Nucula Approved for Severe Asthma

On Nov. 4, 2015, the U.S. Food and Drug Administration (FDA) approved GlaxoSmithKline’s Nucala® (mepolizumab) injection for use as an add-on maintenance treatment of severe eosinophilic asthma in patients at least 12 years of age. Nucala is the first humanized interleukin-5 (IL-5) antagonist monoclonal antibody to be approved. Dosing is 100mg subcutaneously once every four weeks. It cannot be self-administered, so it will be injected by a health care professional into the patient's abdomen, thigh or upper arm. GlaxoSmithKline plans on launching Nucala by the end of December. It will be available through a limited network of specialty pharmacies that includes Accredo. Full prescribing information can be found at: www.nucala.com

At a Glance

- **Brand (Generic) Drug:** Nucala® (mepolizumab)
- **Manufacturer:** GlaxoSmithKline
- **Date Approved:** Nov. 4, 2015
- **Date Launched:** According to the manufacturer, Nucala will begin shipping by the end of December 2015.
- **Indications:** Add-on maintenance treatment of patients with severe asthma aged 12 years and older, and with an eosinophilic phenotype.
- **Dosage Forms Available:** 100 mg of lyophilized powder in a single-dose vial for reconstitution
- **Estimated Cost:** Pricing information is not yet available.
- **Specialty Status:**
  - Nucala will be added to Express Scripts’ specialty drug list.
  - Current treatments do not manage symptoms for about 5% of the estimated 25.7 million people in the U.S. who have asthma. For many of these resistant cases, Nucala could be added to inhaled corticosteroids and other current asthma treatments.
  - Nucala reduces severe asthma attacks by blocking to IL-5 receptors. Blocking the action of IL-5 decreases eosinophils, white blood cells that contribute to increased sensitivity of the airways among asthma patients.
  - Nucala is not approved to treat other eosinophilic conditions, to relieve acute bronchial spasms or to alleviate status asthmaticus (severe asthma attacks that do not respond to treatment).
  - Herpes zoster (shingles) infections occurred in two patients who were receiving Nucala in clinical trials. Patients may want to consider getting a shingles vaccination before starting therapy with Nucala.
  - Teva’s reslizumab is another IL-5 antagonist monoclonal antibody under FDA review for treating severe eosinophilic asthma. This product is also administered by health care professional, but as an intravenous infusion. FDA is expected to rule on the approval of this drug by Mar. 30, 2016.