

Single Administration of Escalating Doses of EP-104GI Leads to Improvements in Frequency and Severity of Dysphagia Up to 52 Weeks in The RESOLVE Phase 1b/2 Study in Eosinophilic Esophagitis

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BACKGROUND

- Dysphagia presents as a cardinal symptom of Eosinophilic esophagitis (EoE).¹
- EP-104GI is a novel proprietary formulation of injectable fluticasone propionate, designed to provide sustained drug release over an extended period.²
- EP-104GI is currently investigated for the treatment of EoE.²
- Safety, pharmacokinetic and exploratory efficacy results on dysphagia symptom improvements from baseline in the phase 1b portion of the RESOLVE trial are reported.

METHODS

- In this open-label dose escalation portion of RESOLVE, EP-104GI was injected at baseline (Day 0) in escalating dose cohorts (by number of injection sites or dose per site; n=3 per cohort). (Fig 1)
- Fluticasone propionate concentration was assessed at baseline, 2H, 24H, and 2, 4, 8 12, 24 and 52 weeks post-treatment.
- Biopsies were collected during endoscopy. Dysphagia was assessed using the Straumann Dysphagia Index (SDI) [0-9].^{3,4} (Fig 1)
- SDI and treatment-emergent adverse events (TEAEs) data are included (cut-off Sept. 1st, 2026).

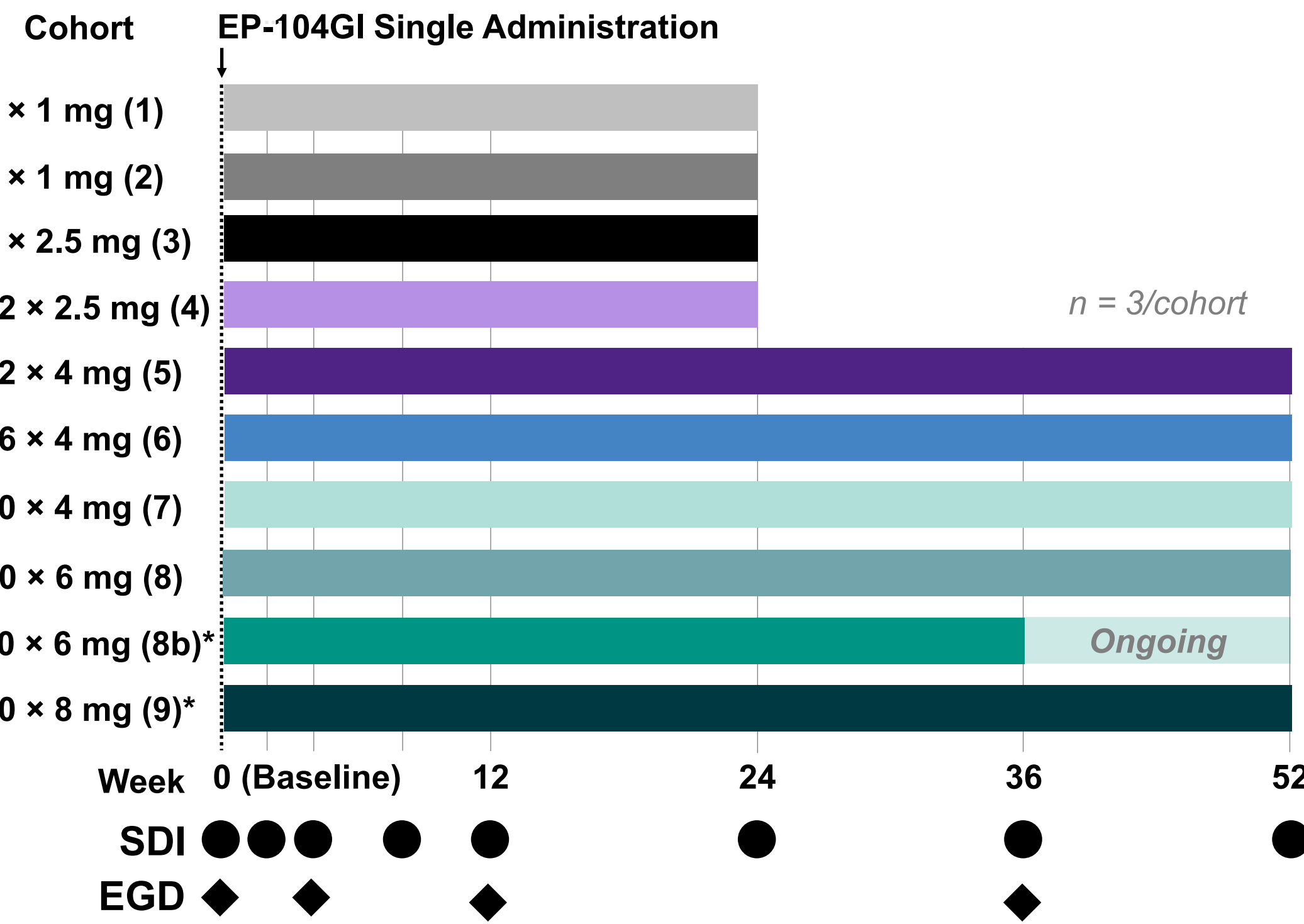


Figure 1. RESOLVE (NCT05608681): Phase 1b/2, multicenter trial, evaluating the pharmacokinetics, safety, and tolerability of EP-104GI injection in adults with EoE

