Persistent Improvement in Dysphagia Symptoms for 52 Weeks Following a Single Administration of EP-104GI in RESOLVE, an Ongoing Phase 1b/2 Trial in Eosinophilic Esophagitis

Dellon E. S., MD[1], Afif W, MD, MSC, FRCPC.[2], Nguyen N., MD, PhD, FRACP[3], Ko H. H., MC, BSC(Pharm), FRCPC[4], Bredenoord A. J., MD, PhD,[5], Peck V., BJ[1], Malone A., PhD[1], Kowalski M. M., MD, PhD[1]

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

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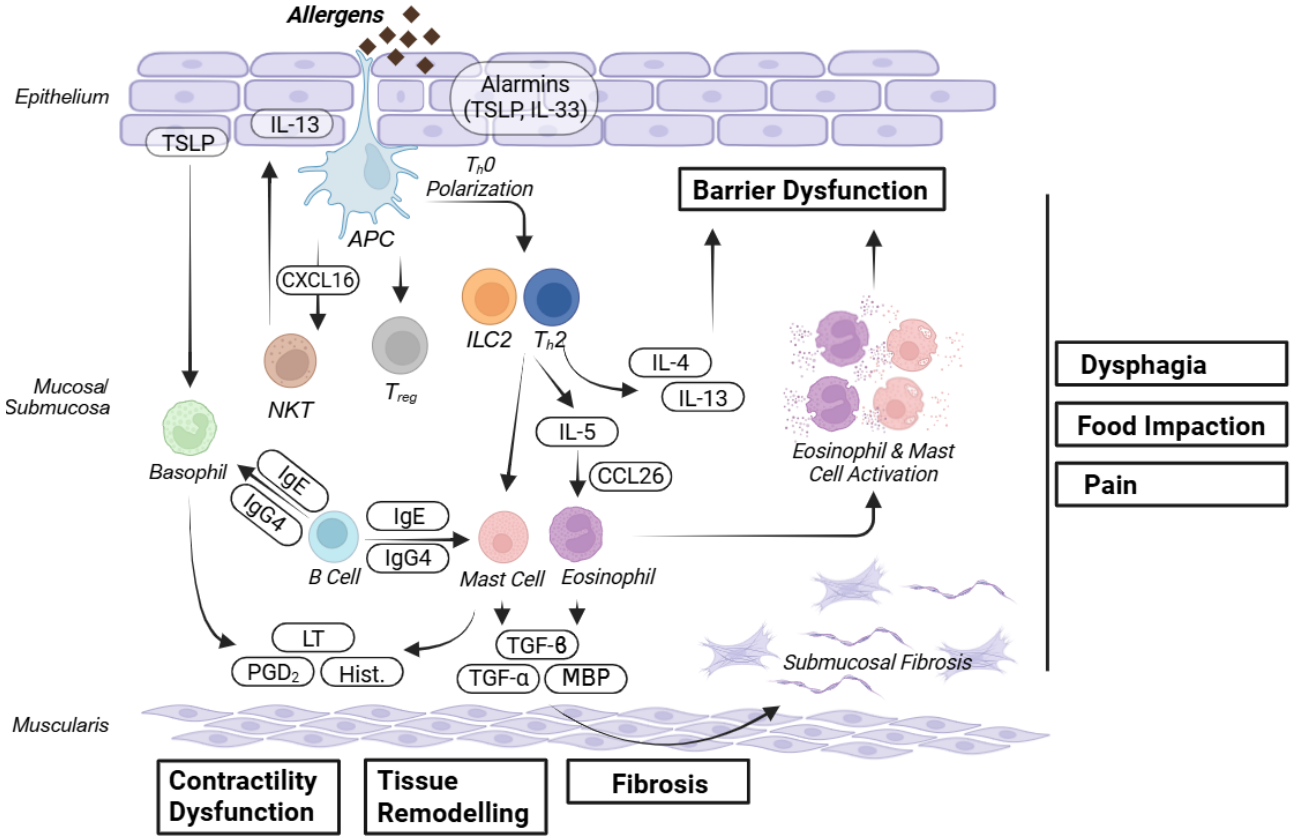
EP-104GI In Eosinophilic Esophagitis

