Trelegy™ Ellipta® (fluticasone furoate/umeclidinium/vilanterol) – New drug approval

- On September 18, 2017, GlaxoSmithKline and Innoviva and Theravance Biopharma announced the FDA approval of Trelegy Ellipta (fluticasone furoate [FF]/umeclidinium [UMEC]/vilanterol [VI]), for the long-term, once-daily, maintenance treatment of patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema, who are on a fixed-dose combination of Breo® Ellipta® (FF/VI) for airflow obstruction and reducing exacerbations in whom additional treatment of airflow obstruction is desired or for patients who are already receiving Incruse® Ellipta® (UMEC) and a fixed-dose combination of FF and VI.
    - Trelegy Ellipta is not indicated for relief of acute bronchospasm or for the treatment of asthma.
- According to the Centers for Disease Control and Prevention, about 15.7 million Americans have been diagnosed with COPD. It is the third leading cause of death in the U.S. The inability to breathe normally can consume patient's daily lives and make simple activities, like walking upstairs, an everyday struggle.
- Trelegy Ellipta is the first once-daily single inhaler triple therapy approved in the U.S. Trelegy Ellipta contains an inhaled corticosteroid (FF), a long-acting muscarinic antagonist (UMEC), and a long-acting $beta_2$-adrenergic agonist (VI).
- The efficacy of Trelegy Ellipta was based primarily on the co-administration of UMEC and FF/VI in two 12-week treatment studies. Comparative *in vitro* data provide support for reliance on co-administration studies with UMEC and FF/VI. The primary endpoint was the change from baseline in trough forced expiratory volume in 1 second (FEV_1) at day 85.
    - For both studies, UMEC and FF/VI demonstrated a statistically significant increase in FEV_1 vs. placebo and FF/VI.
    - In addition, in two 52-week trials that evaluated FF/VI vs. VI monotherapy, FF/VI was associated with a reduction in the mean annual rate of moderate and severe COPD exacerbations compared to VI monotherapy.
- Like other products containing long-acting $beta_2$ agonists, Trelegy Ellipta carries a boxed warning for asthma-related death.
- Trelegy Ellipta is contraindicated in patients with severe hypersensitivity to milk proteins or who have demonstrated hypersensitivity to FF, UMEC, VI or any of the excipients.
- Other warnings and precautions of Trelegy Ellipta include deterioration of disease and acute episodes, excessive use of Trelegy Ellipta and use with other long-acting $beta_2$-agonists, local effects of inhaled corticosteroids; pneumonia, immunosuppression; transferring patients from systemic corticosteroid therapy; hypercorticism and adrenal suppression; drug interactions with strong cytochrome P450 3A4 inhibitors; paradoxical bronchospasm; hypersensitivity reactions, including anaphylaxis; cardiovascular effects; reduction in bone mineral density; glaucoma and cataracts and worsening of narrow-angle glaucoma; worsening of urinary retention; coexisting conditions; and hypokalemia and hyperglycemia.
- The most common adverse reactions (≥ 1%) with Trelegy Ellipta use were headache, back pain, dysgeusia, diarrhea, cough, oropharyngeal pain, and gastroenteritis.

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- The recommended dosage of Trelegy Ellipta is 1 inhalation once daily by the orally inhaled route only.

    — Trelegy Ellipta should not be used more than one-time every 24 hours.
    — After inhalation, the patient should rinse his/her mouth with water without swallowing to help reduce the risk of oropharyngeal candidiasis.

- GlaxoSmithKline plans to launch Trelegy Ellipta shortly. Trelegy Ellipta will be available as an inhaler containing 2 foil blister strips of powder formulation for oral inhalation. One strip contains FF (100 mcg per blister) and the other contains a blend of UMEC and VI (62.5 mcg and 25 mcg per blister, respectively), which together create one dose.