# Single Administration of Escalating Doses of EP-104GI Leads to Persistent Improvements in Histological Features of Eosinophilic Esophagitis Over 36 Weeks in RESOLVE, a Phase 1b/2 Dose Escalation and Optimization Trial

Christopher Ma,[1] Nam Nguyen,[2] Hin Hin Ko,[3] Vincent Ho,[4] Waqqas Afif,[5] Gerald Holtmann,[6] Evan S. Dellon,[7] Christine Dobek,[8] Andrew Dye,[8] Mark Kowalski,[8] Amanda Malone[8]

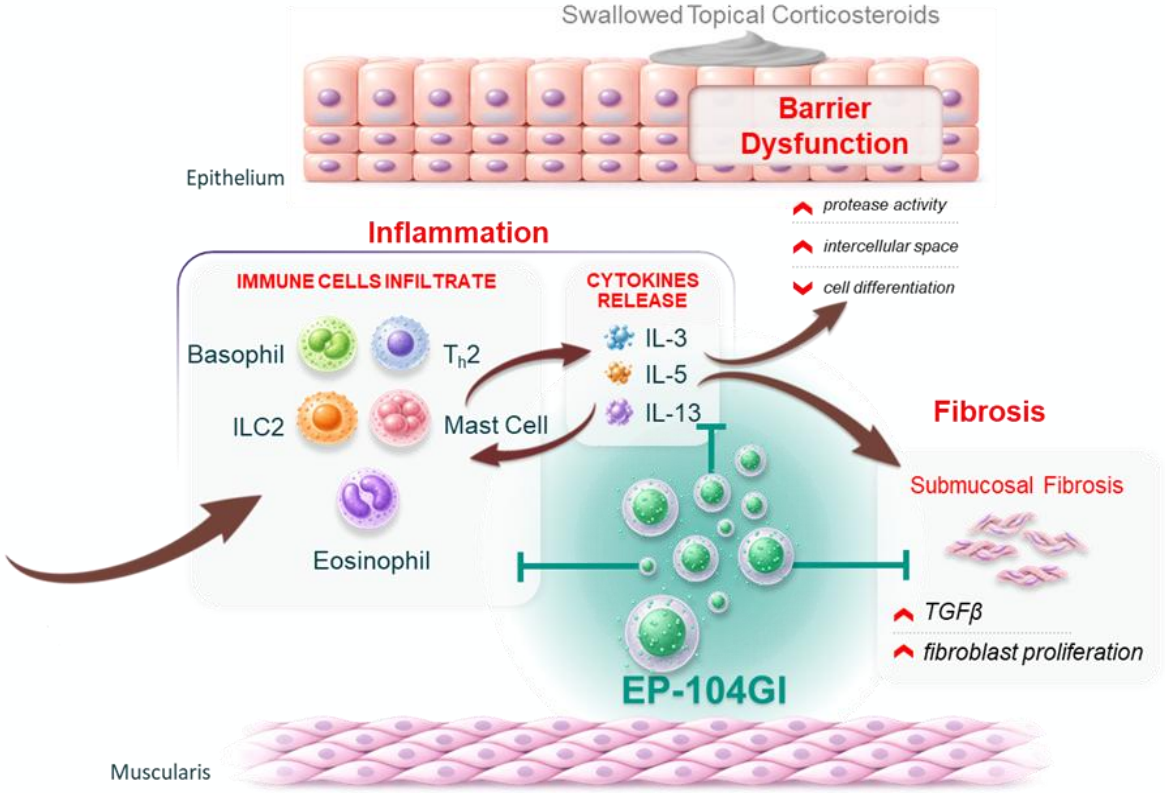
[1]University of Calgary, Calgary, Canada [2]Royal Adelaide Hospital, Adelaide, Australia [3]G.I. Research Institute, Vancouver, Canada [4] University of Western Sydney, Sydney, Australia. [5]McGill University Health Center, Montreal, Canada [6]Princess Alexandra Hospital, Woolloongabba, Australia [7]UNC School of Medicine, NC, USA [8]Eupraxia Pharmaceuticals Inc. Victoria, Canada

Digestive Disease Week 2026 | May 2–5, 2026 | Chicago, IL

# The Eosinophilic Esophagitis (EoE) Inflammatory Cascade

- EoE causes esophageal inflammation that can progress to fibrosis and remodeling [1]
- EoE can lead to debilitating dysphagia, pain, and food impaction [1]
- Corticosteroids are recommended for the treatment of EoE and can reduce inflammation
  - *Their impact may be limited by local delivery challenges, and poor long-term treatment adherence* [2]