- Local inflammation in eosinophilic esophagitis (EoE) leads to burdensome symptoms such as dysphagia[1]
- 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]

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

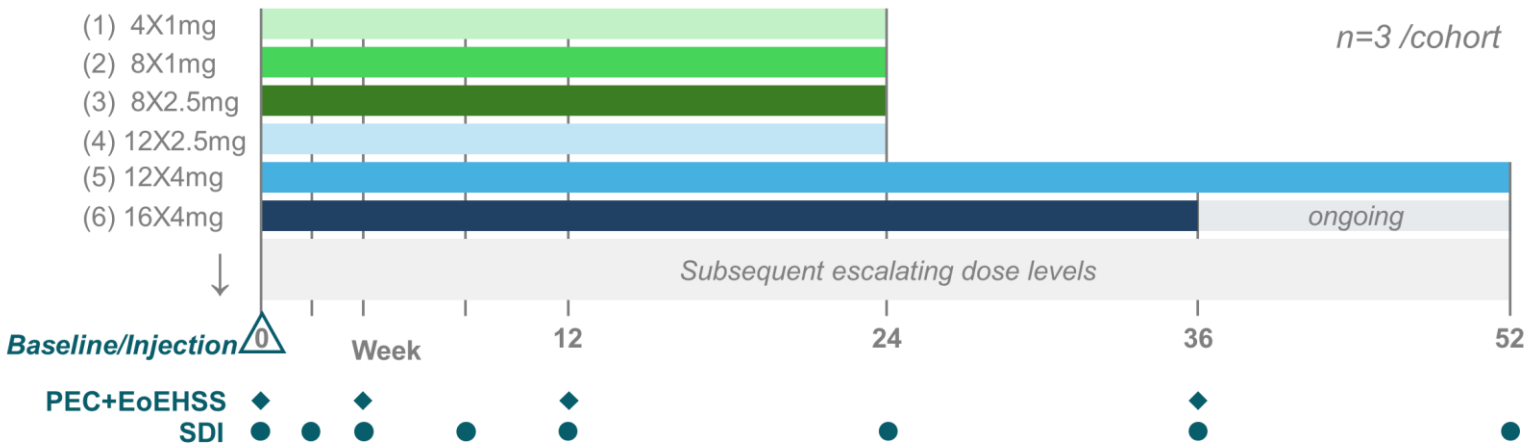
RESOLVE Trial

RESOLVE (NCT05608681) is a 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)

