Dupixent® (dupilumab) – New indication

- On May 20, 2022, Regeneron and Sanofi announced the FDA approval of Dupixent (dupilumab), for the treatment of adult and pediatric patients aged 12 years and older, weighing at least 40 kg, with eosinophilic esophagitis (EoE).

- Dupixent is also approved:

    - For the treatment of adult and pediatric patients aged 6 years and older with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable.
    - As an add-on maintenance treatment of adult and pediatric patients aged 6 years and older with moderate-to-severe asthma characterized by an eosinophilic phenotype or with oral corticosteroid dependent asthma.
    - As an add-on maintenance treatment in adult patients with inadequately controlled chronic rhinosinusitis with nasal polyposis.

- EoE is a chronic inflammatory disease driven by type 2 inflammation that damages the esophagus and prevents it from working properly. For people with EoE, swallowing even small amounts of food can be a painful and worrisome choking experience. An estimated 160,000 patients are living with EoE in the U.S.

- The approval of Dupixent for the new indication was based on a single randomized, double-blind, placebo-controlled study, including two 24-week treatment periods (Parts A and B), in 240 adult and pediatric patients with EoE. In both parts, patients were randomized to receive Dupixent or placebo. The co-primary endpoints in Parts A and B were the (1) proportion of patients achieving histological remission defined as peak esophageal intraepithelial eosinophil count of ≤6 eos/hpf at week 24; and (2) the absolute change in the subject-reported Dysphagia Symptom Questionnaire (DSQ) score from baseline to week 24.

    - In Part A, 59.5% and 5.1% of patients treated with Dupixent and placebo, respectively, achieved histological remission (treatment difference 57.0, 95% CI: 40.9, 73.1). The absolute change from baseline in DSQ score was -21.9 and -9.6, respectively (treatment difference -12.3, 95% CI: -19.1, -5.5).
    - In Part B, 58.8% and 6.3% of patients treated with Dupixent and placebo, respectively, achieved histological remission (treatment difference 53.5, 95% CI: 41.2, 65.8). The absolute change from baseline in DSQ score was -23.8 and -13.9, respectively (treatment difference -9.9, 95% CI: -14.8, -5.0).

- The most common adverse reactions (≥ 2%) with Dupixent use in EoE were injection site reactions, upper respiratory tract infections, arthralgia, and herpes viral infections.

- The recommended dose of Dupixent for the treatment of EoE is 300 mg given subcutaneously every week.

    - Refer to the Dupixent drug label for dosing for all its other indications and additional dosing recommendations.

At Optum, we help create a healthier world, one insight, one connection, one person at a time. All Optum trademarks and logos are owned by Optum, Inc., in the U.S. and other jurisdictions. All other trademarks are the property of their respective owners. This document contains information that is considered proprietary to Optum Rx and should not be reproduced without the express written consent of Optum Rx. RxNews® is published by the Optum Rx Clinical Services Department.

© 2022 Optum, Inc. All rights reserved. ORX6547968A-TEMPLATE_220208