## Model of EP-104GI Mode of Action In Eosinophilic Esophagitis




1. Dellon et al. (2025) AJG. 120(1):31-59.; 2. Główczewski et al. (2022) J Clin Med 11(5):1454;

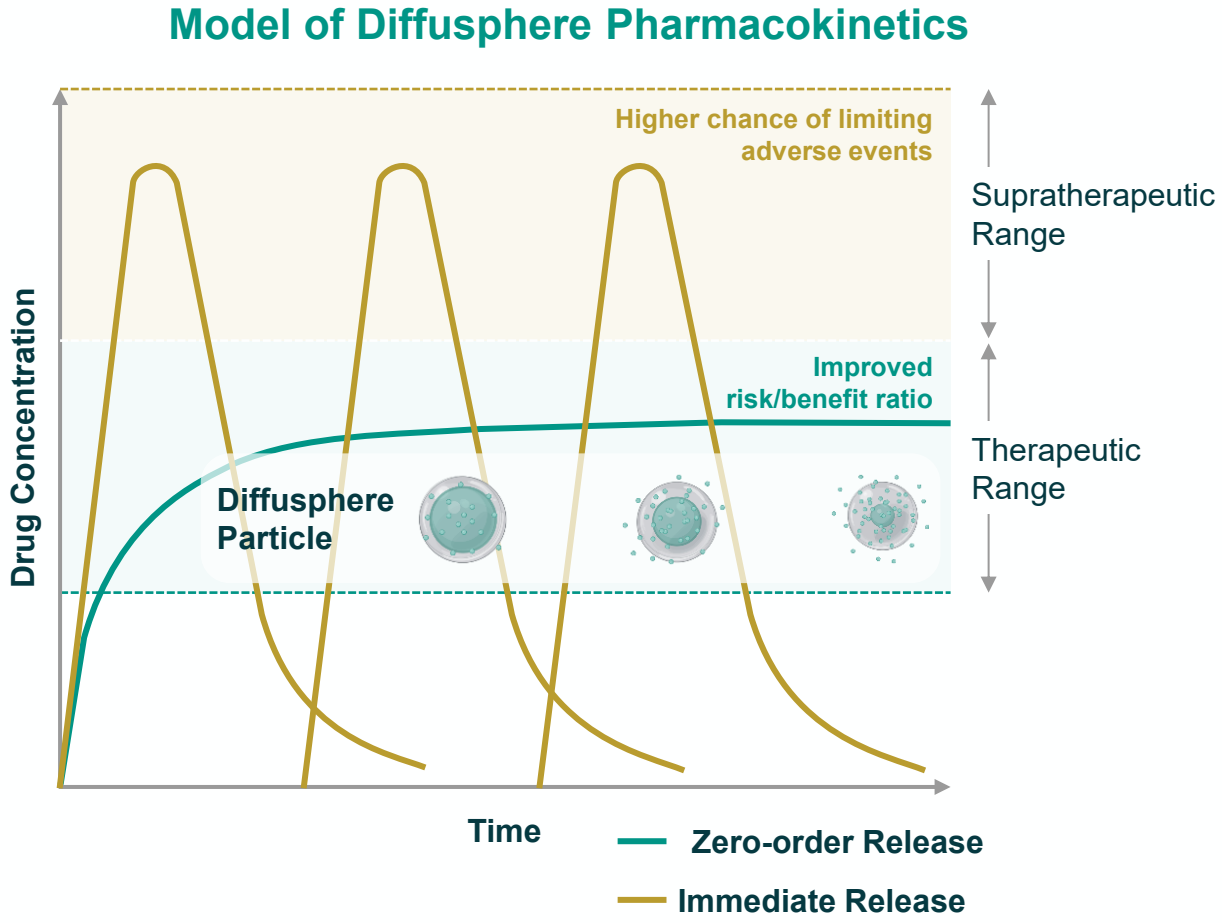
# EP-104GI & The Eosinophilic Esophagitis (EoE) Inflammatory Cascade

## EP-104GI

**Investigated for the treatment of EoE**

Long-acting, injectable fluticasone particles providing controlled, local release [1]

*A fluticasone propionate core is coated in a polymer membrane designed to release drug at a near-constant rate*




1. Webb et al. (2024) AJG 119(10S):p S445-S446

# RESOLVE (NCT05608681) is a Phase 1b/2 Multicenter, Open-Label, Dose-Escalation and Optimization Trial of EP-104GI In EoE