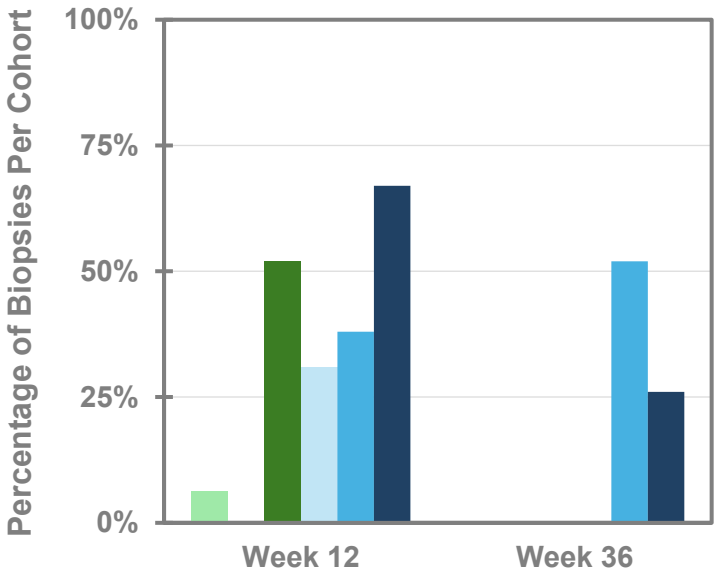


RESOLVE-I Dose Escalation Study Design

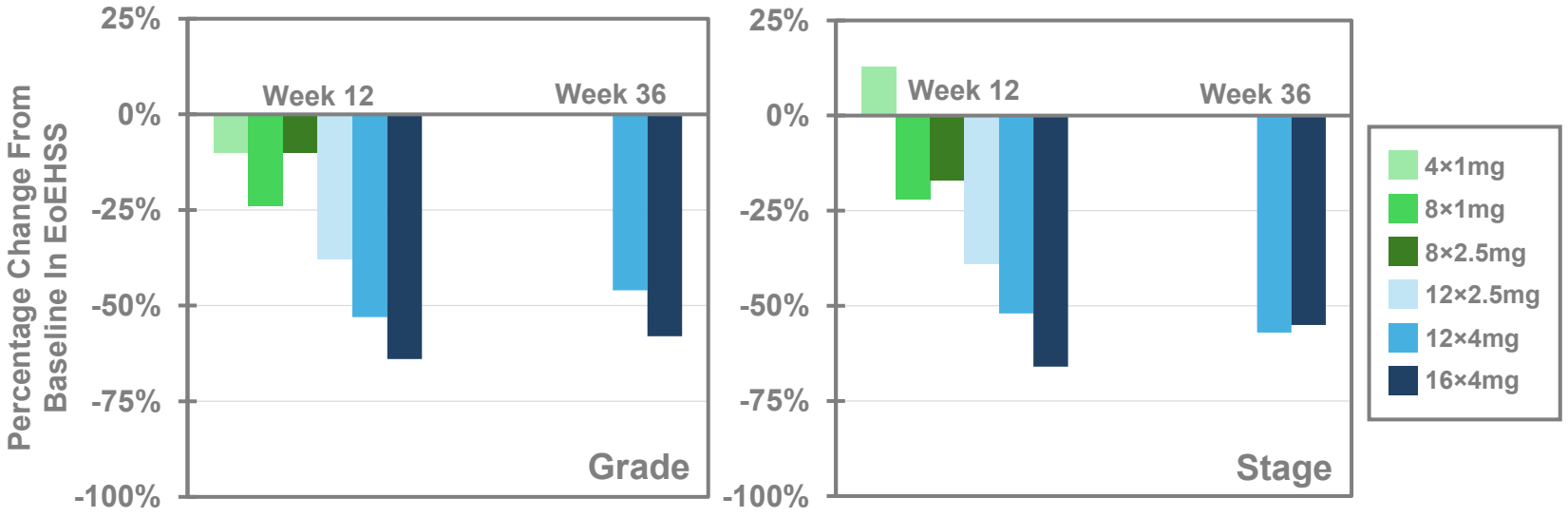
Safety, Tolerability And Efficacy of EP-104GI Over 36-Week Follow Up

- EP-104GI administration has been reported to be feasible, safe and well tolerated over up to 36 weeks follow-up[1,2]
  - No oral or gastrointestinal candidiasis, signs of adrenal suppression, or other dose-limiting toxicity were reported
  - Systemic levels of fluticasone remain near constant and <20pg/mL following an initial peak
- Overall, esophageal inflammation markers and histological scores showed escalating responses[1,2]

