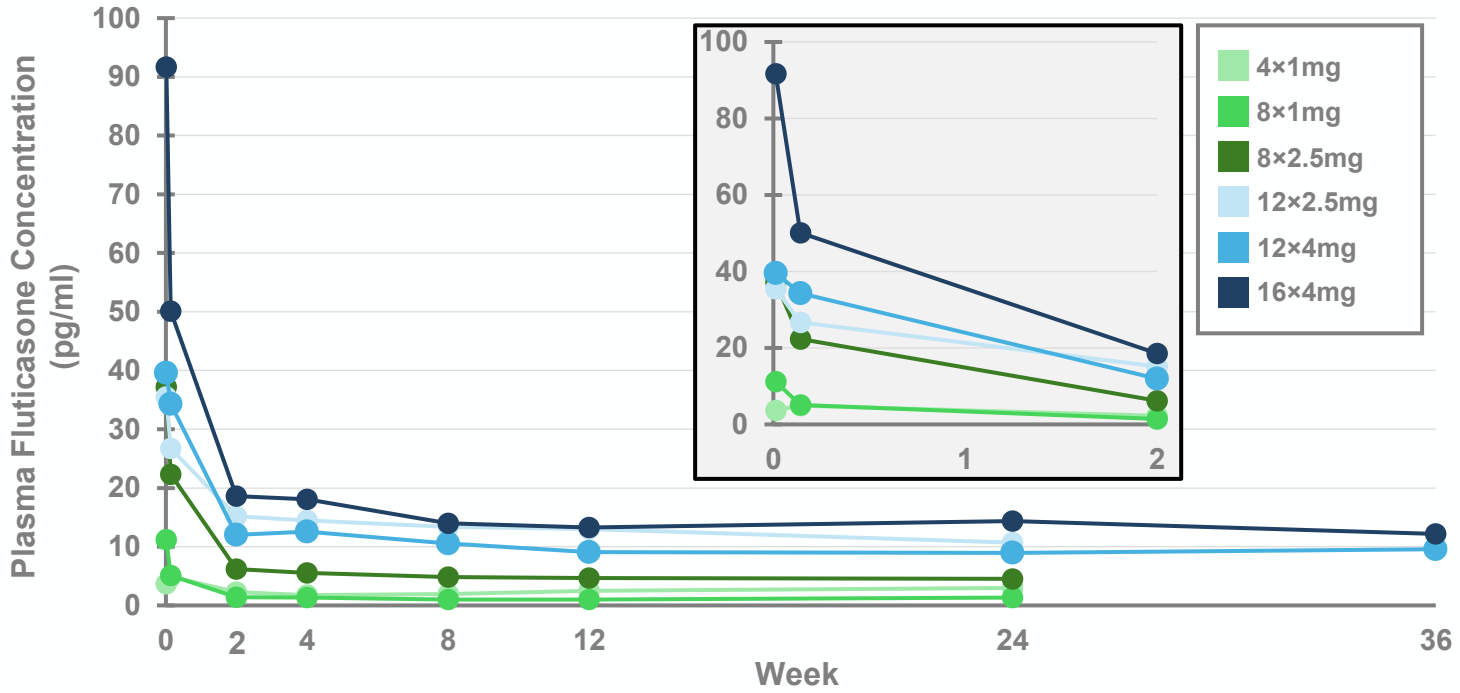
- Dysphagia Symptoms assessed by Straumann Dysphagia Index (SDI)