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

RESULTS

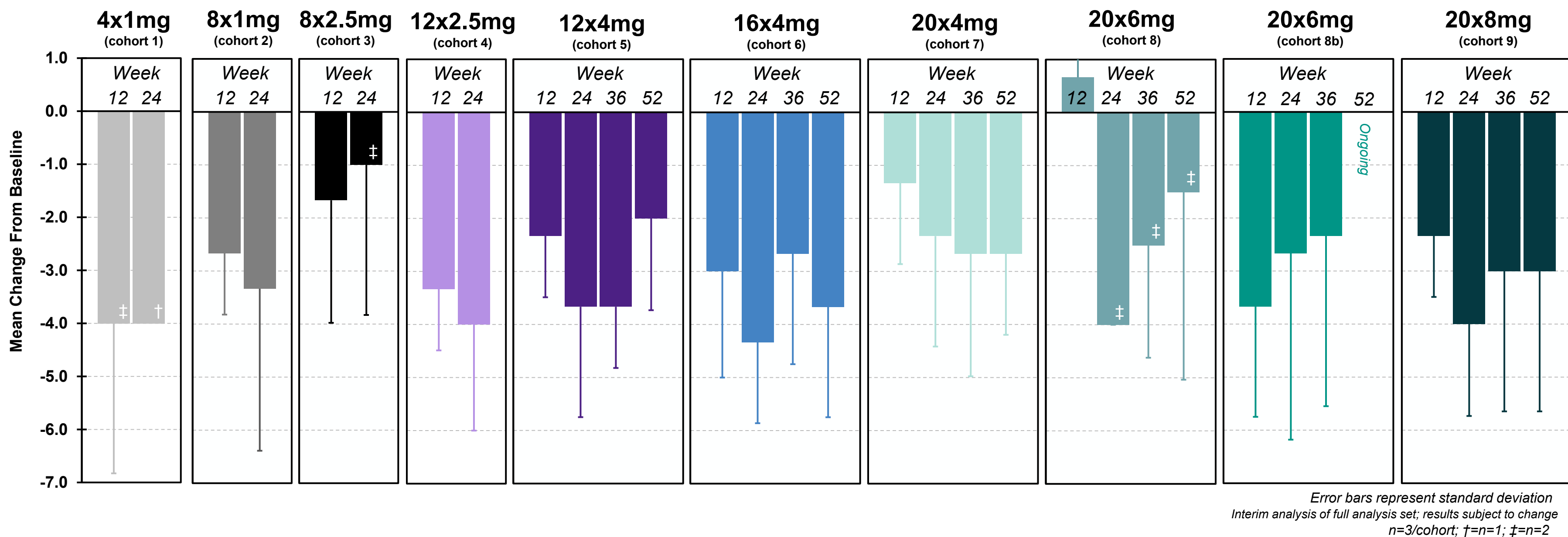


Figure 2. Mean Change From Baseline In SDI Score Per Cohort (Full Analysis Set***)

