Trelegy Ellipta® (fluticasone furoate/umeclidinium/vilanterol) – New indication

- On September 9, 2020, GlaxoSmithKline announced the FDA approval of Trelegy Ellipta (fluticasone furoate/umeclidinium/vilanterol), for the maintenance treatment of asthma in patients aged 18 years and older.
    - Trelegy Ellipta is NOT indicated for the relief of acute bronchospasm.
- Trelegy Ellipta is also approved for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD).
- In addition to the new indication, the FDA also approved a new strength of Trelegy Ellipta for asthma (fluticasone furoate/umeclidinium/vilanterol 200 mcg/62.5 mcg/25 mcg).
    - Trelegy Ellipta 100 mcg/62.5 mcg/25 mcg is approved for both COPD and asthma.
- The approval of Trelegy Ellipta for the new indication was based on a randomized, double-blind, active-controlled confirmatory trial of 24 to 52 weeks' duration in 2,436 adult patients with asthma inadequately controlled on their current treatments of combination therapy. In the randomized portion of the study, patients received either Trelegy Ellipta or Breo Ellipta® (fluticasone furoate/vilanterol). The primary efficacy endpoint was change from baseline in trough forced expiratory volume in 1 second (FEV_1) at week 24.
    - Both Trelegy Ellipta 100 mcg/62.5 mcg/25 mcg and Trelegy Ellipta 200 mcg/62.5 mcg/25 mcg showed statistically significant improvements in lung function vs. Breo Ellipta 100 mcg/25 mcg and Breo Ellipta 200 mcg/25 mcg.
    - The difference in change from baseline in trough FEV_1 for Trelegy Ellipta 100 mcg/62.5 mcg/25 mcg vs. Breo Ellipta 100 mcg/25 mcg was 110 mL (95% CI: 66, 153; $p < 0.001$).
    - The difference in change from baseline in trough FEV_1 for Trelegy Ellipta 200 mcg/62.5 mcg/25 mcg vs. Breo Ellipta 200 mcg/25 mcg was 92 mL (95% CI: 49, 135; $p < 0.001$).
- The most common adverse reactions (≥ 2%) with Trelegy Ellipta use for asthma were pharyngitis/nasopharyngitis, upper respiratory tract infection/viral upper respiratory tract infection, bronchitis, respiratory tract infection/viral respiratory tract infection, sinusitis/acute sinusitis, urinary tract infection, rhinitis, influenza, headache, and back pain.
- The recommended starting dosage of Trelegy Ellipta for maintenance treatment of asthma is fluticasone furoate 100 mcg, umeclidinium 62.5 mcg, and vilanterol 25 mcg (1 actuation) or fluticasone furoate 200 mcg, umeclidinium 62.5 mcg, and vilanterol 25 mcg (1 actuation) once daily, by oral inhalation.
    - The maximum recommended dosage is 1 inhalation of Trelegy Ellipta 200 mcg/62.5 mcg/25 mcg once daily.
    - After inhalation, the mouth should be rinsed with water without swallowing to help reduce the risk of oropharyngeal candidiasis.
    - Refer to the Trelegy Ellipta drug label for dosing for COPD.

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- GlaxoSmithKline's launch plans for the new Trelegy Ellipta 200 mcg/62.5 mcg/25 mcg strength are pending.

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