RESOLVE-I Dose Escalation Study Design

Low And Constant Plasma Fluticasone Levels Following Administration

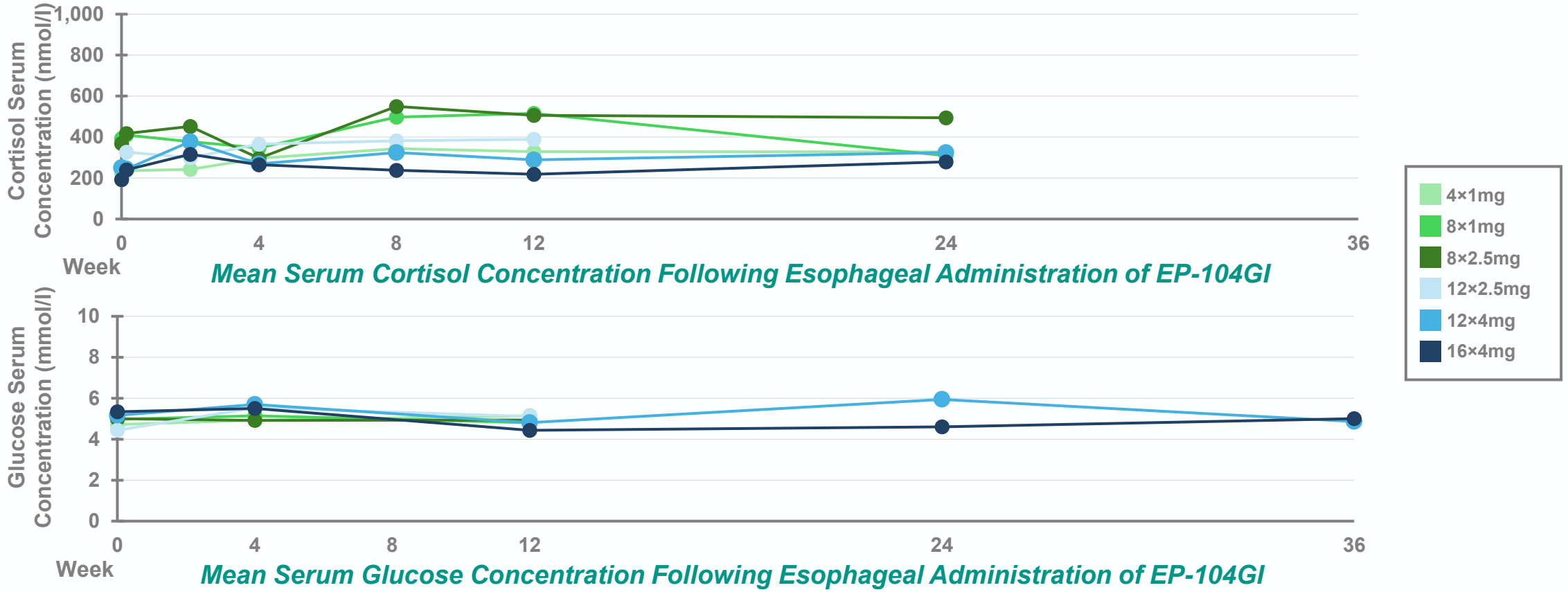
- Systemic levels of fluticasone remain near constant and <20 pg/mL shortly (2 weeks) following an initial peak



Mean Plasma Fluticasone Concentration Following Esophageal Administration of EP-104GI

No Dose-Limiting Toxicity Observed to Date

- Serum concentrations of glucose and cortisol remained stable following EP-104GI administration
- No serious adverse events reported
- Most treatment-emergent adverse events unlikely related to EP-104GI*



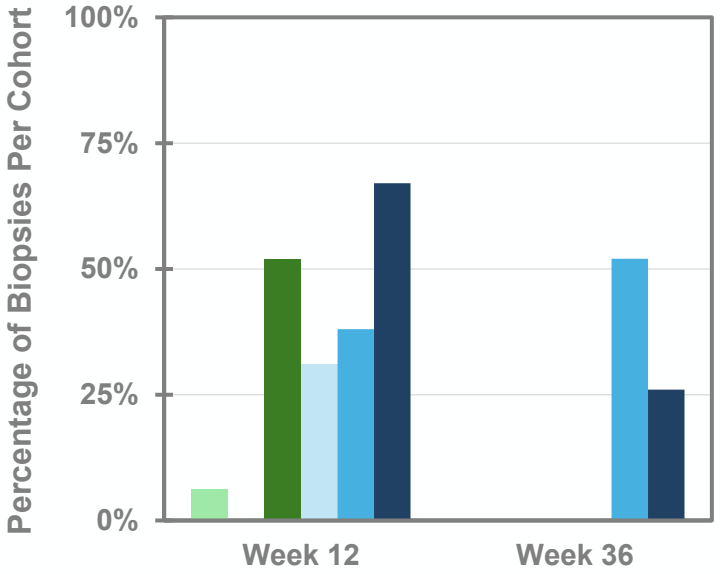
Mean Serum Cortisol Concentration Following Esophageal Administration of EP-104GI

Mean Serum Glucose Concentration Following Esophageal Administration of EP-104GI

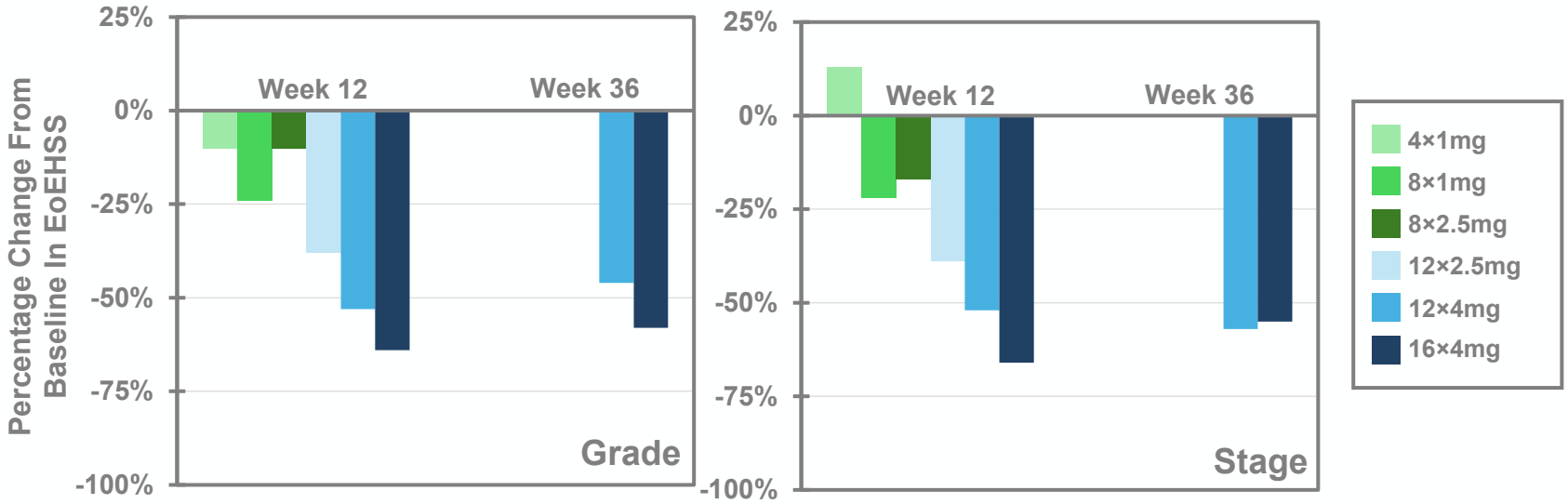
** Treatment-emergent adverse events related to EP-104GI administration included chest pain, nausea, throat tightness, pressure sensation and esophageal sensitivity*

