

# Improvements in Dysphagia Following Single Administration of EP-104GI Persist Over 52 Weeks During Dose Escalation in The Ongoing RESOLVE Phase 1b/2 Trial in Eosinophilic Esophagitis

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## BACKGROUND

- Eosinophilic esophagitis (EoE) is a chronic, immune-mediated disease where local inflammation and fibrosis lead to dysphagia, pain, and food impaction <sup>1</sup>
- EP-104GI is a novel formulation of injectable fluticasone propionate, coated in a polymer layer, designed to release drug at near-constant rate for extended periods.
  - It provides sustained, drug release within esophageal submucosa and is currently investigated for the treatment of EoE <sup>2</sup>
- Provisional results on safety, tolerability and dysphagia symptoms from the open-label Phase 1b part of the RESOLVE trial, 52 weeks after a single administration of EP-104GI are presented.

## METHODS

- RESOLVE (NCT05608681) is a Phase 1b/2, multicenter trial, evaluating the pharmacokinetics, safety, and tolerability of EP-104GI in adults with EoE.
- In the open-label Phase1b, dose escalation portion, EP-104GI was injected at baseline (Day 0) in the esophageal wall during endoscopy in escalating dose cohorts (by number of sites or dose per site; n=3 per cohort) (Fig 1)
- Exploratory dysphagia symptoms were assessed using the Straumann Dysphagia Index (SDI) [0-9] (Fig 1) <sup>3,4</sup>
  - A reduction of 3 points or more in SDI has been proposed as a response threshold <sup>3</sup>
- Data on systemic fluticasone propionate pharmacokinetics, treatment-emergent adverse events and SDI scores (cut-off date Sept. 1, 2026) are included.

