Fasenra® (benralizumab) – New indication

- On September 18, 2024, AstraZeneca announced the FDA approval of Fasenra (benralizumab), for the treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA).

- Fasenra is also approved as add-on maintenance treatment of adult and pediatric patients aged 6 years and older with severe asthma, and with an eosinophilic phenotype.

- EGPA is a rare, immune-mediated inflammatory disease that is caused by inflammation of small to medium-sized blood vessels. It is estimated that approximately 15,000 patients are affected with the disease in the U.S. EGPA can result in damage to multiple organs, including lungs, upper airway, skin, heart, gastrointestinal tract and nerves.

- The approval of Fasenra for the new indication was based on MANDARA, a randomized, double-blind, active-controlled, noninferiority study in 140 adults with EGPA. Patients were required to have asthma, eosinophilia, and a history of relapsing or refractory disease treated with background prednisolone/prednisone with or without immunosuppressive therapy. Patients were randomized to receive Fasenra or Nucala® (mepolizumab) (another drug currently approved for EGPA) in addition to continued background therapy. The primary endpoint was the proportion of patients in remission, defined as Birmingham Vasculitis Activity Score (BVAS)=0 (no active vasculitis) plus prednisolone/prednisone dose ≤ 4 mg/day, at both week 36 and week 48.

    — Fasenra demonstrated non-inferiority to Nucala for the primary endpoint of remission. Remission was achieved in 59% of patients with Fasenra vs. 57% with Nucala (difference of 2.7, 95% CI: -13, 18).

- The recommended dosage of Fasenra for EGPA is 30 mg (one injection) administered once every 4 weeks by subcutaneous (SC) injection.

    — The Fasenra prefilled syringe formulation is for administration by a healthcare provider. The Fasenra Pen is intended for administration by patients/caregivers. Patients/caregivers may inject after proper training in SC injection technique, and after the healthcare provider determines it is appropriate.
    — Refer to the Fasenra drug label for dosing for asthma.