ASTRAZENECA PLC
Form 6-K
March 18, 2015

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 March 2015
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-_____

ASTRAZENECA ANNOUNCES POSITIVE PHASE III

TOP-LINE RESULTS FOR PT003 FROM THE PINNACLE 1 AND PINNACLE 2 STUDIES IN COPD

AstraZeneca today announced positive top-line results from the Phase III PINNACLE programme, which included two pivotal 24-week studies (PINNACLE 1 and PINNACLE 2) to investigate the potential of PT003 to improve lung

function in patients with Chronic Obstructive Pulmonary Disease (COPD).

PT003 is a twice-daily fixed-dose combination of glycopyrronium, a long-acting muscarinic antagonist (LAMA) and formoterol fumarate, a long-acting beta-2 agonist (LABA). PT003 is the first LAMA/LABA combination to be delivered in a pressurised metered dose inhaler (pMDI) using the unique porous particle co-suspension technology developed by Pearl Therapeutics, which was acquired by AstraZeneca in 2013. The development programme also included assessment of the individual components of PT003 - glycopyrronium pMDI (PT001) and formoterol fumarate (PT005) pMDI. The successful completion of the PINNACLE studies marks the first Phase III outcomes from a series of pipeline candidates under development by AstraZeneca using Pearl's novel technology.

In both the PINNACLE 1 and PINNACLE 2 studies, the primary objective was to assess benefits on lung function as measured by trough forced expiratory volume in one second (FEV1). PT003 demonstrated statistically significant improvements in trough FEV1 versus PT001, PT005 and placebo. Both PT001 and PT005 also demonstrated statistically significant improvements in trough FEV1 compared to placebo.

In PINNACLE 1 and PINNACLE 2, the most common adverse events across all treatment arms, including placebo, were nasopharyngitis, upper respiratory tract infection, and dyspnea. The incidence of adverse events was generally similar across all treatment groups. The Phase III programme also included a 28-week extension study, PINNACLE 3, the safety information from which is not yet available.

Briggs Morrison, Executive Vice President, Global Medicines Development and Chief Medical Officer at AstraZeneca, said: "These positive top-line results demonstrate the potential of PT003 as a novel treatment for patients suffering with the debilitating and chronic symptoms of COPD. The ability to deliver a unique LAMA/LABA formulation in a single pressurised metered dose device is important for helping some 30% of patients around the world who use an aerosol inhaler. Today's results are also encouraging for the development of our investigative triple-drug combination of LAMA/LABA and inhaled corticosteroids."
AstraZeneca plans to file global regulatory applications for PT003 commencing in 2015. Data from the PINNACLE 1, 2, and 3 Phase III studies will be presented at a scientific meeting later in the year.

NOTES TO EDITORS

The PINNACLE Phase III Pivotal Programme
The PT003 Phase III pivotal programme consists of PINNACLE 1, PINNACLE 2, and an extension study, PINNACLE 3. Overall the Phase III pivotal programme enrolled over 3,700 patients with COPD at over 275 study sites.

PINNACLE 1 and PINNACLE 2 were Phase III randomised, double-blind, multi-centre, placebo-controlled studies. In both studies, the efficacy and safety of PT003 administered twice daily via pressurised metered dose inhaler (pMDI) was compared to its monotherapy components: glycopyrronium (PT001), a LAMA, and formoterol fumarate (PT005), a LABA, and placebo. PT001 and PT005 were also compared to placebo. In PINNACLE 1, open-label tiotropium was included as an active control. Both studies were conducted over 24 weeks in subjects with COPD.

The primary objective of both studies was improvement in lung function as assessed by trough forced expiratory volume in one second (FEV1).
PINNACLE 3 was a multi-centre, randomised, double-blind, parallel-group, chronic dosing, active-controlled, 28-week safety extension study of the two pivotal 24-week studies (PINNACLE 1 and 2). It was designed to evaluate the long-term safety, tolerability, and efficacy of PT003 administered twice daily via pMDI compared to PT001 and PT005 in patients with moderate to very severe COPD over a total observation period of 52 weeks. Open-label tiotropium served as the active control.

About COPD
COPD 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 300 million people worldwide and is predicted to be the third leading cause of death by 2020. Although COPD is widely regarded as a disease of the elderly, 50 per cent of patients are estimated to be between 50 and 65 years of age, meaning half of the COPD population is likely to be affected at a stage in their life when they are at the peak of their earning potential and are likely to have major family responsibilities.

About Pearl Therapeutics
Pearl Therapeutics is a wholly owned subsidiary of AstraZeneca, following its acquisition in 2013. The company is focused on developing inhaled combination therapies for the treatment of highly prevalent respiratory diseases, including COPD and asthma. Pearl Therapeutics' unique porous particle co-suspension technology allows for the production of unique fixed-dose combinations of different classes of drugs at different concentrations in a single pressurised metered dose inhaler (pMDI) device. Fixed-dose combination therapies can simplify treatment for patients, improving the potential for convenience and compliance versus the use of separate inhalers. Non-adherence is a well-documented issue in COPD and is associated with detrimental effects on patient outcomes.

About AstraZeneca in Respiratory Disease
AstraZeneca has a long heritage in respiratory disease with 40 years of experience and a strong franchise of marketed products. Our efforts to find ground-breaking medicines and to develop new technologies are underpinned by a deep understanding of the biology of respiratory diseases and our extensive experience in primary care medicine.

Our strategy is to deliver a range of differentiated therapies, including novel combinations, new devices, and innovative product offerings to treat respiratory diseases, including asthma, chronic obstructive pulmonary disease (COPD) and idiopathic pulmonary fibrosis (IPF). Our innovative precision approaches will ensure the right treatment for the right patient.

AstraZeneca's respiratory portfolio includes asthma and COPD medicine Symbicort and asthma medicine Pulmicort as well as COPD treatments, Eklira Genuair, Tudorza Pressair and Duaklir Genuair.

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 cardiovascular, metabolic, respiratory, inflammation, autoimmune, oncology, infection and neuroscience diseases. 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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18 March 2015

-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: 18 March 2015

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