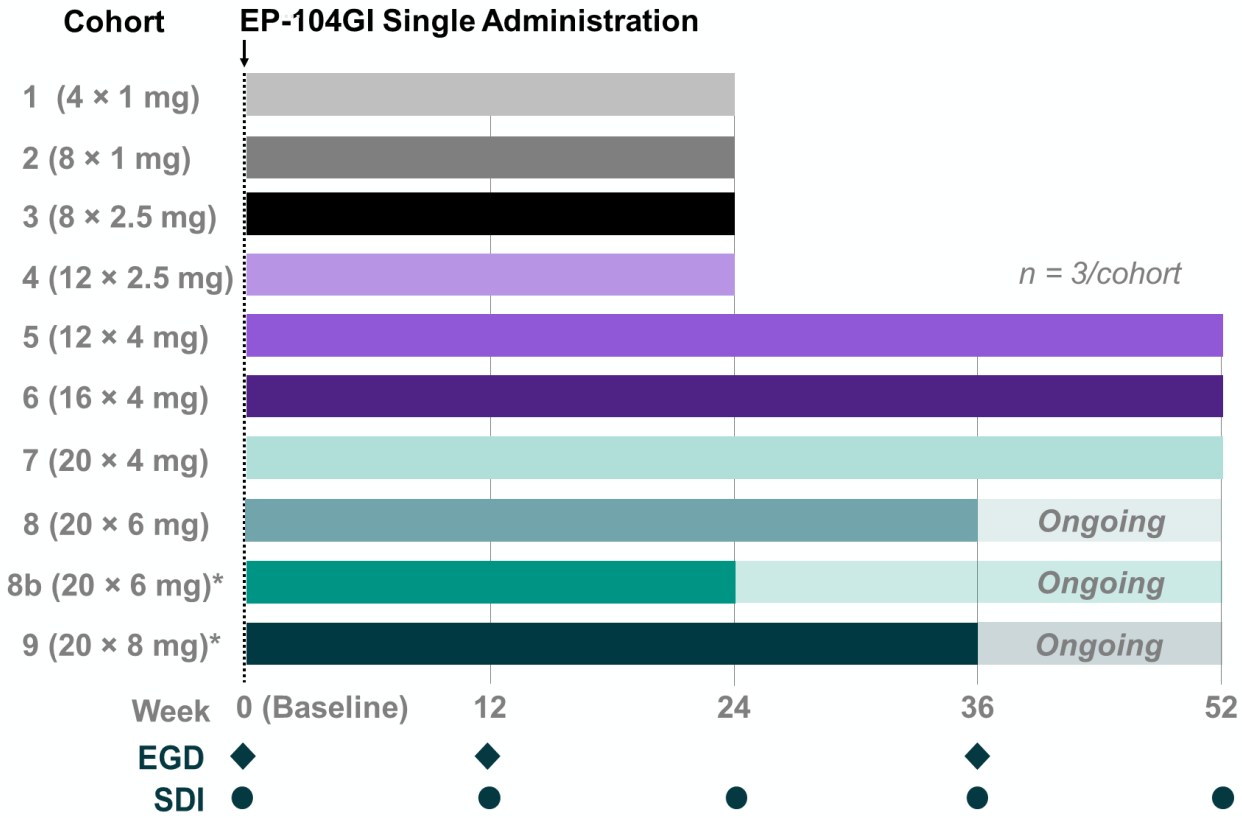
## *Part I – Phase 1b / Dose Escalation*

### *Study Procedures*

- Single administration of EP-104GI at baseline
- Post-administration follow-up
  - 24 weeks (4 × 1 mg–12 × 2.5 mg)
  - 52 weeks (12 x 4 mg–20 x 8 mg)

### *Endpoints*

- Pharmacokinetics
- Safety & tolerability
- Esophageal Inflammation & Remodeling
  - Peak Eosinophil Count (PEC)
  - EoE Histology Scoring System (EoEHSS)
  - Hirano Eosinophilic Esophagitis Endoscopic Reference Score (EREFS)
- Dysphagia symptoms
  - Straumann Dysphagia Index (SDI)