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



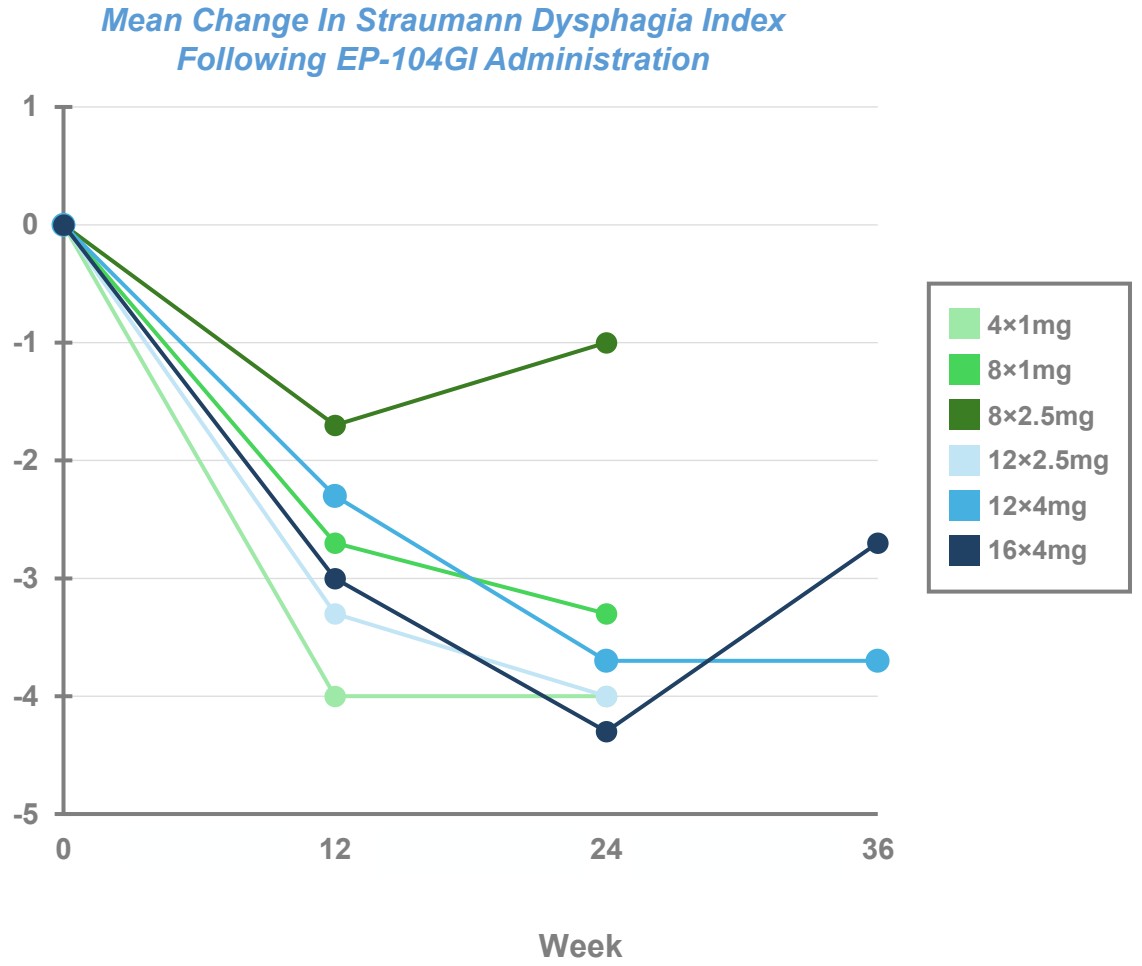
Mean Relative Change In Eosinophilic Esophagitis Histology Scoring System Total Score Following EP-104GI Administration



1. Malone et al. (2025) Gastroenterology, 169:1 S-402 2. Dellon et al. (October 24-29 2025) Results from Dose Escalation Cohorts 1-6 of RESOLVE, an Ongoing Phase 1b/2a Study of EP-104GI (Long-acting Fluticasone Propionate Injectable Suspension) For Eosinophilic Esophagitis [Poster presentation] American College of Gastroenterology Annual Meeting, Phoenix

