Dupixent® (dupilumab) – New indication

- On April 18, 2025, Sanofi and Regeneron announced the FDA approval of Dupixent (dupilumab), for the **treatment of adult and pediatric patients aged 12 years and older with chronic spontaneous urticaria (CSU) who remain symptomatic despite H1 antihistamine treatment**.
    - Dupixent is not indicated for treatment of other forms of urticaria.
- Dupixent is also approved for the treatment of atopic dermatitis, asthma, chronic rhinosinusitis with nasal polyps, eosinophilic esophagitis, prurigo nodularis, and chronic obstructive pulmonary disease.
- The approval of Dupixent for the new indication was based on CUPID, three randomized, double-blind, placebo-controlled studies in adult and pediatric patients aged 12 years and older with CSU. CUPID Study A and Study C included patients who remained symptomatic despite H1 antihistamine treatment and were anti-IgE treatment naïve, while CUPID Study B included patients who remained symptomatic despite H1 antihistamine and anti-IgE treatments. The efficacy of Dupixent was based only on CUPID Study A and Study C; Study B did not meet the primary endpoint.
- CUPID Study A and C included a total of 284 adult and pediatric patients. The primary endpoint was change from baseline in itch severity score over 7 days (ISS7) at week 24. The ISS7 score was defined as the sum of the daily itch severity scores (ISS), from 0 to 3, recorded at the same time of the day for a 7-day period, ranging from 0 to 21.
    - In CUPID Study A, the change from baseline in ISS7 at week 24 was -10.44 in the Dupixent group vs. -6.02 in the placebo group (least-squares mean difference -4.42, 95% CI: -6.84, -2.01).
    - In CUPID Study C, the change from baseline in ISS7 at week 24 was -8.50 in the Dupixent group vs. -6.13 in the placebo group (least-squares mean difference -2.37, 95% CI: -4.48, -0.27).
- The most common adverse reaction (≥ 2%) with Dupixent use in CSU was injection site reactions.
- The recommended subcutaneous dosage of Dupixent for adult patients with CSU is an initial dose of 600 mg (two 300 mg injections), followed by 300 mg given every 2 weeks.
- The recommended dosage of Dupixent for pediatric patients 12 to 17 years of age with CSU is weight based:
    - 30 to less than 60 kg: initial loading dose of 400 mg (two 200 mg injections) followed by 200 mg every 2 weeks.
    - 60 kg or more: initial loading dose of 600 mg (two 300 mg injections) followed by 300 mg every 2 weeks.
- Refer to the Dupixent drug label for dosing for all its other indications.