Nucala® (mepolizumab) – New orphan indication

- On December 12, 2017, the FDA announced the approval of GlaxoSmithKline's Nucala (mepolizumab) for the treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA).

- Nucala is also approved for the add-on maintenance treatment of patients with severe asthma aged 12 years and older, and with an eosinophilic phenotype.

    — Nucala is not indicated for the relief of acute bronchospasm or status asthmaticus.

- According to the National Institutes of Health, EGPA (formerly known as Churg-Strauss syndrome) is a condition characterized by asthma, high levels of eosinophils, and inflammation of blood vessels. The inflamed vessels can affect the lungs, gastrointestinal tract, skin, heart and nervous system.

- Approximately 0.11 to 2.66 new cases per 1 million people are diagnosed with EGPA each year, with an overall prevalence of 10.7 to 14 per 1,000,000 adults. In the U.S., there are approximately 5000 patients with EGPA.

- The safety and efficacy of Nucala were based on data from a 52-week clinical trial of 136 patients with EGPA. Patients received Nucala or placebo while continuing oral corticosteroid therapy. The primary efficacy assessments measured Nucala's treatment impact on disease remission.

    — Patients receiving Nucala achieved a significantly greater accrued time in remission vs. placebo (Odds Ratio [OR] = 5.9, 95% CI: 2.7, 13.0).
    — A significantly higher proportion of patients receiving Nucala achieved remission at both weeks 36 and 48 vs. placebo (OR = 16.7, 95% CI: 3.6, 77.6).
    — Significantly more patients who received Nucala achieved remission within the first 24 weeks and remained in remission for the remainder of the 52-week study treatment period vs. placebo (19% vs. 1%, respectively; OR = 19.7; 95% CI: 2.3, 167.9).

- The recommended dosage of Nucala for the treatment of EGPA is 300 mg administered once every 4 weeks by subcutaneous (SC) injection as 3 separate 100 mg injections into the upper arm, thigh or abdomen.

    — Nucala should be reconstituted and administered by a healthcare professional.
    — It is recommended that the individual 100-mg injections be administered at least 5 cm (approximately 2 inches) apart if more than 1 injection is administered at the same site.
    — The recommended dosage of Nucala for the treatment of severe asthma is 100 mg administered once every 4 weeks by SC injection into the upper arm, thigh, or abdomen.