Dupixent® (dupilumab) – Expanded indication

- On September 13, 2024, Regeneron announced the FDA approval of Dupixent (dupilumab), as an add-on maintenance treatment in adult and pediatric patients aged 12 years and older with inadequately controlled chronic rhinosinusitis with nasal polyps (CRSwNP).
    - Dupixent was previously approved for this indication in adults only.
- Dupixent is also approved for the treatment of atopic dermatitis, asthma, eosinophilic esophagitis, and prurigo nodularis.
- CRSwNP is a chronic disease of the upper airway that obstructs the sinuses and nasal passages. Systemic steroids and surgery are the standard treatment for CRSwNP in this age group, but many patients may still experience uncontrolled symptoms and the recurrence of nasal polyps.
    - In the U.S., the prevalence of inadequately controlled CRSwNP in adolescents is approximately 9,000.
- The approval of Dupixent for the expanded indication was supported by evidence from adequate and well-controlled studies in adults with inadequately controlled CRSwNP with the following additional data:
    - Pharmacokinetic data from adult and pediatric patients aged 12 years and older with moderate-to-severe asthma and adult patients with inadequately controlled CRSwNP
    - Safety data in pediatric patients aged 12 years and older with moderate-to-severe asthma.
- The recommended dosage of Dupixent for adult and pediatric patients 12 years of age and older for CRSwNP is 300 mg given every other week.
    - Refer to the Dupixent drug label for dosing for all its other indications.