Dupixent® (dupilumab) – New indication and new warnings

- On October 19, 2018, Regeneron Pharmaceuticals and Sanofi announced the FDA approval of Dupixent (dupilumab), as an add-on maintenance treatment in patients with moderate-to-severe asthma aged 12 years and older with an eosinophilic phenotype or with oral corticosteroid dependent asthma.
    - Dupixent is not indicated for the relief of acute bronchospasm or status asthmaticus.
- Dupixent is also approved for the treatment of adult patients with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable.
- The efficacy and safety of Dupixent as an add-on maintenance treatment for asthma was demonstrated in three trials which enrolled a total of 2,888 patients. Trials 1 and 2 evaluated the frequency of severe asthma exacerbations. Trial 1 was a dose-ranging study and the primary analysis population was patients with baseline blood eosinophil count ≥ 300 cells/mcL. In trial 3, which evaluated oral corticosteroid-dependent patients, the primary endpoint was the percent reduction from baseline in the oral corticosteroid dose (OCS).
    - In trial 1, the rate of severe exacerbations was 0.30 (95% CI: 0.13 to 0.68) and 0.20 (95% CI: 0.08 to 0.52) for Dupixent 200 mg and 300 mg every 2 weeks, respectively, compared to a placebo rate of 1.04 (95% CI: 0.57 to 1.90).
    - In trial 2, the overall rate of severe exacerbations was 0.46 and 0.52 for Dupixent 200 mg and 300 mg, respectively, compared to matched placebo rates of 0.87 and 0.97. In patients with a baseline blood eosinophil count ≥ 300 cells/mcL, the rate of exacerbations was 0.37 (95% CI: 0.29 to 0.48) and 0.40 (95% CI: 0.32 to 0.51) for Dupixent 200 mg and 300 mg, respectively, compared to matched placebo rates of 1.08 (95% CI: 0.85 to 1.38) and 1.24 (95% CI: 0.97 to 1.57).
    - In trial 3, the mean percent reduction in daily OCS dose from baseline was 70% (95% CI: 60 to 80) in patients receiving Dupixent vs. 42% (95% CI: 33 to 51) in patients receiving placebo.
- In addition, new warnings were added to the Dupixent drug label regarding eosinophilic conditions, acute asthma symptoms or deteriorating disease, and reduction of corticosteroid dosage.
- The recommended dose of Dupixent for the new indication is an initial subcutaneous (SC) dose of 400 mg (two 200 mg injections) followed by 200 mg given every other week or an initial dose of 600 mg (two 300 mg injections) followed by 300 mg given every other week.
    - For patients with oral corticosteroids-dependent asthma, or with co-morbid moderate-to-severe atopic dermatitis for which Dupixent is indicated, patients should be started on an initial dose of 600 mg followed by 300 mg given every other week.
    - Dupixent is intended for use under the guidance of a healthcare provider. A patient may self-inject Dupixent after training in SC injection technique.
    - Dupixent should be administered into the thigh or abdomen (except for the 2 inches around the navel). The upper arm can also be used with caregiver administration.

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- Refer to the Dupixent drug label for dosing recommendations for the treatment of atopic dermatitis.