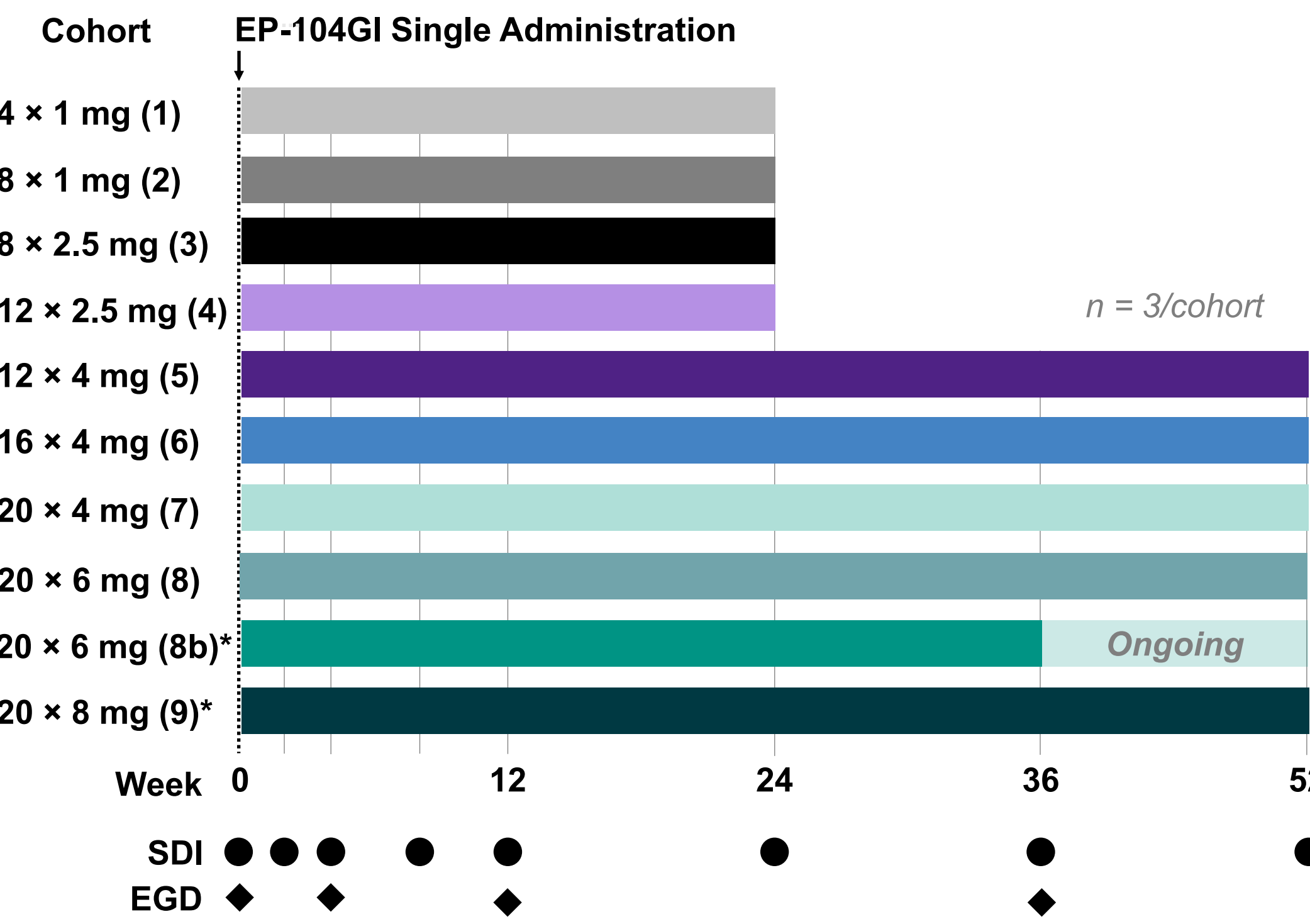


Figure 1. RESOLVE-I Dose Escalation Study Design

## REFERENCES

1. Dellon et al. (2025) AJG 120(1):31-59. 2. Malone et al. (2025) Gastroenterology, 169:1 S-402. 3. Straumann et al. (2010) Gastroenterology 139(5):1526-37, 1537.e1. 4. Schoepfer et al. (2016) Dis Esophagus. 29(8):959-966

Abbreviations: EoE, Eosinophilic esophagitis; SDI, Straumann Dysphagia Index

## RESULTS

Table 1. Treatment-Emergent Adverse Events (Safety Analysis Set\*\*)

| Dose Cohort                     | 4 x 1 mg<br>(cohort 1) | 8 x 1 mg<br>(cohort 2) | 8 x 2.5 mg<br>(cohort 3) | 12 x 2.5 mg<br>(cohort 4) | 12 x 4 mg<br>(cohort 5) | 16 x 4 mg<br>(cohort 6) | 20 x 4 mg<br>(cohort 7) | 20 x 6 mg<br>(cohort 8) | 20 x 6 mg<br>(cohort 8b) | 20 x 8 mg<br>(cohort 9) | Total     |
|---------------------------------|------------------------|------------------------|--------------------------|---------------------------|-------------------------|-------------------------|-------------------------|-------------------------|--------------------------|-------------------------|-----------|
| n                               | 3                      | 3                      | 3                        | 3                         | 3                       | 3                       | 4**                     | 3                       | 4**                      | 3                       | 32        |
| Any TEAE                        | 3 (100)                | 1 (33.3)               | 2 (66.7)                 | 2 (66.7)                  | 2 (66.7)                | 2 (66.7)                | 4 (100)                 | 3 (100)                 | 4 (100)                  | 3 (100)                 | 26 (81.2) |
| Serious TEAEs                   | 0 (0)                  | 0 (0)                  | 0 (0)                    | 0 (0)                     | 0 (0)                   | 0 (0)                   | 0 (0)                   | 0 (0)                   | 0 (0)                    | 0 (0)                   | 0 (0)     |
| Most Common TEAE (≥3/32; n (%)) |                        |                        |                          |                           |                         |                         |                         |                         |                          |                         |           |
| Nausea                          | 1 (33.3)               | 0 (0)                  | 0 (0)                    | 1 (33.3)                  | 0 (0)                   | 0 (0)                   | 1 (25)                  | 1 (33.3)                | 1 (25)                   | 0 (0)                   | 5 (15.6)  |
| Chest pain                      | 0 (0)                  | 0 (0)                  | 1 (33.3)                 | 0 (0)                     | 0 (0)                   | 0 (0)                   | 0 (0)                   | 1 (33.3)                | 1 (25)                   | 1 (33.3)                | 4 (12.5)  |
| Dyspepsia                       | 0 (0)                  | 0 (0)                  | 0 (0)                    | 0 (0)                     | 0 (0)                   | 0 (0)                   | 0 (0)                   | 1 (33.3)                | 3 (75)                   | 0 (0)                   | 4 (12.5)  |
| Nasopharyngitis                 | 0 (0)                  | 0 (0)                  | 0 (0)                    | 0 (0)                     | 1 (33.3)                | 0 (0)                   | 1 (25)                  | 0 (0)                   | 2 (50)                   | 0 (0)                   | 4 (12.5)  |
| Dizziness                       | 0 (0)                  | 0 (0)                  | 0 (0)                    | 0 (0)                     | 0 (0)                   | 0 (0)                   | 1 (25)                  | 1 (33.3)                | 1 (25)                   | 0 (0)                   | 3 (9.4)   |
| Fatigue                         | 0 (0)                  | 0 (0)                  | 0 (0)                    | 0 (0)                     | 0 (0)                   | 0 (0)                   | 1 (25)                  | 0 (0)                   | 2 (50)                   | 0 (0)                   | 3 (9.4)   |

