Utibron™ Neohaler® and Seebri™ Neohaler® – New Drug Approvals

- On October 29, 2015, Novartis announced the FDA approval of Utibron Neohaler (indacaterol/glycopyrrolate) and Seebri Neohaler (glycopyrrolate) for the long-term, maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD).
  - Utibron is not indicated for the relief of acute bronchospasm or for the treatment of asthma.
- COPD affects about 27 million people in the U.S. and is the third leading cause of death. COPD is a chronic, progressive lung disease that makes it difficult to breathe.
- Utibron is a combination of indacaterol, a long-acting beta2-adrenergic agonist (LABA), and glycopyrrolate, a long-acting muscarinic antagonist (LAMA). Seebri contains glycopyrrolate. Both indacaterol and glycopyrrolate act as bronchodilators, causing the muscles in the lungs to relax.
  - Additional LABA/LAMA combination products are available: Anoro™ Ellipta® (vilanterol/umeclidinium) and Stiolo™ Respimat® (olodaterol/tiotropium).
  - Additional LAMA products are available: Incruse™ Ellipta® (umeclidinium), Spiriva® (tiotropium), and Tudorza™ Pressair® (aclidinium).
- The efficacy and safety of Utibron were based on the results from the EXPEDITION trial program, which included 2,654 patients with COPD and consisted of two 12-week efficacy studies (FLIGHT 1 & 2) and one 52-week safety study (FLIGHT 3).
  - Utibron demonstrated superior and sustained improvements in lung function at week 12, compared to its individual components (indacaterol 27.5 mcg and glycopyrrolate 15.6 mcg) as well as placebo.
- Like other LABAs, Utibron carries a boxed warning for risk of asthma-related death.
- Other warnings and precautions of Utibron and Seebri include: deterioration of disease and acute episodes; paradoxical bronchospasm; immediate hypersensitivity reactions; worsening of narrow-angle glaucoma; and worsening of urinary retention.
  - In addition, for Utibron, do not use in combination with an additional medicine containing LABA because of risk of overdose; use with caution in patients with cardiovascular or coexisting conditions (eg, convulsive disorders, thyrotoxicosis, sensitivity to sympathomimetic drugs).
- The most common adverse events (≥ 2% and higher than placebo) with Utibron use were nasopharyngitis and hypertension; with Seebri use were upper respiratory tract infection and nasopharyngitis.
- The recommended dose of Utibron and Seebri is the inhalation of the powder contents of one capsule twice-daily.

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— Only use Utibron and Seebri capsules with the Neohaler device.

- Novartis plans to launch Utibron and Seebri in the first quarter of 2016. Utibron will be available as capsules containing 27.5 mcg of indacaterol and 15.6 mcg glycopyrrolate inhalation powder. Seebri will be available as capsules containing 15.6 mg glycopyrrolate inhalation powder.