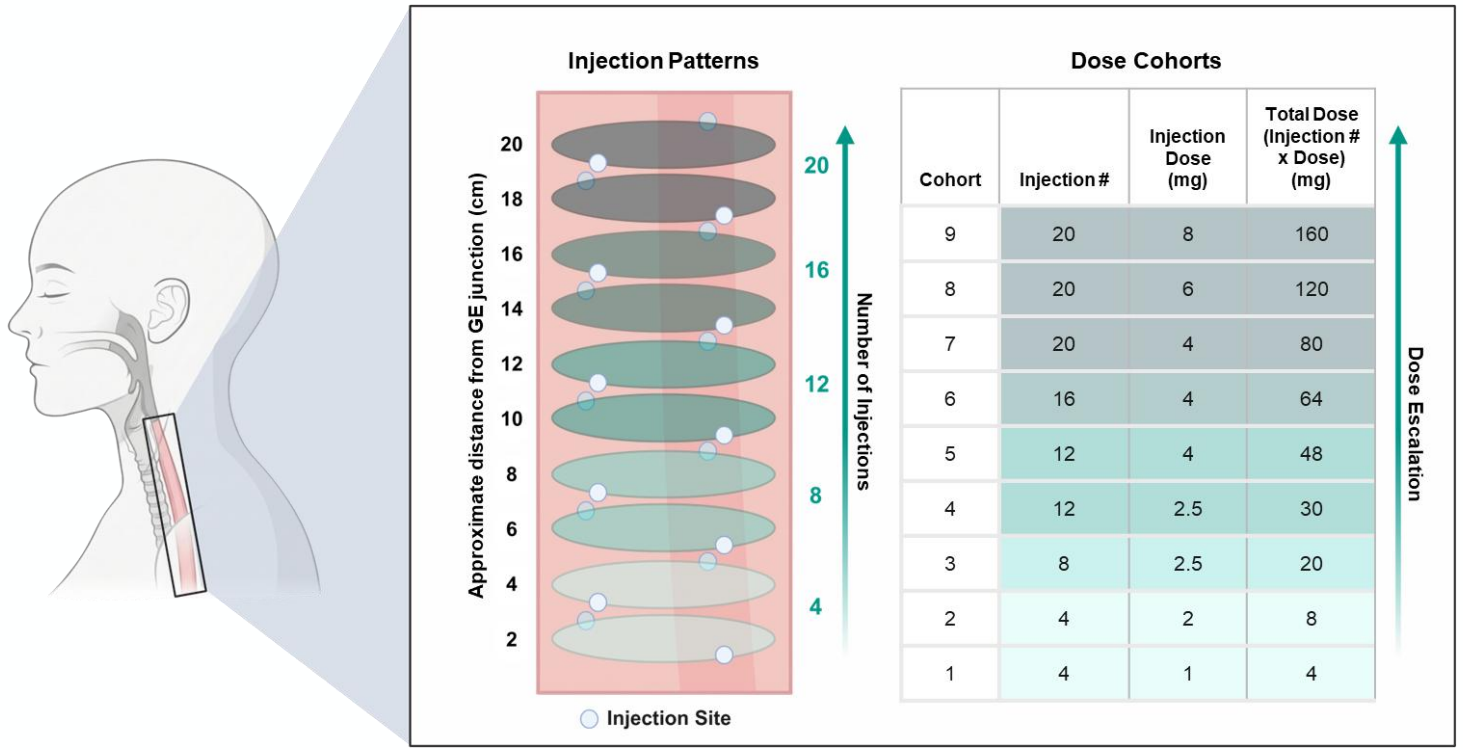

* Administration for 2 dose cohorts (8b & 9) was performed with updated needle/catheter combinations

EGD, esophagogastroduodenoscopy; EoE, eosinophilic esophagitis; EoEHSS, Eosinophilic Esophagitis Histology Scoring System; EREFS, Eosinophilic Esophagitis Reference Score; PEC, Peak Eosinophil Counts; SDI, Straumann Dysphagia Index.

# EP-104GI is Administered in a Single Procedure, at Baseline

- EP-104GI was injected in the esophagus submucosa during endoscopy with a through-the-scope injector
- Injected in alternating quadrants in levels separated by 2 cm
- EP-104GI was injected in dose cohorts in escalating:
  - number of sites (4, 8, 12, 16, 20)
    or
  - dose per site (1, 2.5, 4, 6, 8 mg)

## EP-104GI Injection Patterns in Phase 1b Dose Escalation in RESOLVE



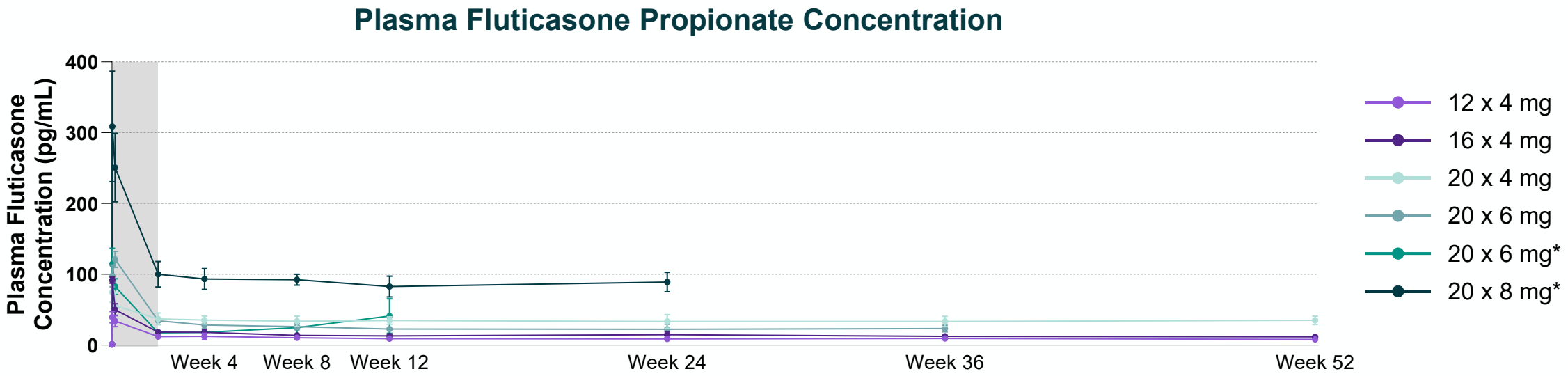

**Dose Cohorts**

| Cohort | Injection # | Injection Dose (mg) | Total Dose (Injection # x Dose) (mg) |
|---|---|---|---|
| 9 | 20 | 8 | 160 |
| 8 | 20 | 6 | 120 |
| 7 | 20 | 4 | 80 |
| 6 | 16 | 4 | 64 |
| 5 | 12 | 4 | 48 |
| 4 | 12 | 2.5 | 30 |
| 3 | 8 | 2.5 | 20 |
| 2 | 4 | 2 | 8 |
| 1 | 4 | 1 | 4 |