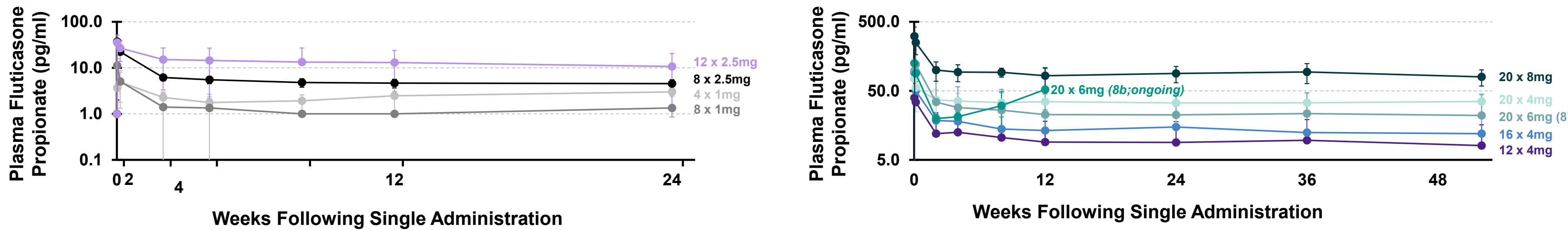


Figure 1. Fluticasone Propionate Plasma Concentration After EP-104GI Administration (Full Analysis Set)

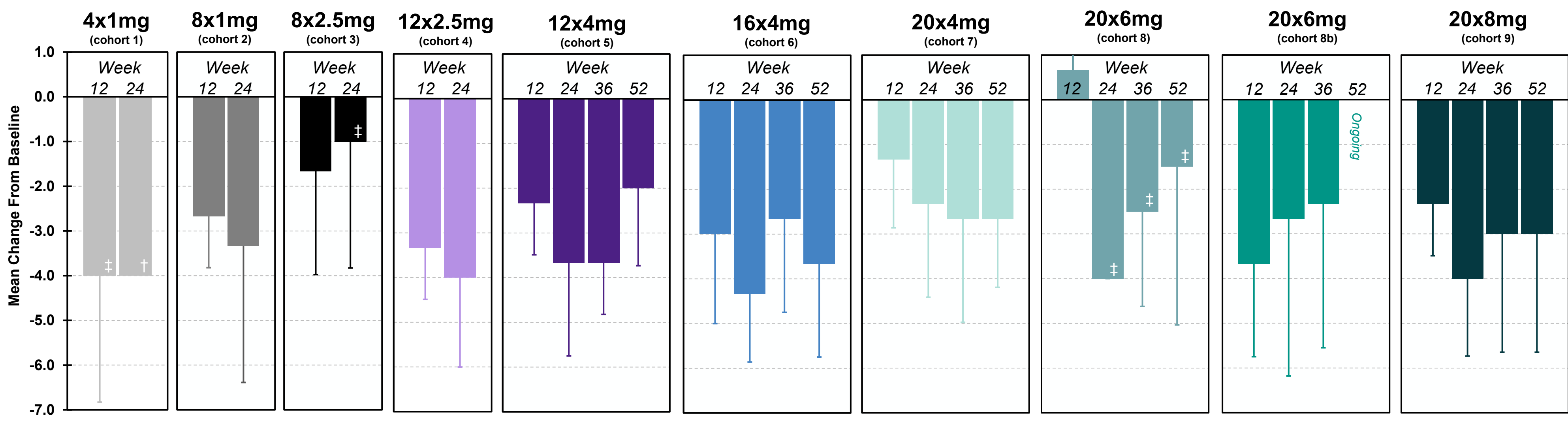


Figure 2. Mean Change From Baseline In SDI Score Per Cohort (Full Analysis Set\*\*\*)

