FDA approves Dupixent (dupilumab) for children with eosinophilic esophagitis

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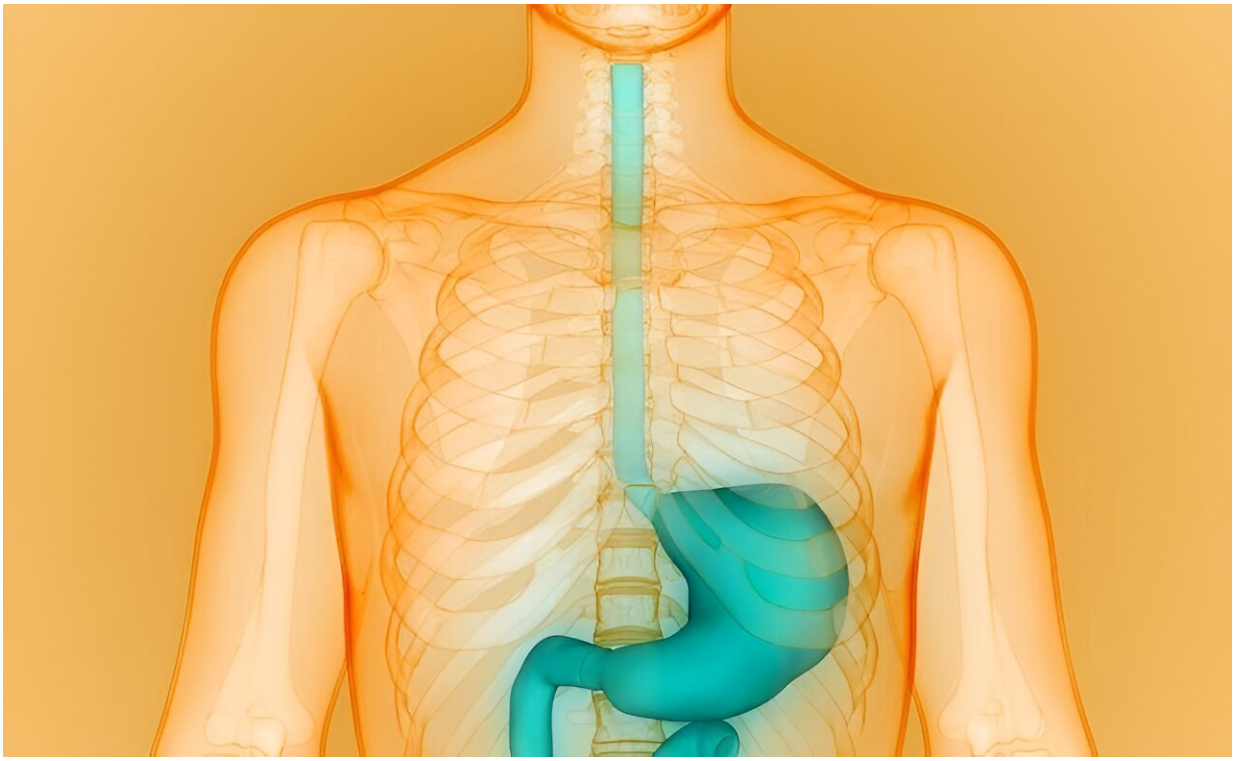

The U.S. Food and Drug Administration has approved Regeneron's Dupixent (dupilumab) for the treatment of pediatric patients (aged one to 11 years) with eosinophilic esophagitis (EoE).

This approval, for children weighing at least 15 kg, expands the May 2022 FDA approval for patients with EoE aged 12 years and older weighing at least 40 kg.

The approval is based on data from the Phase III EoE KIDS trial with two parts (part A and B). The study revealed that at 16 weeks, 66 percent of children who received higher-dose Dupixent at tiered dosing regimens based on weight achieved histological disease remission (no more than six eosinophils/high power field), the primary end point, versus 3 percent receiving placebo.

At week 52, histological remission was sustained for 17 of 32 children (53 percent) receiving Dupixent in parts A and B; histological remission was also achieved in eight of 15 children (53 percent) who switched to Dupixent from placebo in part B.

At week 16, based on caregiver reports, a greater decrease in the proportion of days with one or more signs of EoE was seen in children treated with Dupixent versus placebo.

"With this approval, Dupixent becomes the first and only treatment option for EoE patients aged one and older, weighing at least 15 kg," George D. Yancopoulos, M.D., Ph.D., president and chief scientific officer at Regeneron and a principal inventor of Dupixent, said in a statement.

"By targeting the underlying type 2 inflammation that contributes to this disease, Dupixent has the potential to transform the standard of care for these children as it has for adults and adolescents with EoE."

More information: Press Release