ArmonAir™ RespiClick® (fluticasone) – New Drug Approval

- On January 30, 2017, Teva announced the FDA approval of ArmonAir RespiClick (fluticasone), for the maintenance treatment of asthma as prophylactic therapy in patients 12 years of age and older.
    - ArmonAir RespiClick is not indicated for the relief of acute bronchospasm.
- ArmonAir RespiClick contains fluticasone propionate, a corticosteroid.
- The safety and efficacy of ArmonAir RespiClick were evaluated in 2,130 patients with asthma. The development program included two confirmatory trials, a 26-week safety trial, and two dose-ranging trials. The efficacy of ArmonAir RespiClick is based primarily on the dose-ranging trials and confirmatory trials.
    - Compared to placebo, ArmonAir RespiClick showed clinically relevant and greater benefit in the improvement of lung function, as measured by forced expiratory volume in 1 second (FEV_1).
- ArmonAir RespiClick is contraindicated in the primary treatment of status asthmaticus or other acute episodes of asthma where intensive measures are required, and in patients with known or severe hypersensitivity to milk proteins or known hypersensitivity to fluticasone or any of the excipients.
- Other warnings and precautions of ArmonAir RespiClick include local effects of inhaled corticosteroids (ICS), acute asthma episodes, immunosuppression, transferring patients from systemic corticosteroid therapy, hypercorticism and adrenal suppression, reduction in bone mineral density, effect on growth, glaucoma and cataracts, paradoxical bronchospasm, drug interactions with strong cytochrome P450 3A4 inhibitors, and eosinophilic conditions and Churg-Strauss syndrome.
- The most common adverse reactions (≥ 3%) with ArmonAir RespiClick use were nasopharyngitis, upper respiratory tract infection, oral candidiasis, headache, and cough.
- The recommended dose of ArmonAir RespiClick is 1 inhalation twice daily approximately 12 hours apart by the orally inhaled route.
    - The specific starting dose is based on the individual patient's asthma severity.
    - ArmonAir RespiClick should not be used more than 2 times every 24 hours, and should not be used with a spacer or volume holding chamber.
- Teva plans to launch ArmonAir RespiClick later this year. ArmonAir RespiClick will be available as a breath-activated, multi-dose dry powder inhaler in three strengths: 55 mcg, 113 mcg, and 232 mcg.