Dose Escalation

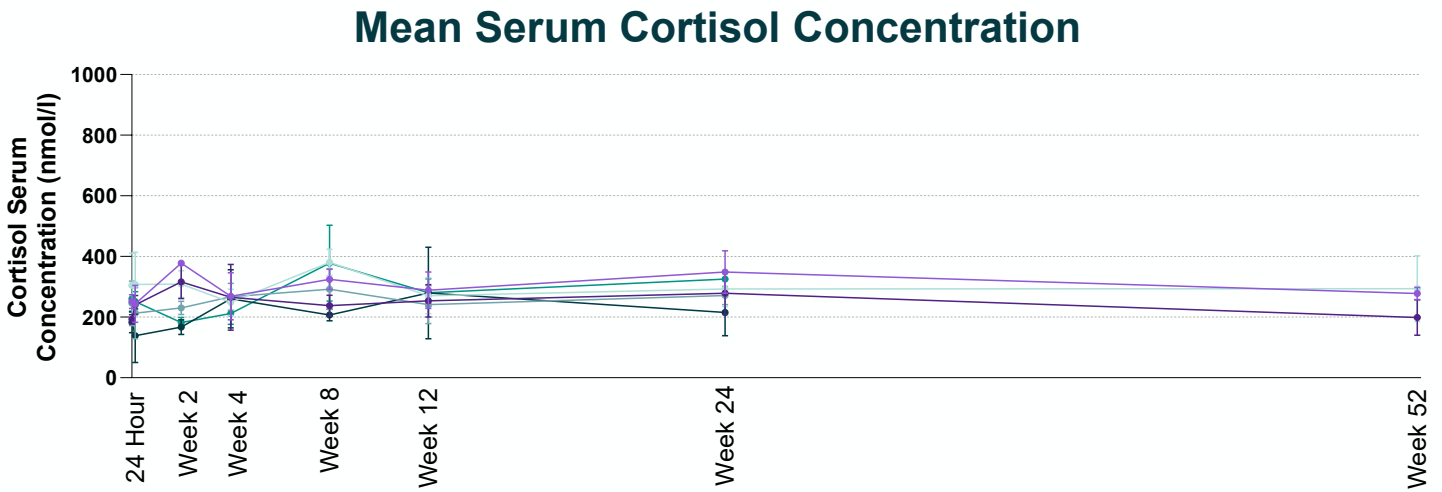
# Plasma Fluticasone Concentration Remains Constant Over 36/52 Weeks

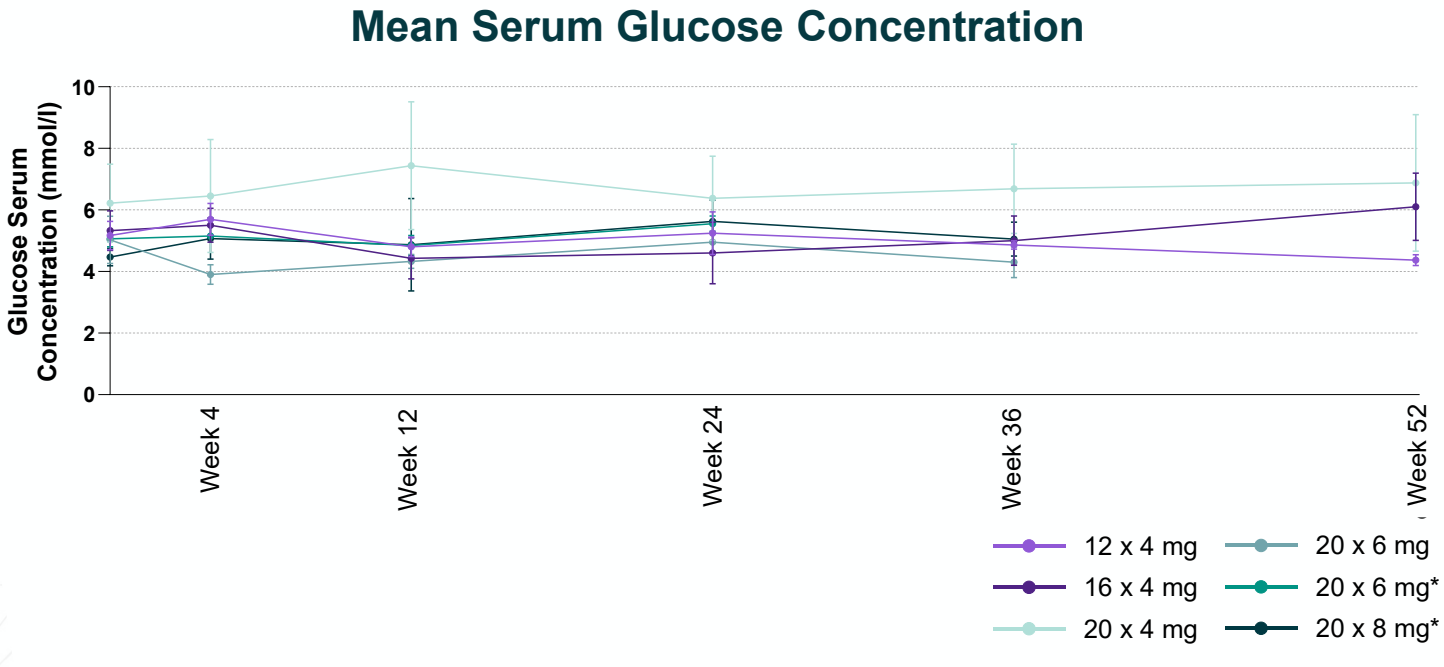
- Following administration at baseline, systemic levels of fluticasone remain near constant and ≤100 pg/mL following an initial peak



