Dupixent® (dupilumab) – New drug approval

- On March 28, 2017, Sanofi and Regeneron announced the FDA approval of Dupixent (dupilumab) for the treatment of adult patients with moderate-to-severe atopic dermatitis (AD) whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable.
    - Dupixent can be used with or without topical corticosteroids (TCS).
- AD, the most common form of eczema, is a chronic inflammatory skin disease. Moderate-to-severe AD is characterized by rashes often covering much of the body, and can include intense, persistent itching and skin dryness, cracking, redness, crusting, and oozing. Itch is one of the most burdensome symptoms for patients and can be debilitating.
    - Of the adults with uncontrolled moderate-to-severe AD in the U.S., it is estimated that 300,000 are most in need of new treatment options.
- Dupixent is the first biologic approved for the treatment of moderate-to-severe AD. It inhibits interleukin-4 and interleukin-13 cytokine-induced responses, including the release of proinflammatory cytokines.
- The safety and efficacy of Dupixent were based on data from three placebo-controlled trials in 2,119 patients with moderate-to-severe AD not adequately controlled by topical medications. Trials 1 and 2 were monotherapy studies and trial 3 was a concomitant trial in which patients received Dupixent or placebo with concomitant TCS and as needed topical calcineurin inhibitors. The primary endpoint was improvement in disease severity defined as the change from baseline to week 16 in the proportion of patients with an Investigator's Global Assessment (IGA) of 0 (clear) or 1 (almost clear) and at least a 2 point improvement.
    - Across the three trials, 36% – 39% of patients who received Dupixent achieved the primary endpoint vs. 9% – 12% of patients who received placebo.
    - In addition, 44% – 69% of patients in the Dupixent group achieved at least a 75% improvement in the Eczema Area and Severity Index score from baseline vs. 12% – 23% of patients in the placebo group.
    - More patients who received Dupixent achieved a significant reduction in itch vs. placebo (36% – 59% vs. 10% – 20%, respectively).
- Warnings and precautions of Dupixent include hypersensitivity, conjunctivitis and keratitis, comorbid asthma, and parasitic (Helminth) infections.
- The most common adverse reactions (≥ 1%) with Dupixent use were injection site reactions, conjunctivitis, blepharitis, oral herpes, keratitis, eye pruritus, other herpes simplex virus infection, and dry eye.
- The recommended dose of Dupixent is an initial dose of 600 mg [two 300 mg subcutaneous (SC) injections], followed by 300 mg given every other week.
    - Dupixent can be used with or without TCS. Topical calcineurin inhibitors may be used, but should be reserved for problem areas only, such as the face, neck, intertriginous and genital areas.
    - For the initial 600 mg dose, each of the 300 mg SC injections should be administered at a different injection site (eg, thigh, abdomen, upper arm).

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- Sanofi and Regeneron have launched Dupixent MyWay™, a comprehensive and specialized program that provides financial assistance for eligible patients and offers support and services from nurses and specialists.

- The wholesale acquisition cost of Dupixent is $37,000 annually.

- Sanofi and Regeneron plan to launch Dupixent later this week. Dupixent will be available as 300 mg/2 mL single-dose pre-filled syringes with and without a needle shield.