Dupixent® (dupilumab) – New indication

- On June 26, 2019, the FDA announced the approval of Regeneron and Sanofi's Dupixent (dupilumab), as an add-on maintenance treatment in adult patients with inadequately controlled chronic rhinosinusitis with nasal polyposis (CRSwNP).

- Dupixent is also approved for the treatment of atopic dermatitis and asthma.

- CRSwNP is a chronic disease of the upper airway that obstructs the sinuses and nasal passages. It can lead to breathing difficulties, nasal congestion and discharge, reduced or loss of sense of smell and taste, and facial pressure.

    — Many patients with CRSwNP also have other inflammatory diseases such as asthma.

- The approval of Dupixent for this new indication was based on two double-blind studies in 724 patients with CRSwNP who were symptomatic despite taking intranasal corticosteroids. Patients received Dupixent or placebo. The co-primary endpoints were change from baseline to week 24 in bilateral endoscopic nasal polyps score (NPS; 0 to 8 scale) and change from baseline to week 24 in nasal congestion/obstruction score averaged over 28 days (NC; 0 to 3 scale). For both endpoints, a reduction in score indicates improvement.

    — NPS score: least squares (LS) mean change from baseline was -1.89 and -1.71 for Dupixent vs. 0.17 and 0.10 for placebo (difference: -2.06 and -1.80).
    — NC score: LS mean change from baseline was -1.34 and -1.25 for Dupixent vs. -0.45 and -0.38 for placebo (difference: -0.89 and -0.87).

- The most common adverse reactions (≥ 1%) with Dupixent use for CRSwNP were injection site reactions, eosinophilia, insomnia, toothache, gastritis, arthralgia, and conjunctivitis.

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

    — Refer to the Dupixent drug label for dosing for its other indications.