# EP-104GI Was Well Tolerated to Date Over 36 And 52 Weeks

- To date, EP-104GI was generally safe and well tolerated for all dose cohorts that completed 36 or 52 weeks following administration
- No clinically significant signs of adrenal suppression, glucose derangement, or other dose-limiting toxicity reported to date
- Most frequently reported AEs are typical of an endoscopy procedure



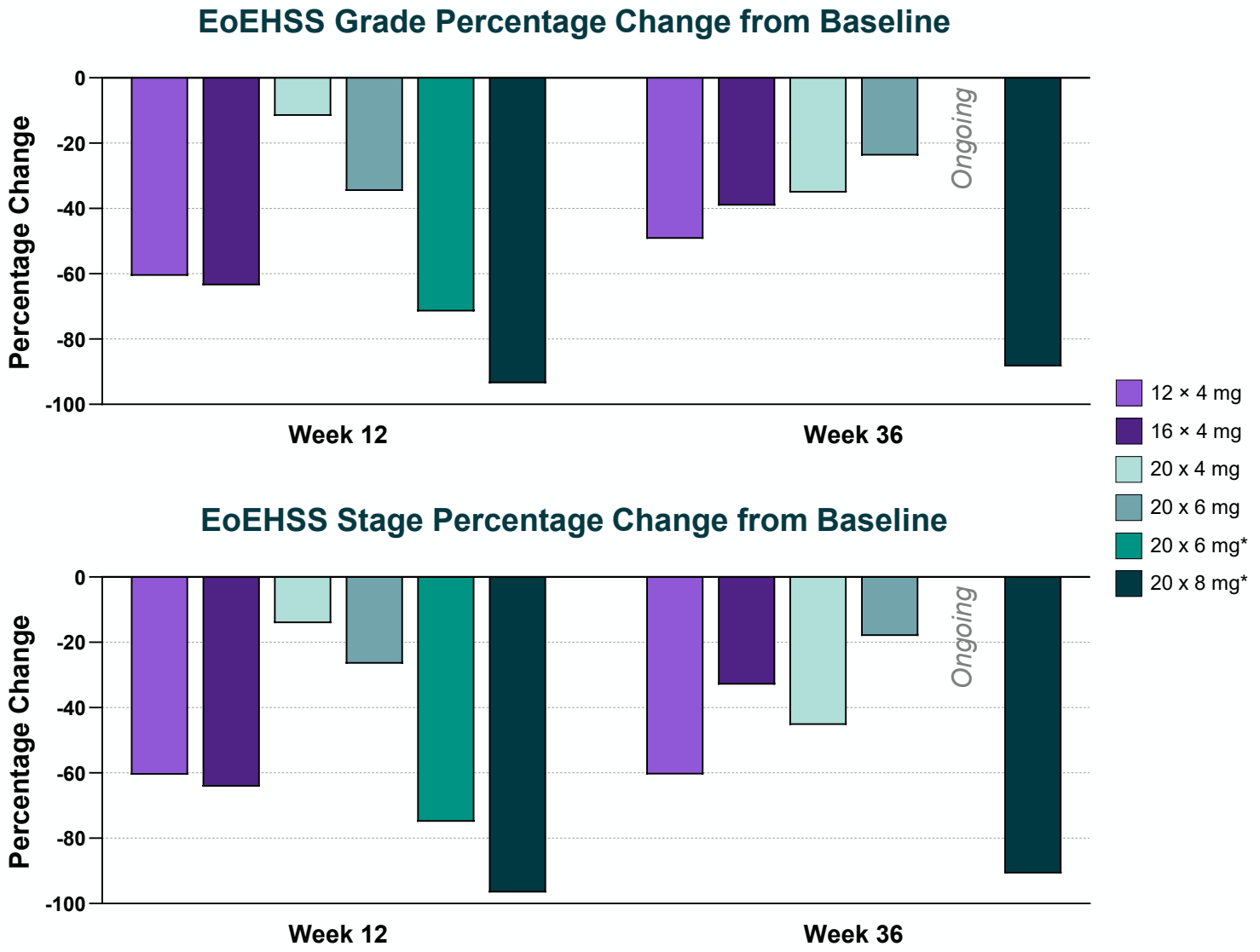

AE, adverse event.

