Fasenra™ (benralizumab) – New drug approval

- On November 14, 2017, AstraZeneca announced the FDA approval of Fasenra (benralizumab), for the add-on maintenance treatment of patients with severe asthma aged 12 years and older, and with an eosinophilic phenotype.
    - Fasenra is not for the treatment of other eosinophilic conditions.
    - Fasenra is not for the relief of acute bronchospasm or status asthmaticus.
- About 10% of asthma patients have severe asthma which may be uncontrolled despite high doses of standard-of-care asthma controller medicines and can require the use of chronic oral corticosteroids (OCS). Severe, uncontrolled asthma is debilitating and potentially fatal with patients experiencing frequent exacerbations and significant limitations on lung function and quality of life.
- Fasenra is a monoclonal antibody that binds directly to the interleukin-5α receptor and recruits natural killer cells to induce direct, rapid and near-complete depletion of eosinophils. Eosinophils lead to frequent exacerbations, impaired lung function and asthma symptoms.
- The FDA approval of Fasenra is based on 2 pivotal exacerbation studies, SIROCCO and CALIMA, and an OCS-sparing trial, ZONDA. A total of 2,730 patients were evaluated in these studies. Results for Fasenra showed:
    - Up to 51% reduction in the annual asthma exacerbation rate vs. placebo.
    - Significant improvement in lung function as measured by forced expiratory volume in one second of up to 159 mL vs. placebo.
    - The median percent reduction in daily OCS dose from baseline was 75% in patients receiving Fasenra vs. 25% in patients receiving placebo.
- 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 dose of Fasenra is 30 mg administered once every 4 weeks for the first 3 doses, and then once every 8 weeks thereafter by subcutaneous injection into the upper arm, thigh, or abdomen.
    - Fasenra should be administered by a healthcare professional.
- AstraZeneca has launched Fasenra. Fasenra is available as a 30 mg/mL solution in a single-dose prefilled syringe.

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