Reduction In Inflammation And Histological Features

- **Overall, inflammation markers and histological scores show an escalating response for doses reported to date**
- **Week 36:** Improvements **>30%** in Esophageal Biopsies With Peak Eosinophil Count (PEC) ≤6/hpf
- **Week 36:** Improvements **>45%** in EoE Histology Scoring System (EoEHSS) grade and stage scores



Mean Percentage of Esophageal Biopsies With Peak Eosinophil Count ≤6/hpf Following EP-104GI Administration

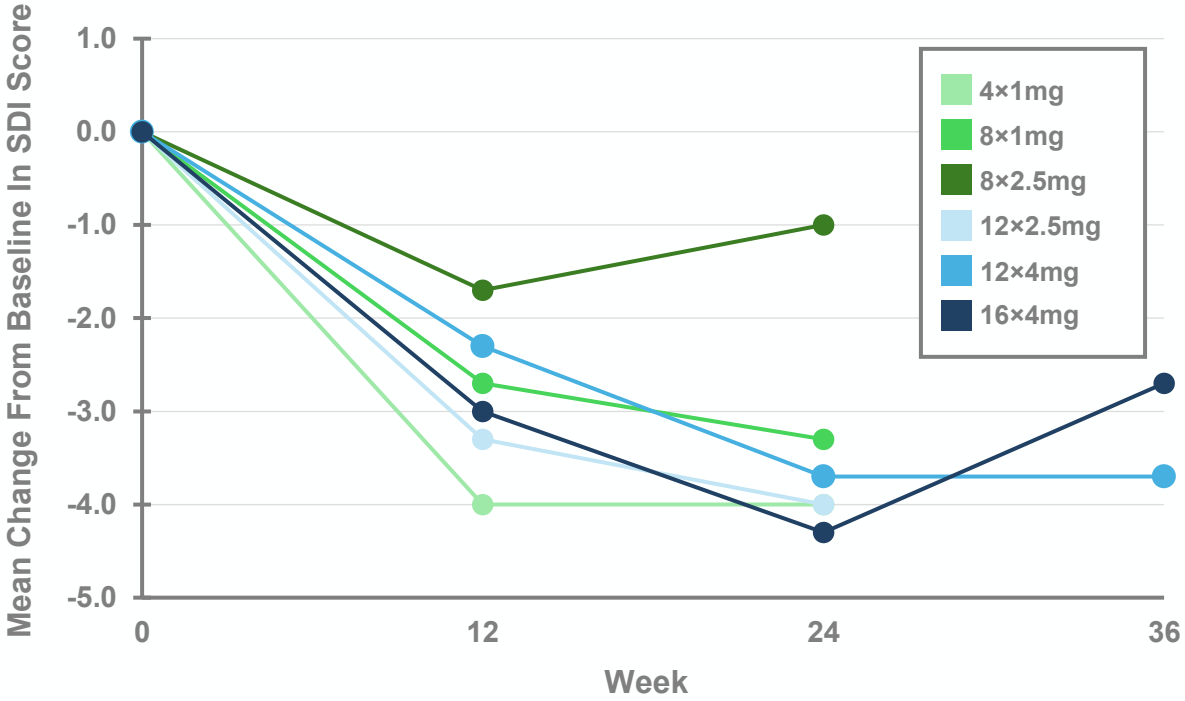


Mean Relative Change In Total Score of Eosinophilic Esophagitis Histology Scoring System

Improvements In Dysphagia Up to 36 Weeks

- **Sustained, 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 [1]
- **Week 36:** Doses of 12×4mg and 16×4mg maintained mean improvements >2.5



Mean Change In Straumann Dysphagia Index Following EP-104GI Administration

1. Schoepfer et al. (2016) Dis Esophagus. 29(8):959-966.

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 after a single administration of EP-104GI in esophageal inflammation and long-term improvements in dysphagia support the continued investigation of escalating dose levels over a 52-week post-dose follow-up period