# Dose Escalation of EP-104GI Improves EoE Histopathology Over 36 Weeks

## EoEHSS

- Assesses inflammatory & fibrotic histopathological features of EoE: [1]
  - Grade (severity)
  - Stage (extent)

- By week 36, reductions were observed across all cohorts
  - Grade: From -23% to -88%
  - Stage: From -14% to -90%
- Greatest improvements observed in the highest dose cohort at all timepoints




EoE, eosinophilic eosophagitis; EoEHSS, Eosinophilic Esophagitis Histology Scoring System.

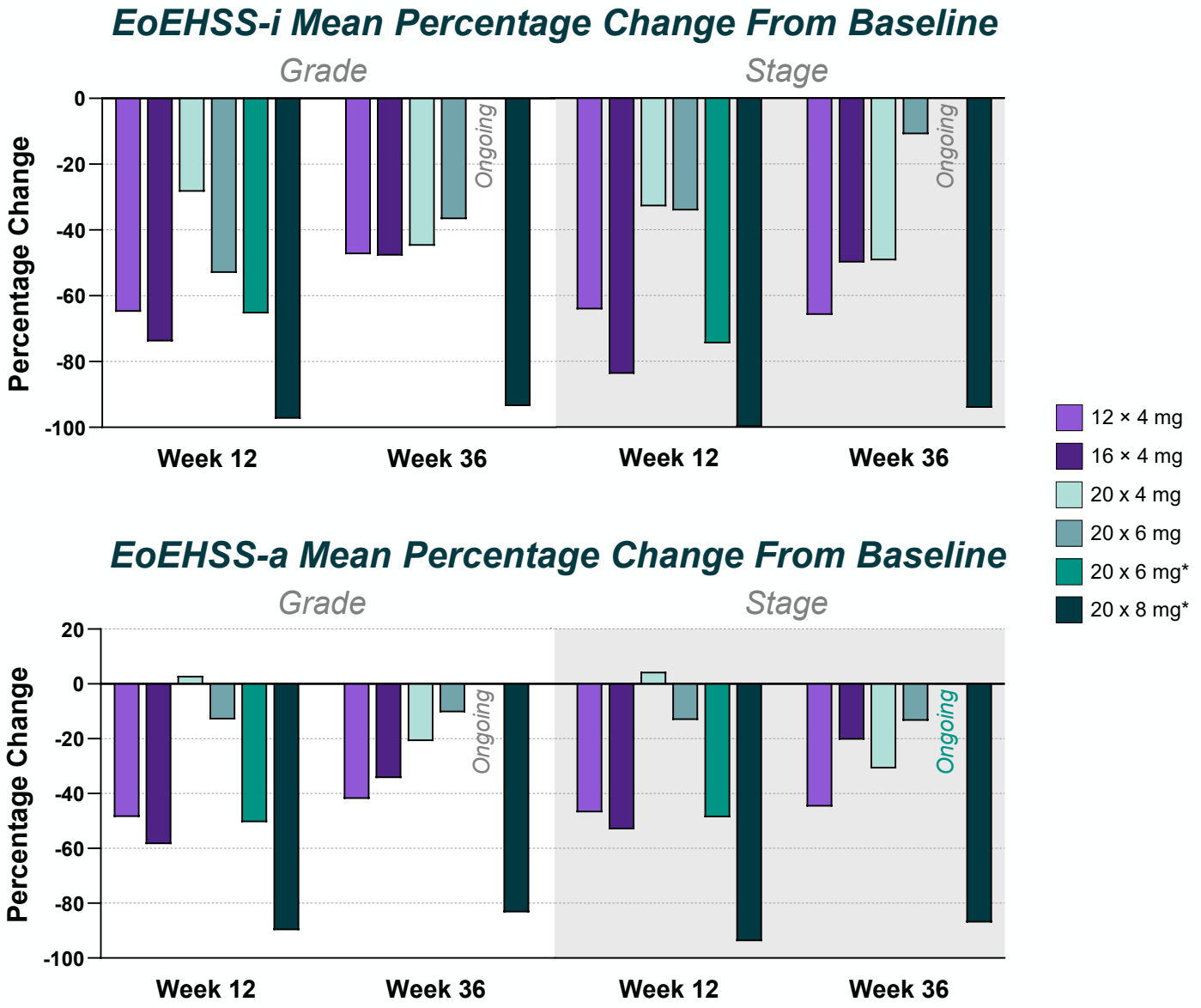
1. Collins et al. (2016) Dis Esophagus. 30(3):1-8.

