Nucala® (mepolizumab) – Expanded indication

- On September 12, 2019, GlaxoSmithKline announced the FDA approval of Nucala (mepolizumab), add-on maintenance treatment of patients with severe asthma aged 6 years and older, and with an eosinophilic phenotype.
    - Nucala was previously approved for this indication in patients 12 years of age and older.
    - Nucala is not indicated for the relief of acute bronchospasm or status asthmaticus.
- Nucala is also approved for the treatment of adult patients with eosinophilic granulomatosis with polyangiitis.
- The use of Nucala in children aged 6 to 11 years with severe asthma, and with an eosinophilic phenotype, is supported by evidence from adequate and well-controlled trials in adults and adolescents with additional pharmacokinetic, pharmacodynamic, and safety data in children aged 6 to 11 years. Based upon the pharmacokinetic data from this trial, a dose of 40 mg subcutaneous (SC) every 4 weeks was determined to have similar exposure to adults and adolescents administered a dose of 100 mg SC.
    - The efficacy of Nucala in children aged 6 to 11 years is extrapolated from efficacy in adults and adolescents with support from pharmacokinetic analyses showing similar drug exposure levels for 40 mg administered SC every 4 weeks in children aged 6 to 11 years compared with adults and adolescents.
- The recommended dose of Nucala for the treatment of severe asthma in patients aged 6 to 11 years is 40 mg administered once every 4 weeks by SC injection into the upper arm, thigh, or abdomen.
    - Refer to the Nucala drug label for dosing for all other indications.