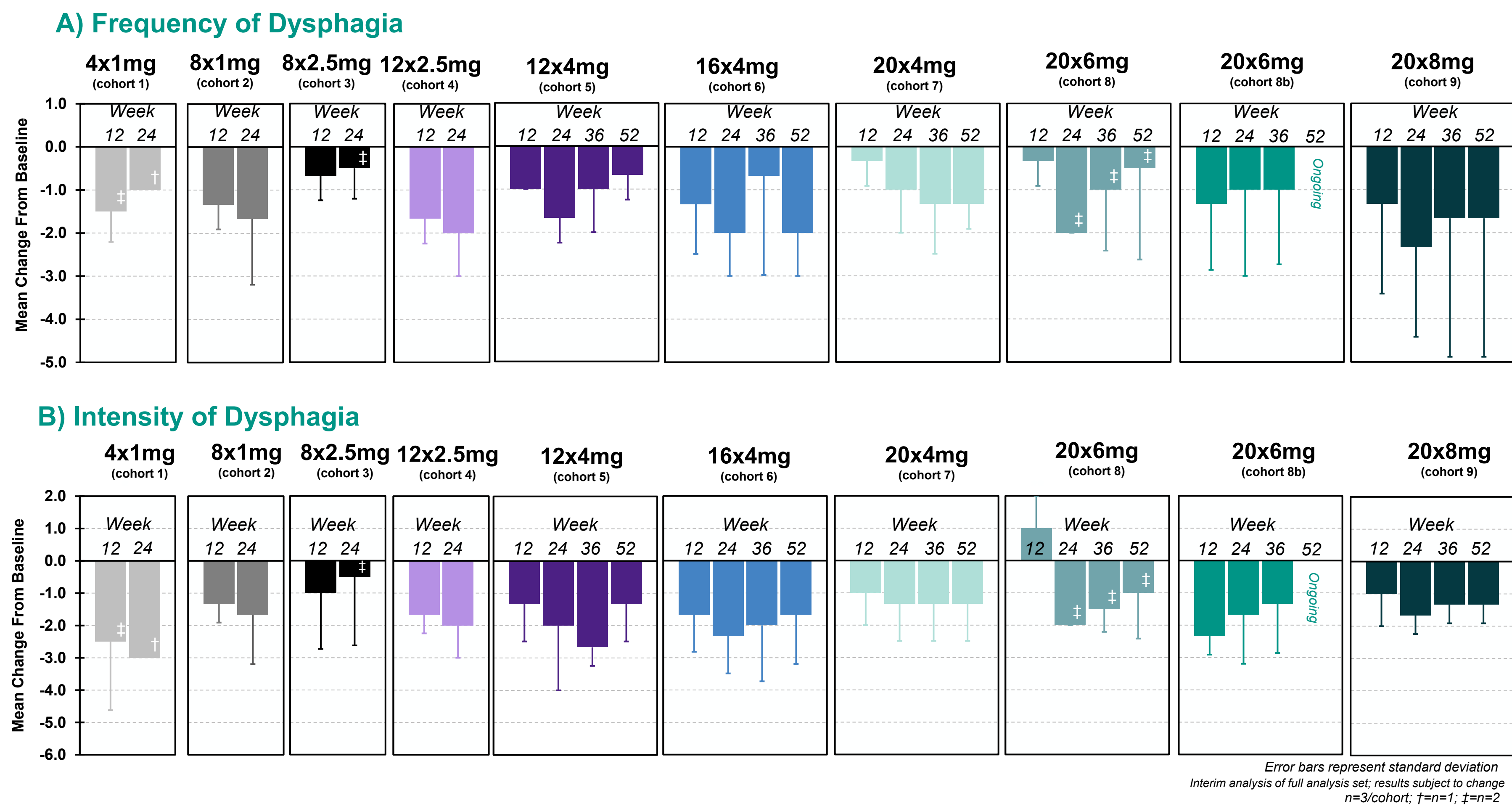


Figure 3. Mean Change From Baseline In SDI Subscales Per Cohort (Full Analysis Set***)

- All dose cohorts showed mean reductions in SDI total scores (mean $\pm$ SD; [min, max]) at week 24 [-1.0 $\pm$ 2.8, -4.3 $\pm$ 1.5], 36 [-2.3 $\pm$ 2.3, -3.7 $\pm$ 1.2] and 52 [-1.5 $\pm$ 3.5, -3.7 $\pm$ 2.0], indicating persistent improvement from baseline. (Fig 2)
- Participants reported consistent improvements from baseline in both frequency and intensity of dysphagia with EP-104GI treatment. Each shows improvements except for cohort 8 (week 12). These were consistent with SDI changes from baseline. (Fig 3a-b)

CONCLUSIONS

- EP-104GI was generally safe and well tolerated with no treatment-related SAEs.
- Improvements from baseline in SDI score over 52 weeks were supported by consistent improvements in both frequency and intensity symptom subscales.
- These results support the potential of EP-104GI as a long-term duration treatment for dysphagia in EoE.
- The ongoing Phase 2, randomized, controlled portion of RESOLVE is investigating EP-104GI in a larger number of participants.

- EP-104GI was generally safe and well tolerated for all doses, with no treatment-related serious adverse events (SAEs).
- Most common (>3/32**) TEAEs were nausea (15.6%), chest pain (12.5%), dyspepsia (12.5%), nasopharyngitis (12.5%), dizziness (9.4%), and fatigue (9.4%).
- Mean plasma fluticasone propionate concentrations remained at constant systemic levels (<100 pg/ml) over 52 weeks, following an initial 2-week peak (mean $\pm$ SD; $\leq$ 309 $\pm$ 111 pg/ml), for all dose cohorts.
- Study limitations include small cohort numbers, lack of placebo control and open-label design.

* 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

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