Table 2. Number of Participants with ≥3 Points Improvement From Baseline (Full Analysis Set\*\*\*)

| Dose Cohort                                                      | 4 x 1 mg<br>(cohort 1) | 8 x 1 mg<br>(cohort 2) | 8 x 2.5 mg<br>(cohort 3) | 12 x 2.5 mg<br>(cohort 4) | 12 x 4 mg<br>(cohort 5) | 16 x 4 mg<br>(cohort 6) | 20 x 4 mg<br>(cohort 7) | 20 x 6 mg<br>(cohort 8) | 20 x 6 mg<br>(cohort 8b*) | 20 x 8 mg<br>(cohort 9) |
|------------------------------------------------------------------|------------------------|------------------------|--------------------------|---------------------------|-------------------------|-------------------------|-------------------------|-------------------------|---------------------------|-------------------------|
| Mean SDI Score at Baseline                                       |                        |                        |                          |                           |                         |                         |                         |                         |                           |                         |
| Baseline                                                         | 5.3 ±0.6               | 6.7 ±0.6               | 6 ±1.0                   | 7.3 ±1.2                  | 5.7 ±0.6                | 6.3 ±0.6                | 5.0 ±0.0                | 5.0 ±1.0                | 6.0 ±0.0                  | 5.7 ±1.2                |
| Number of Participants with Reduction of ≥3 Points From Baseline |                        |                        |                          |                           |                         |                         |                         |                         |                           |                         |
| Week 12                                                          | 1/2                    | 1/3                    | 2/3                      | 2/3                       | 2/3                     | 2/3                     | 1/3                     | 0/3                     | 2/3                       | 2/3                     |
| Week 24                                                          | 1/1                    | 2/3                    | 1/2                      | 2/3                       | 2/3                     | 3/3                     | 2/3                     | 2/2                     | 2/3                       | 2/3                     |
| Week 36                                                          | -                      | -                      | -                        | -                         | 3/3                     | 1/3                     | 2/3                     | 1/2                     | 1/3                       | 2/3                     |
| Week 52                                                          | -                      | -                      | -                        | -                         | 2/3                     | 2/3                     | 2/3                     | 1/2                     | ongoing                   | 2/3                     |

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

\*\* The safety analysis set includes all treated participants including two participants (from cohort 7 & 8) with injection protocol deviations excluded from the full analysis set

\*\*\* The full analysis set includes only participants treated per protocol, without additional participant enrollment

- EP-104GI was generally safe and well tolerated for all doses, with no drug-related serious adverse events. (Tab 1)
- Single administration of EP-104GI at baseline led to plasma fluticasone propionate concentrations typically <100 pg/ml over 52 weeks, following an initial peak (Fig 1)
- Dose cohorts showed overall substantial reductions in SDI total scores at week 24, 36 and 52, indicating consistent improvement from baseline (Fig 2)
  - At week 36 and 52, all dose cohorts reported to date persistent mean improvements per cohort of at least 2.3 and 1.5 points, respectively (Fig 2)
- Participants reporting SDI improvements from baseline of ≥3 points are reported in Tab 2

## CONCLUSIONS

- Administration of EP-104GI was generally safe and well tolerated to date
- The study found persistent improvements from baseline in dysphagia and in ratios of SDI responders over 52 weeks following a single administration of EP-104GI in participants with EoE
- These results overall support the potential of EP-104GI as a long-term, single administration treatment for dysphagia in EoE
- Study limitations include a small number of participants by cohort and the lack of a placebo control; doses of 20x6mg and 20x8mg are currently investigated in a greater number of subjects in the phase 2, placebo-controlled part of RESOLVE