Dupixent® (dupilumab) – Expanded indication

- On October 20, 2021, Sanofi and Regeneron announced the FDA approval of Dupixent (dupilumab), as an add-on maintenance treatment of patients aged 6 years and older with moderate-to-severe asthma characterized by an eosinophilic phenotype or with oral corticosteroid dependent asthma.
    - Dupixent was previously approved for this indication in patients aged 12 years and older.
    - Dupixent is not indicated for the relief of acute bronchospasm or status asthmaticus.
- Dupixent is also approved for treatment of atopic dermatitis and chronic rhinosinusitis with nasal polyposis.
- The approval of Dupixent for the expanded indication was based on a 52-week, randomized, double-blind, placebo-controlled study in 408 patients 6 to 11 years of age, with moderate-to-severe asthma. Patients received Dupixent or placebo. The primary endpoint was the annualized rate of severe asthma exacerbation events.
    - In patients with an eosinophilic asthma phenotype (baseline blood eosinophil count ≥ 300 cell/mcL), the annual rate of severe asthma exacerbations was 0.24 with Dupixent vs. 0.67 with placebo (rate ratio 0.35, 95% CI: 0.22, 0.56).
- The recommended dose of Dupixent for the treatment of pediatric patients aged 6 to 11 years of age is based on body weight. In patients 15 to less than 30 kg, the initial and subsequent doses are 100 mg every other week or 300 mg every four weeks administered subcutaneously. In patients greater than or equal to 30 kg, the dose is 200 mg every other week.
- Refer to the Dupixent drug label for complete dosing and administration recommendations for this use and Dupixent's other indications.