AirDuo™ RespiClick® (fluticasone/salmeterol) – New Drug Approval

- On January 30, 2017, Teva announced the FDA approval of AirDuo RespiClick (fluticasone/salmeterol), for the treatment of asthma in patients aged 12 years and older.
    - AirDuo RespiClick is only for patients uncontrolled on an ICS or whose disease severity clearly warrants an ICS/long-acting beta agonist (LABA).
    - AirDuo RespiClick is not indicated for the relief of acute bronchospasm.
- AirDuo RespiClick is a combination product containing a corticosteroid (fluticasone) and a LABA (salmeterol).
- The safety and efficacy of AirDuo RespiClick were evaluated in 3,004 patients with asthma. The development program included two confirmatory trials, a 26-week safety trial, and three dose-ranging trials. The efficacy of AirDuo RespiClick is based primarily on the dose-ranging trials and confirmatory trials.
    - Compared to placebo, AirDuo RespiClick showed clinically relevant and greater benefit in the improvement of lung function, as measured by FEV_1.
- AirDuo RespiClick carries a boxed warning regarding the risk of asthma-related death.
- AirDuo 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 AirDuo RespiClick include deterioration of disease and acute episodes, excessive use of AirDuo RespiClick and use with other LABAs, local effects of ICSs, immunosuppression, transferring patients from systemic corticosteroid therapy, hypercorticism and adrenal suppression, drug interactions with strong cytochrome P450 3A inhibitors, paradoxical bronchospasm and upper airway symptoms, cardiovascular and central nervous system effects, reduction in bone mineral density, effect on growth, glaucoma and cataracts, eosinophilic conditions and Churg-Strauss syndrome, coexisting conditions, and hypokalemia and hyperglycemia.
- The most common adverse reactions (≥ 3%) with AirDuo RespiClick use were nasopharyngitis, oral candidiasis, back pain, headache, and cough.
- The recommended dose of AirDuo 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.
    - AirDuo 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 AirDuo RespiClick later this year. AirDuo RespiClick will be available as a breath-activated, multi-dose dry powder inhaler of fluticasone/salmeterol in three strengths: 55 mcg/14 mcg, 113 mcg/14 mcg, and 232 mcg/14 mcg.