Bevespi Aerosphere™ (glycopyrrolate/formoterol fumarate) – New Drug Approval

- On April 25, 2016, AstraZeneca announced the FDA approval of Bevespi Aerosphere (glycopyrrolate/formoterol fumarate) for the long-term, maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema.
  
  — Bevespi Aerosphere is not indicated for the relief of acute bronchospasm or for the treatment of asthma.

- Bevespi Aerosphere is a twice-daily, fixed dose dual bronchodilator combining glycopyrrolate, a long-acting muscarinic antagonist (LAMA), and formoterol fumarate, a long-acting beta-2-agonist (LABA).

- Bevespi Aerosphere delivers medication via a pressurized metered dose inhaler (pMDI) and Co-Suspension™ Technology, which enables consistent delivery of one or more medicines from a single pMDI.
  
  — Additional LABA/LAMA combination products are available: Anoro™ Ellipta® (vilanterol/umeclidinium), Stiolto™ Respimat® (olodaterol/tiotropium), and Utibron™ Neohaler® (indacaterol/glycopyrrolate).
  
  — Additional LABA products are available: formoterol (Foradil®, Perforomist®), Arcapta™ Neohaler™ (indacaterol), Serevent® Diskus® (salmeterol) and Striverdi® Respimat® (olodaterol).
  
  — Additional LAMA products are available: Incruse™ Ellipta® (umeclidinium), Seebri™ Neohaler® (glycopyrrolate), Spiriva® (tiotropium), and Tudorza® Pressair® (aclidinium).

- The FDA approval of Bevespi Aerosphere is based on data from clinical trials of over 3,700 patients with COPD. Bevespi Aerosphere achieved statistically significant improvements in morning pre-dose forced expiratory volume in 1 second (FEV1) at 24 weeks (p < 0.001) vs. its individual components and placebo.

- Similar to other LABAs, Bevespi Aerosphere carries a boxed warning for asthma-related death.

- All LABAs are contraindicated in patients with asthma without use of a long-term asthma control medication. Bevespi Aerosphere is not indicated for the treatment of asthma.

- Other warnings and precautions of Bevespi Aerosphere include deterioration of disease and acute episodes, excessive use of Bevespi and use with other LABAs, paradoxical bronchospasm, immediate hypersensitivity reactions, cardiovascular effects, coexisting conditions, hypokalemia and hyperglycemia, worsening of narrow-angle glaucoma, and worsening of urinary retention.

- The most common adverse events (≥ 2% and more common than placebo) with Bevespi Aerospace use were urinary tract infection and cough.

- The recommended dose of Bevespi Aerospace is two inhalations taken twice daily in the morning and evening by the orally inhaled route only.
  
  — Patients should not take more than two inhalations twice daily.

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AstraZeneca plans to launch Bevespi Aerosphere in the first quarter of 2017. Bevespi Aerosphere will be available as a pMDI that delivers 9 mcg of glycopyrrolate and 4.8 mcg of formoterol fumarate per inhalation. Each canister contains 120 inhalations with an attached dose counter.