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Summary

IMPROVEMENTS IN HISTOPATHOLOGICAL FEATURES OF EOSINOPHILIC ESOPHAGITIS FOLLOWING A SINGLE ADMINISTRATION OF EP-104GI DURING DOSE ESCALATION IN THE PHASE 1B/2 RESOLVE STUDY

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Single injection of EP-104GI, a long-acting esophageal wall-injected fluticasone formulation, demonstrated sustained improvements in both inflammatory and structural histopathology in adult eosinophilic esophagitis patients for 36 weeks in the phase 1b RESOLVE dose-escalation trial.

KEY POINTS

- The highest dose cohort (20 injections × 8mg) showed inflammatory subscore reductions of 93-94% (grade/stage) and structural subscore reductions of 83-87% at 36 weeks following single administration.
- All dose cohorts assessed at 36 weeks showed histopathological improvements from baseline by EoEHSS, with improvements in both inflammatory and structural features.
- Individual inflammatory features in the 20×8mg cohort improved substantially: eosinophil abscesses and surface layering decreased 100%, eosinophil infiltration decreased 89-92%, and surface epithelial alteration decreased 93-91%.
- Structural features in the 20×8mg cohort also improved: basal cell hyperplasia decreased 87-89%, distended intercellular space decreased 72-81%, and lamina propria fibrosis decreased 83%.
- EP-104GI was generally safe and well tolerated across all dose cohorts with no dose-limiting toxicities; the most common adverse event was nausea and no serious treatment-emergent adverse events were reported.

– The 20×6mg and 20×8mg dose regimens have been selected for optimization in the ongoing blinded, placebo-controlled randomized phase 2 portion of the RESOLVE trial.

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