Safety, Tolerability And Efficacy of EP-104GI Over 36-Week Follow Up

- Improvements in patient-reported dysphagia following single administration of EP-104GI persisted up to 36 weeks follow-up[1,2]
- At week 36, dose cohort of 12×4mg maintained mean improvements >2.5[1,2]



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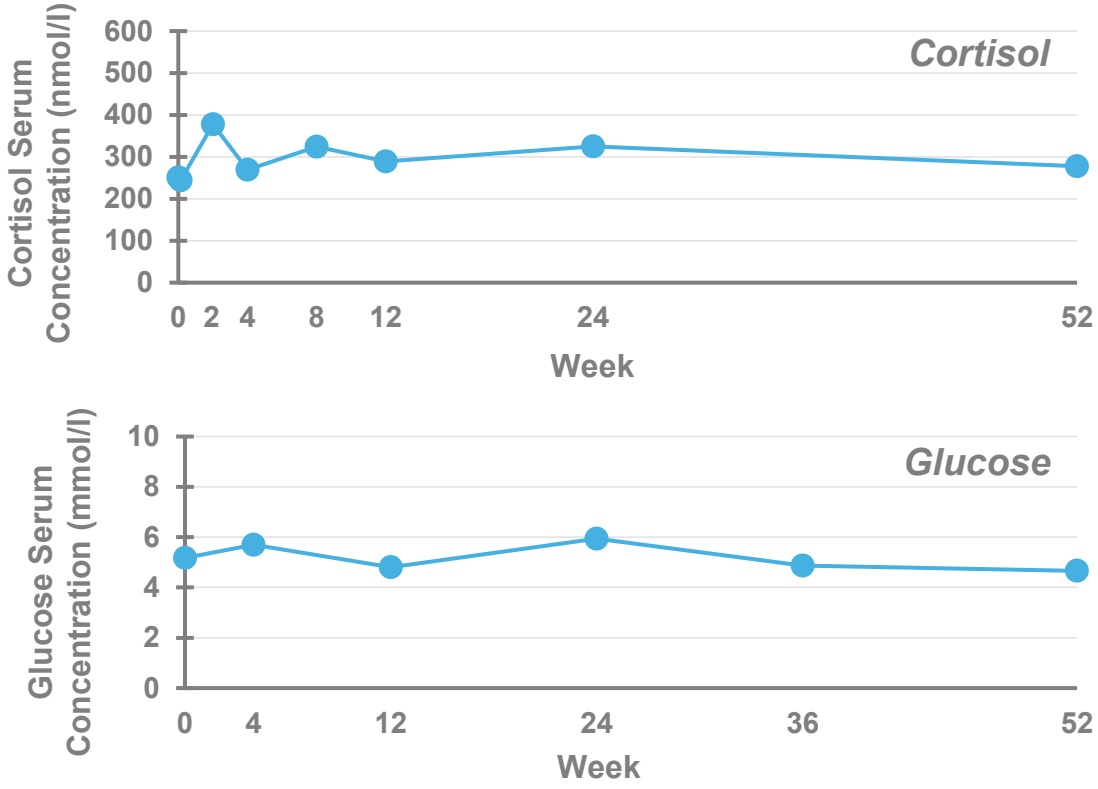
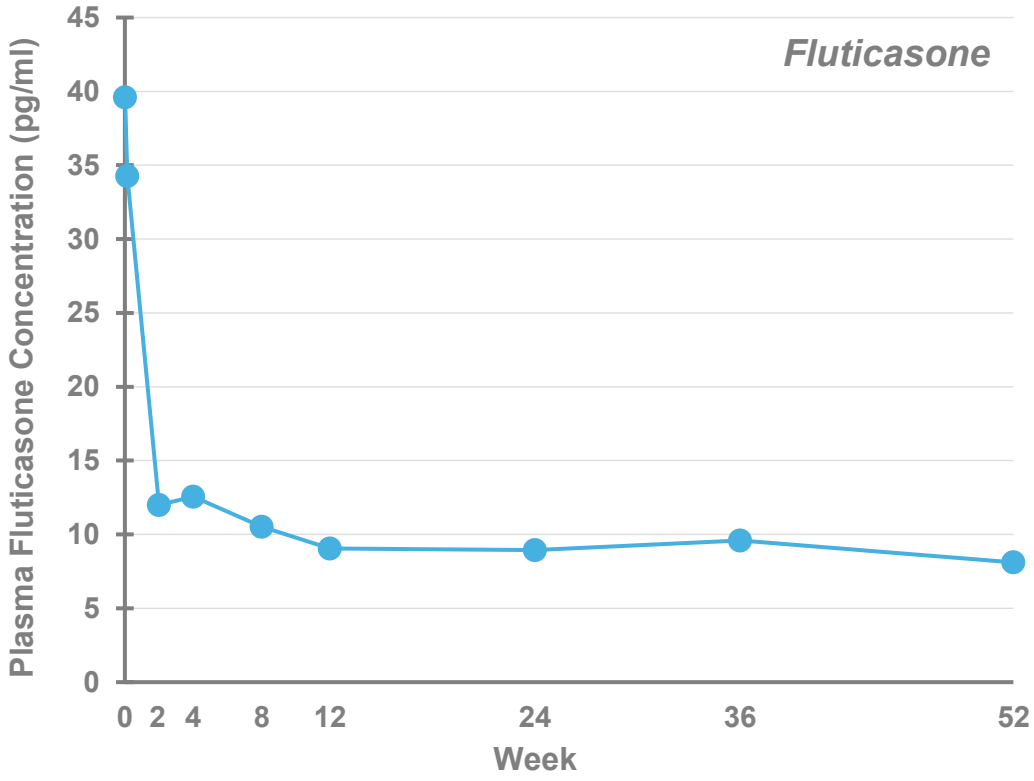
No Dose-Limiting Toxicity Reported Over 52 Weeks For EP-104GI 12x4mg

