Fasenra® (benralizumab) – New formulation approval

- On October 4, 2019, AstraZeneca announced the FDA approval of Fasenra (benralizumab) single-dose autoinjector, for the add-on maintenance treatment of patients with severe asthma aged 12 years and older, and with an eosinophilic phenotype.
    - Fasenra is not indicated for treatment of other eosinophilic conditions.
    - Fasenra is not indicated for the relief of acute bronchospasm or status asthmaticus.
- Fasenra autoinjector is intended for administration by patients/caregivers. Patients/caregivers may inject after proper training in subcutaneous (SC) injection technique and after the healthcare provider determines it is appropriate.
- Fasenra was previously approved as a single-dose prefilled syringe. However, the prefilled syringe requires administration by a healthcare provider.
- Warnings and precautions of Fasenra include hypersensitivity reactions, acute asthma symptoms or deteriorating disease, reduction of corticosteroid dosage, and parasitic (helminth) infection.
- The most common adverse reactions (≥ 5%) with Fasenra use were headache and pharyngitis.
- The recommended dosage of Fasenra for severe asthma is 30 mg administered once every 4 weeks for the first 3 doses, and then once every 8 weeks thereafter by SC injection into the upper arm, thigh, or abdomen.
- AstraZeneca's launch plans for the single-dose autoinjector are pending. The new formulation will be available as a 30 mg/mL strength autoinjector (Fasenra Pen).