Nucala® (mepolizumab) – New indication

- On May 22, 2025, GSK announced the FDA approval of Nucala (mepolizumab), for the **add-on maintenance treatment of adult patients with inadequately controlled chronic obstructive pulmonary disease (COPD) and an eosinophilic phenotype**.
    - Nucala is not indicated for the relief of acute bronchospasm.
- Nucala is also approved for the treatment of severe asthma, chronic rhinosinusitis with nasal polyps, eosinophilic granulomatosis with polyangiitis, and hypereosinophilic syndrome.
- The approval of Nucala for the new indication was based on MATINEE and METREX, two randomized, double-blind, placebo-controlled studies in adult patients with inadequately controlled COPD and an eosinophilic phenotype. Patients were randomized to receive Nucala or placebo. While 1,640 adults were enrolled in the trials, the efficacy population consisted of 1,266 adults. The primary endpoint for the MATINEE and METREX trials was the annualized rate of moderate or severe exacerbations during the 52 to 104-week and 52-week treatment periods, respectively.
    - In MATINEE, the annualized rate of exacerbations was 0.80 with Nucala vs. 1.01 with placebo (rate ratio 0.79, 95% CI: 0.66, 0.94).
    - In METREX, the annualized rate of exacerbations was 1.40 with Nucala vs. 1.71 with placebo (rate ratio 0.82, 95% CI: 0.68, 0.98).
- The most common adverse reactions (≥ 5%) with Nucala use for COPD were back pain, diarrhea, and cough.
- The recommended dose of Nucala for the treatment of COPD is **100 mg subcutaneously every 4 weeks**.
    - Refer to the Nucala drug label for dosing for all its other indications