# EP-104GI Treatment Improves Inflammatory and Structural Features of EoE

## EoEHSS Sub scores

- EoEHSS **inflammatory** (EoEHSS-i) sub score
  - *Based on features of inflammation*
- EoEHSS **architectural** (EoEHSS-a) sub score
  - *Based on features of esophageal remodeling*

- For most cohorts, both inflammatory and structural features of EoE improve over 36 weeks
- Largest improvements at week 36 were observed for the highest dose in both sub scores (83–94%)

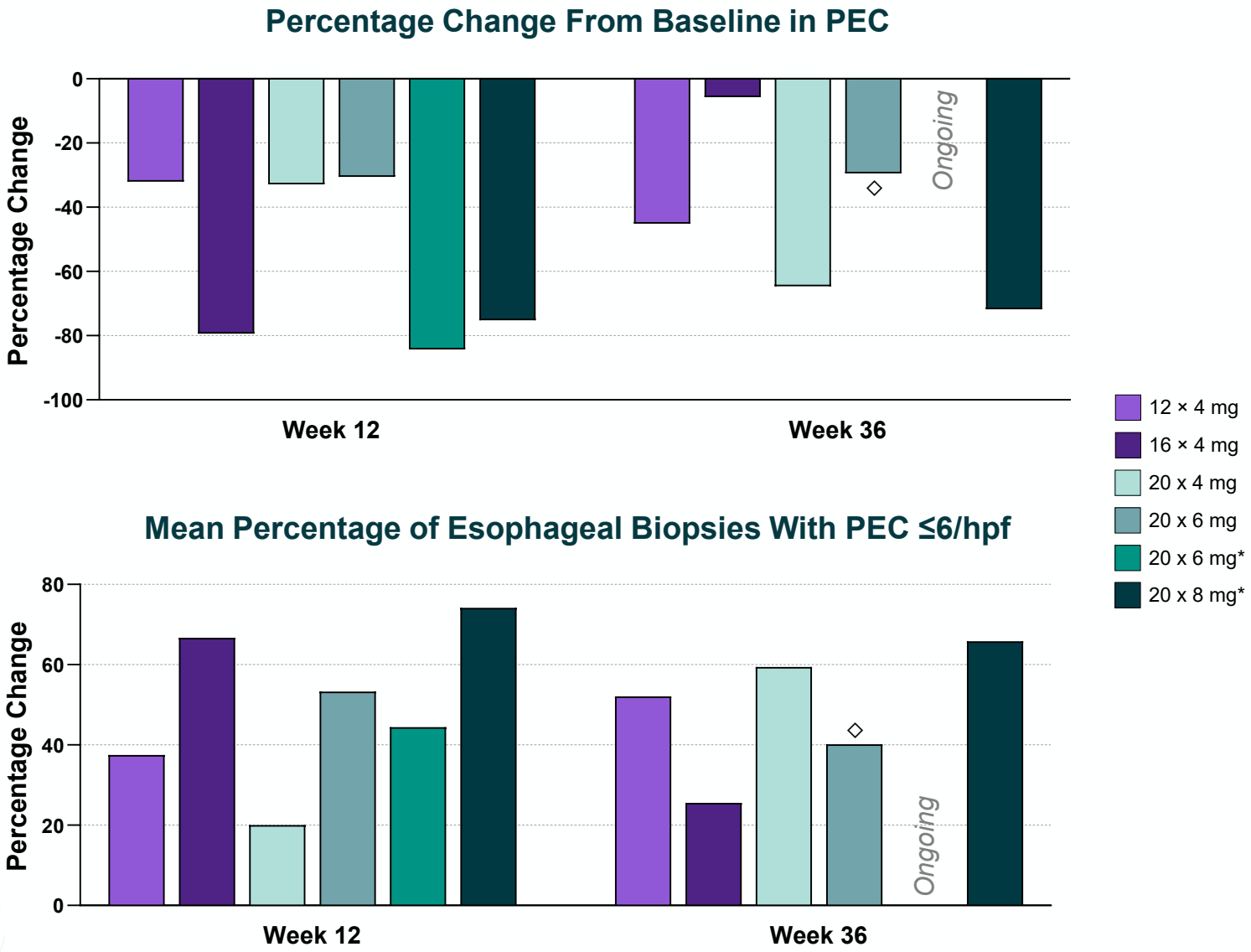



EoE, eosinophilic eosophagitis; EoEHSS-i, Eosinophilic Esophagitis Histology Scoring System inflammatory; EoEHSS-a, Eosinophilic Esophagitis Histology Scoring System architectural.

1. Min et al. (2021) JACI 149(2):782–787.e1.

# Consistent Improvements in Eosinophil Counts

- Changes from baseline in Peak Eosinophil Count (PEC) at week 36 showed improvements across cohorts
- Proportion of esophageal biopsies with PEC ≤6/hpf trended upward with increasing doses
- Overall, effects of EP-104GI on PEC are consistent with improvements in EoEHSS




Eos, eosinophils; EoEHSS, Eosinophilic Esophagitis Histology Scoring System; hpf, high-power field; PEC, peak eosinophil count.

n = 3/cohort, except for ◇, where n = 2

# Conclusions

- Administration of EP-104GI has been feasible, safe, and well tolerated to date, with no signs of adrenal suppression, or other dose-limiting toxicity over 36 weeks or 52 weeks
- These results demonstrate long-term improvements in extent and severity of EoE histopathology up to 36 weeks following a single EP-104GI treatment
- Overall, our results support the continued dose optimization of EP-104GI (20 x 6 mg & 20 x 8 mg) for the treatment of EoE in the ongoing part 2 of the RESOLVE trial

EoE, eosinophilic eosophagitis.