- No serious adverse events have been reported and EP-104GI has been well tolerated*
- Serum concentrations of glucose and cortisol remained stable following EP-104GI administration
- Systemic levels of fluticasone remain near constant and <20pg/mL following post-administration peak

Concentrations Following Esophageal Administration of EP-104GI 12×4mg



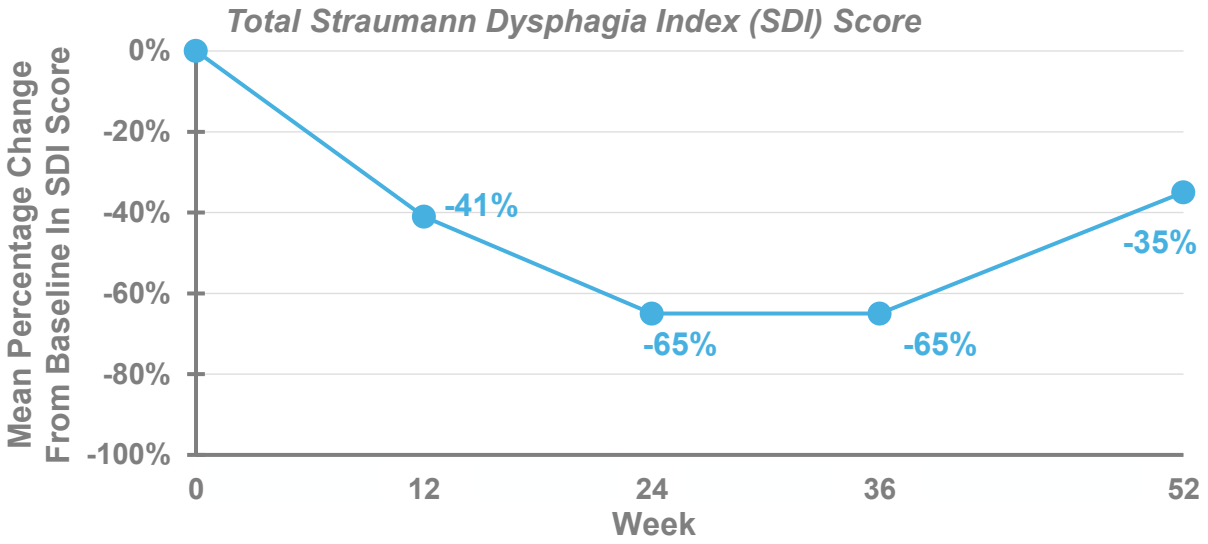


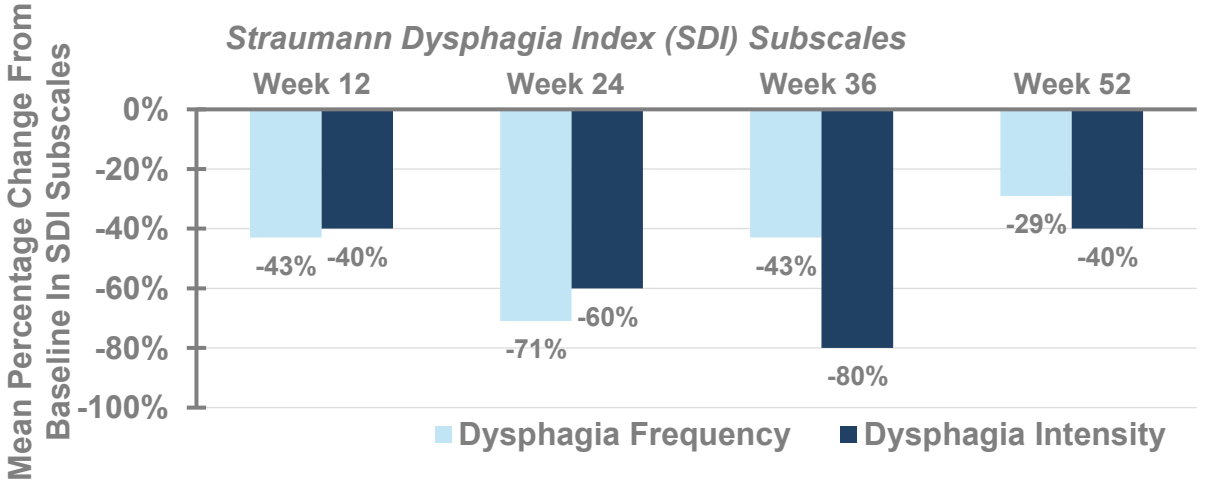
** Treatment-emergent adverse events related to EP-104GI administration for doses reported to date included chest pain, nausea, throat tightness, pressure sensation and esophageal sensitivity*

Reported Improvements In Dysphagia Up to 52 Weeks For EP-104GI 12x4mg

- **Persistent, long-term improvement in patient-reported dysphagia over 52 weeks, following single administration of 12×4mg EP-104GI**
- Following administration of 12×4mg EP-104GI, mean absolute changes from baseline of -2.3, -3.7, -3.7 and -2.0 at week 12, 24, 36 and 52, respectively
- Mean relative improvements between 35% and 65% over 52 weeks
- Individual subscales show improvements in both frequency and severity of reported dysphagia

Reported Improvements In Dysphagia Following 12×4mg EP-104GI Administration





Conclusions

- This is the first report of persistent, clinically meaningful improvement in dysphagia over 52 weeks following a single administration of 12×4mg of EP-104GI in participants with EoE
- Administration of 12×4mg EP1-04GI has been feasible, safe and well tolerated to date, with no oral or gastrointestinal candidiasis, signs of adrenal suppression, or other dose-limiting toxicity reported over 52 weeks
- Overall, our results support the continued investigation of escalating dose levels of EP-104GI for the treatment of EoE in the ongoing RESOLVE trial