## Nucala® (mepolizumab) – New indication

- On July 29, 2021, GlaxoSmithKline announced the FDA approval of Nucala (mepolizumab), for the add-on maintenance treatment of chronic rhinosinusitis with nasal polyps (CRSwNP) in adult patients 18 years of age and older with inadequate response to nasal corticosteroids.

- Nucala is also approved for maintenance treatment of severe asthma, eosinophilic granulomatosis with polyangiitis, and hypereosinophilic syndrome.

- The approval of Nucala for the new indication was based on a randomized, double-blind, placebo-controlled study in 407 adult patients with CRSwNP. Patients received Nucala or placebo while continuing nasal corticosteroid therapy. The co-primary endpoints were change from baseline to week 52 in total endoscopic nasal polyp score (NPS) (0 to 8 scale) and change from baseline in nasal obstruction visual analog scale (VAS) score (0 to 10 scale) during weeks 49 to 52. The key secondary endpoint was the time to first nasal surgery (nasal polypectomy) up to week 52.

    - The mean change from baseline in total endoscopic NPS was 0.06 and -0.87 for placebo and Nucala, respectively (treatment difference -0.93, 95% CI: -1.31, -0.55).
    - The mean change from baseline in nasal obstruction VAS score was -2.54 and -4.40 for placebo and Nucala, respectively (treatment difference -1.86, 95% CI: -2.53, -1.19).
    - The proportion of patients who had surgery was significantly reduced by 57% (hazard ratio: 0.43, 95% CI: 0.25, 0.76) in the group treated with Nucala vs. placebo. By week 52, 9% of patients who received Nucala had surgery vs. 23% with placebo.

- The most common adverse reactions (≥ 5%) with Nucala use for the treatment of CRSwNP were oropharyngeal pain and arthralgia.

- The recommended dosage of Nucala for the treatment of CRSwNP is 100 mg administered once every 4 weeks by subcutaneous injection into the upper arm, thigh, or abdomen.

    - Refer to the Nucala drug label for dosing for all its other indications.