ASTRAZENECA PLC
Form 6-K
August 23, 2018

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 August 2018

Commission File Number: 001-11960

AstraZeneca PLC

1 Francis Crick Avenue
Cambridge Biomedical Campus
Cambridge CB2 0AA
United Kingdom

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 PLC

INDEX TO EXHIBITS

1.
AstraZeneca PIIIb trial update for Bevespi in COPD

23 August 2018 07:00 BST

AstraZeneca provides update on AERISTO Phase IIIb trial for
Bevespi Aerosphere in chronic obstructive pulmonary disease

AstraZeneca today announced top-line results from the AERISTO Phase IIIb trial for Bevespi Aerosphere (glycopyrronium/formoterol fumarate) in patients with moderate to very severe chronic obstructive pulmonary disease (COPD). In the trial, Bevespi Aerosphere demonstrated non-inferiority to umeclidinium/vilanterol on peak forced expiratory volume in one second (FEV1) but did not demonstrate superiority on peak FEV1 or non-inferiority on trough FEV1.

Dr Colin Reisner, Head of Respiratory, Global Medicines Development, said: "The efficacy and safety of Bevespi Aerosphere has been established by the Phase III PINNACLE trial programme involving more than 5,000 patients. The performance of Bevespi Aerosphere in AERISTO is inconsistent with previous data. A full analysis is underway to understand and characterise these findings and will be presented at a forthcoming medical meeting."

The 24-week AERISTO Phase IIIb trial was a randomised, double-blinded, double-dummy, multicentre, parallel-group trial designed to assess the efficacy and safety of Bevespi Aerosphere compared with umeclidinium/vilanterol. The primary endpoints were peak change from baseline in FEV1 where non-inferiority and superiority were measured and change from baseline in trough FEV1 where non-inferiority was measured. In the trial, 1,119 patients were randomised to receive either two inhalations twice a day of Bevespi Aerosphere (glycopyrronium/formoterol fumarate 7.2/4.8µg) via pressurised metered-dose inhaler or one inhalation once a day of umeclidinium/vilanterol 62.5/25µg via dry powder inhaler. Safety and tolerability data for Bevespi Aerosphere were consistent with the known profile of the medicine.

Bevespi Aerosphere is approved in the US and Canada for the long-term maintenance treatment of airflow obstruction in COPD. Bevespi Aerosphere is currently under review by the European Medicines Agency with a regulatory decision anticipated in the second half of 2018.

About COPD
COPD is a progressive disease which can cause obstruction of airflow in the lungs resulting in debilitating bouts of breathlessness.1 It affects an estimated 384 million people worldwide and is predicted to be the third leading cause of death by 2020.1,2 At initial diagnosis, approximately one-third of COPD patients have severe or very severe forms of the disease.3 Improving lung function, reducing exacerbations and managing daily symptoms such as breathlessness are important to the management of COPD.1 Moderate to severe COPD is typically managed through long-acting bronchodilator therapy. Despite the availability of effective long-acting bronchodilator monotherapies, many patients remain symptomatic and may require dual long-acting bronchodilator therapy.1,4

About Bevespi Aerosphere

Bevespi Aerosphere is a fixed-dose dual bronchodilator combining glycopyrronium, a long-acting muscarinic agonist (LAMA), and formoterol fumarate, a long-acting beta2-agonist (LABA). Bevespi Aerosphere is the first and only LAMA/LABA with Aerosphere Delivery Technology. Results from an imaging trial have shown that Bevespi Aerosphere effectively delivers medicine to both the large and small airways.5 Aerosphere Delivery Technology is also the platform for potential new medicines including PT010, AstraZeneca's triple combination of budesonide/glycopyrronium/formoterol fumarate.

About AstraZeneca in Respiratory Disease
Respiratory disease is one of AstraZeneca's main therapy areas, and the Company has a growing portfolio of medicines that reached more than 18 million patients in 2017. AstraZeneca's aim is to transform asthma and COPD treatment through inhaled combinations at the core of care, biologics for the unmet needs of specific patient populations, and scientific advancements in disease modification.

The Company is building on a 40-year heritage in respiratory disease and AstraZeneca's capability in inhalation technology spans pressurised metered-dose inhalers and dry powder inhalers, as well as the Aerosphere Delivery Technology. The company also has a growing portfolio of respiratory biologics, including Fasenra (anti-eosinophil, anti-IL-5r), now approved for severe eosinophilic asthma and in development for severe nasal polyposis, and tezepelumab (anti-TSLP), which achieved its Phase IIb primary and secondary endpoints and is continuing development in the Phase III PATHFINDER clinical trial programme. AstraZeneca's research is focused on addressing underlying disease drivers focusing on the lung epithelium, lung immunity and lung regeneration.

About AstraZeneca
AstraZeneca is a global, science-led biopharmaceutical company that focuses on the discovery, development and commercialisation of prescription medicines, primarily for the treatment of diseases in three therapy areas - Oncology, Cardiovascular, Renal & Metabolism and Respiratory. 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 and follow us on Twitter @AstraZeneca.

Media Relations		
Karen Birmingham	UK/Global	+44 203 749 5634
Rob Skelding	UK/Global	+44 203 749 5821
Matt Kent	UK/Global	+44 203 749 5906
Gonzalo Viña	UK/Global	+44 203 749 5916
Jacob Lund	Sweden	+46 8 553 260 20
Michele Meixell	US	+1 302 885 2677

Investor Relations		
Thomas Kudsk Larsen		+44 203 749 5712
Josie Afolabi		+44 203 749 5631
Craig Marks	Finance; Fixed Income	+44 7881 615 764
Henry Wheeler	Oncology	+44 203 749 5797
Mitchell Chan	Oncology; Other	+1 240 477 3771
Christer Gruvris	Cardiovascular; Metabolism	+44 203 749 5711
Nick Stone	Respiratory; Renal	+44 203 749 5716
Jennifer Kretzmann	Retail Investors	+44 203 749 5824
US toll-free		+1 866 381 7277

Adrian Kemp
Company Secretary
AstraZeneca PLC

References
1. Global Strategy for the Diagnosis, Management and Prevention of COPD, Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2018. Available from: http://goldcopd.org. Last accessed June 2018.
2. Mapel DW, Anand AD, Blanchette CM et al. Severity of COPD at initial spirometry-confirmed diagnosis: data from medical charts and administrative claims. Int J Chron Obstruct Pulmon Dis. 2011;6:573-81. doi: 10.2147/COPD.S16975.
3. Cazzola et al. The scientific rationale for combining long-acting beta2-agonists and muscarinic antagonists in COPD. Pulm Pharmacol Ther. 2010: 23(4):257-67
4. Pedersen S et al. Influence of inspiratory flow rate upon the effect of a Turbuhaler. Arch Dis Child. 1990;65:308-10
5. AstraZeneca. Aerosphere Delivery Technology - Global Core Claims Guide.

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: 23 August 2018

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