Patologic accumulation and dysfunction of eosinophils and mast cells are implicated in multiple chronic inflammatory diseases in the gastrointestinal (GI) tract including eosinophilic esophagitis (EoE), gastritis (EG), duodenitis (ED), and colitis—conditions termed eosinophilic gastrointestinal and/or cutaneous diseases (EGIDs). Patients with EGIDs have decreased quality of life due to chronic debilitating and often nonspecific symptoms such as dysphagia, abdominal pain, bloating, nausea, vomiting, and diarrhea.

Figure 1. Pathogenesis of EGIDs

**OBJECTIVES**

- Evaluate the discovery rate of EG and/or EoD among previously unclassified patients with chronic non-specific GI symptoms enrolled in ENIGMA
- Describe patients with new or established diagnoses of EG and/or EoD
- Compare responses to lirentelimab in patients with new vs established diagnoses of EG and/or EoD

**METHODS**

- **ENIGMA** was a phase 2 multi-center, randomized, double-blind, placebo-controlled study of lirentelimab in 65 patients with EG and/or EoD.
  - Patients were eligible for the study if they had:
    - Active moderate-to-severe symptoms based on the daily EG/EoD-SQ questionnaire, which assesses 8 symptoms (each on a scale of 0–10) to produce a Total Symptom Score (TSS; range, 0–80).
    - Confirmed EG and/or EoD, based on histologic biopsy from the stomach (≥10 eos/hpf in 5 hpfs) and/or from the duodenum (≥30 eos/hpf in 3 hpfs)
    - Patients were randomly assigned (1:1:1) to groups that received 4 monthly doses of placebo, a low-dose lirentelimab regimen (first dose 0.3 mg/kg, last doses 1.0 mg/kg), or a high-dose lirentelimab regimen (0.3 mg/kg, 1.0 mg/kg, and last 3.0 mg/kg).
- **OLE** is ongoing; data presented from July 7, 2021

**RESULTS**

- 51 patients entered screening without an established diagnosis of EG or EoD; 15 patients (29%) were diagnosed with EG and/or EoD in ENIGMA criteria for EG and/or EoD, and 65 were randomly assigned to groups given baseline biopsy, 72 met histologic criteria for EG or EoD, 13 patients (18%) were diagnosed with EG and/or EoD (based on ENIGMA OLE criteria) at ENIGMA ENIGMA OLE is ongoing; data presented from July 7, 2021

**CONCLUSIONS/DISCUSSION**

- **Similar Efficacy of Lirentelimab in Patients With New vs Established Diagnoses of Eosinophilic Gastritis and/or Duodenitis in a Randomized Trial**

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1University of Utah, Salt Lake City, UT; 2Rady Children’s Hospital, San Diego, CA; 3Mayo Clinic, Rochester, MN; 4Allakos Inc., Redwood City, CA; 5University of North Carolina, Chapel Hill


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