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**Name of Study:** **Study of Dupilumab in Adult Patients with Active Eosinophilic Esophagitis (EoE)-(Regeneron)**

**LINK:** <https://clinicaltrials.gov/ct2/show/NCT02379052?term=regeneron+eoe&rank=1>

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**ENROLLMENT BEGINS:** May 2016

**ENROLLMENT ENDS:** May 2017 (May add an extension study)

**SUMMARY:** The primary objective of the study is to assess the clinical efficacy of repeat SC dose of dupilumab, compared with placebo, to relieve symptoms in adult patients with active, moderate to severe EoE.

**Inclusion:**

1. Male or female, 18 to 65 years old
2. Documented diagnosis of EoE by endoscopy prior to or at screening. Note: Must include a demonstration of intraepithelial eosinophilic infiltration (peak cell count  $\geq 15$  eosinophils/high power field [eos/hpf] [400X]) from esophageal biopsy specimens from endoscopy performed immediately after at least 8 weeks of treatment with high dose (or twice-daily dosing) proton pump inhibitors (PPIs)
3. History (by patient report) of on average at least 2 episodes of dysphagia (with intake of solids off anti-inflammatory therapy) per week in the 4 weeks prior to screening and on average at least 2 episodes of documented dysphagia per week in the weeks between screening and baseline; dysphagia is defined as trouble swallowing solid food, or having solid food stick, by patient report
4. Must remain on a stabilized diet for at least 6 weeks prior to screening and during the course of the study; stable diet is defined as no initiation of single or multiple elimination diets or reintroduction of previously eliminated food groups

**Exclusion:**

1. Prior participation in a dupilumab (anti-IL-4R) clinical trial

2. Other causes of esophageal eosinophilia or the following diseases: hypereosinophilic syndromes, Churg-Strauss vasculitis, and eosinophilic gastroenteritis
3. History of achalasia, active *Helicobacter pylori* infection, Crohn's disease, ulcerative colitis, celiac disease, and prior esophageal surgery prior to screening
4. Any esophageal stricture unable to be passed with a standard, diagnostic, adult (9 to 10 mm) upper endoscope or any critical esophageal stricture that requires dilation at screening
5. History of bleeding disorders or esophageal varices