



## Trelegy<sup>®</sup> Ellipta<sup>®</sup> (fluticasone furoate/umeclidinium/vilanterol) – Expanded indication

- On April 24, 2018, [GlaxoSmithKline and Innoviva announced](#) the FDA approval of [Trelegy Ellipta \(fluticasone furoate/umeclidinium/vilanterol\)](#), for the long-term, once-daily, maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD). Trelegy Ellipta is also indicated to reduce exacerbations of COPD in patients with a history of exacerbations.
  - Previously, Trelegy Ellipta was indicated for the long-term, once-daily, maintenance treatment of patients with COPD, including chronic bronchitis and/or emphysema, who are on a fixed-dose combination of [Breo<sup>®</sup> Ellipta<sup>®</sup> \(fluticasone furoate/vilanterol\)](#) for airflow obstruction and reducing exacerbations in whom additional treatment of airflow obstruction is desired or for patients who are already receiving [Incruse<sup>®</sup> Ellipta<sup>®</sup> \(umeclidinium\)](#) and a fixed-dose combination of Breo Ellipta.
  - Trelegy Ellipta is not indicated for the relief of acute bronchospasm or for the treatment of asthma.
- The approval of Trelegy Ellipta for the expanded indication was based on the results of the 52-week IMPACT study that enrolled 10,355 patients with COPD with a history of  $\geq 1$  moderate to severe exacerbation. Patients were randomized to Trelegy Ellipta, Breo Ellipta or [Anoro<sup>®</sup> Ellipta<sup>®</sup> \(umeclidinium/vilanterol\)](#) once daily. The primary endpoint was the annual rate of on-treatment moderate/severe exacerbations.
  - Treatment with Trelegy Ellipta statistically significantly reduced the on-treatment annual rate of moderate/severe exacerbations by 15% (95% CI: 10, 20;  $p < 0.001$ ) vs. Breo Ellipta and by 25% (95% CI: 19, 20;  $p < 0.001$ ) vs. Anoro Ellipta.
- In addition, the *Boxed Warning* for asthma-related death was removed from the Trelegy Ellipta drug label.
  - This follows the [FDA recommended](#) changes to combination inhaled corticosteroids and long-acting beta agonists drug labels issued on December 20, 2017.
- The recommended dosage of Trelegy Ellipta is one inhalation once daily by the orally inhaled route.



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