ASTRAZENECA PLC
Form 6-K
April 26, 2016

FORM 6-K

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Report of Foreign Issuer

Pursuant to Rule 13a-16 or 15d-16 of
the Securities Exchange Act of 1934

For the month of April 2016

Commission File Number: 001-11960

AstraZeneca PLC

2 Kingdom Street, London W2 6BD

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.

Form 20-F X Form 40-F __

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): _____

Indicate by check mark whether the registrant by furnishing the information contained in this Form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes __ No X

If "Yes" is marked, indicate below the file number assigned to the Registrant in connection with Rule 12g3-2(b): 82-_____

BEVESPI AEROSPHERETM APPROVED BY
THE US FDA FOR PATIENTS WITH COPD

Demonstrated superior improvement in lung function versus mono-components and placebo

Only long-acting dual bronchodilator delivered through a pressurised metered-dose inhaler (pMDI) and first product to use AstraZeneca's patented Co-SuspensionTM Technology

AstraZeneca has announced that the US Food and Drug Administration has approved Bevespi Aerosphere (glycopyrrolate and formoterol fumarate) inhalation aerosol indicated for the long-term, maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema.

Sean Bohen, Executive Vice-President, Global Medicines Development and Chief Medical Officer, said: "With the approval of Bevespi Aerosphere we are pleased to provide patients with the first LAMA/LABA in a pressurised metered-dose inhaler, delivered using our unique formulation technology. LAMA/LABAs are emerging as a preferred treatment option for many COPD patients. This class aims to provide maximum bronchodilation, which enables patients to breathe better and may help them be more active."

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). The FDA approval is based on the PINNACLE trial programme, which demonstrated that Bevespi Aerosphere achieved statistically significant improvement in morning pre-dose forced expiratory volume in 1 second (FEV1) at 24 weeks ($p<0.001$) versus its mono-components and placebo.

Bevespi Aerosphere is the first product approved using AstraZeneca's Co-Suspension Technology. This technology enables consistent delivery of one or more different medicines from a single pMDI. The technology is being applied to a range of AstraZeneca respiratory inhaled combination therapies currently in clinical development, such as the fixed-dose triple combination of LAMA/LABA/Inhaled corticosteroid (PT010).

About COPD
COPD (chronic obstructive pulmonary disease) is a progressive disease associated mainly with tobacco smoking, air pollution or occupational exposure, which can cause obstruction of airflow in the lungs resulting in debilitating bouts of breathlessness. It affects an estimated 329 million people worldwide and is predicted to be the third leading cause of death by 2030. Improving lung function and managing daily symptoms such as breathlessness are important to the management of COPD. It is estimated that eight out of 10 patients suffer symptoms at night, such as an irritative cough and difficulty breathing, frequent nocturnal awakenings, which leads to insomnia, worry and anxiety.

About AstraZeneca's Co-Suspension Technology
The Co-Suspension Technology uses porous, low-density phospholipid particles, which are designed to form a uniform suspension inside a pressurised metered-dose inhaler (pMDI) and distribution of drug crystals throughout the lungs for release at their sites of deposition.

In addition, Co-Suspension Technology addresses issues often seen when multiple drugs are combined in a pMDI. This technology provides a stable, homogeneous suspension designed to prevent sedimentation of drug crystals over time and to prevent drug crystals from interacting with one another, thus allowing for consistent dosing of one or more different drugs from a single pMDI.

About the PINNACLE studies

The FDA approval of Bevespi Aerosphere is based on data from the PINNACLE 1, PINNACLE 2, and a safety extension study, PINNACLE 3. Overall the Phase III pivotal programme enrolled over 3,700 patients with moderate to very severe COPD.

Bevespi Aerosphere demonstrated statistically significant improvements in lung function as measured by change from baseline in morning pre-dose trough forced expiratory volume in 1 second (FEV1) at 24 weeks ($p<0.001$) versus its individual components (glycopyrrolate 9 mcg and formoterol fumarate 4.8 mcg) and placebo, all dosed twice daily.

Bevespi Aerosphere demonstrated a significant improvement versus placebo on secondary endpoints of peak FEV1 within 2 hours post-dose, and rescue medication usage.

There were no unexpected safety findings with adverse events consistent with previous results from the development program. The most common adverse reactions with Bevespi Aerosphere, (with a ≥ 2% incidence and more common than with placebo) were urinary tract infection (2.6% vs 2.3% with placebo) and cough (4.0% vs 2.7% with placebo).

About Respiratory, Inflammation and Autoimmunity Diseases

Respiratory, Inflammation and Autoimmunity (RIA), one of AstraZeneca's main therapy areas, has five potential medicines in pivotal trials or under registration. In respiratory disease, our aim is to transform asthma and COPD treatment through: Inhaled combinations at the core of care, precision biologics for the unmet needs of specific patient populations, and scientific advancements in disease modification. We are building on a 40-year heritage in respiratory disease, and our capability in inhalation technology spans both pressurised metered-dose inhalers (pMDIs) and dry powder inhalers (DPIs), as well as our unique Co-Suspension Technology.

In Inflammation and Autoimmunity, our aim is to develop innovative therapies for the treatment of autoimmune and rheumatoid diseases, with a lead programme in systemic lupus erythematosus. Across respiratory, inflammation and autoimmune diseases, our research is focused on four key treatable traits: eosinophilic disease, Th2-driven disease, epithelial-driven pathobiology, and autoimmunity.

About AstraZeneca

AstraZeneca is a global, innovation-driven biopharmaceutical business that focuses on the discovery, development and commercialisation of prescription medicines, primarily for the treatment of diseases in three main therapy areas - respiratory, inflammation, autoimmune disease (RIA), cardiovascular and metabolic disease (CVMD) and oncology - as well as in infection and neuroscience. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. For more information please visit: www.astrazeneca.com

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Key: RIA - Respiratory, Inflammation and Autoimmunity, CVMD - Cardiovascular and Metabolic Disease, ING - Infection, Neuroscience and Gastrointestinal

26 April 2016

-ENDS-

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

AstraZeneca PLC

Date: 26 April 2016

By: /s/ Adrian Kemp
Name: Adrian Kemp
Title: Company Secretary