FDA approves first treatment for eosinophilic esophagitis

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The U.S. Food and Drug Administration (FDA) approved the

monoclonal antibody Dupixent (dupilumab) to treat eosinophilic esophagitis patients 12 years and older.

The efficacy and safety of Dupixent was evaluated in a randomized, double-blind, parallel-group (Part A and Part B), multicenter, placebo-controlled trial, in which patients received either placebo or Dupixent every week for 24 weeks.

According to the results of the study, in Part A of the trial, 60 percent of the 42 patients who received Dupixent achieved the predetermined level of reduced eosinophils in the esophagus versus 5 percent of the 39 patients who received a placebo. Patients in Part A receiving Dupixent experienced an average improvement of 22 points in their Dysphagia Symptom Questionnaire (DSQ) score versus 10 points in patients receiving placebo. In Part B, 59 percent of the 80 patients who received Dupixent achieved the predetermined level of reduced eosinophils in the esophagus versus 6 percent of the 79 patients who received a placebo; improvements in DSQ score were 34 and 14 points, respectively.

"As researchers and clinicians have gained knowledge about eosinophilic esophagitis in recent years, more cases of the disorder have been recognized and diagnosed in the U.S.," Jessica Lee, M.D., director of the Division of Gastroenterology in the FDA Center for Drug Evaluation and Research, said in a statement. "Today's approval will fulfill an important unmet need for the increasing number of patients with eosinophilic esophagitis."

Approval of Dupixent was granted to Regeneron Pharmaceuticals.

More information: More Information