ASTRAZENECA PLC
Form 6-K/A
January 26, 2018

FORM 6-K/A
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 January 2018

Commission File Number: 001-11960

AstraZeneca PLC

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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 __
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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

AZ Reports Phase III Results for PT010 in COPD

26 January 2018 18:20 GMT

The following amendments have been made to the 'AZ Reports Phase III Results for PT010 in COPD' announcement released on 26/01/2018.

These amendments are to correct text, delineating the PT010 superiority primary endpoints from the comparator PT009 non-inferiority primary endpoints:

Subhead amended from "eight out of nine" to "six out of seven."

First sentence amended from "in eight out of nine" to "compared with dual combination therapies in six out of seven."

Body copy amended to include: "In total, eight of the nine primary endpoints in the KRONOS trial were met, including two non-inferiority endpoints to qualify PT009, one of the comparators."

ASTRAZENECA REPORTS TOP-LINE PHASE III KRONOS TRIAL RESULTS FOR PT010 TRIPLE COMBINATION THERAPY IN CHRONIC OBSTRUCTIVE PULMONARY DISEASE

PT010 demonstrates significant improvement in six out of seven lung function primary endpoints compared with dual combination therapies

AstraZeneca today announced top-line results from the Phase III KRONOS trial that showed PT010 (budesonide/glycopyrronium/formoterol fumarate 320/14.4/9.6µg, using Aerosphere Delivery Technology, in a pressurised metered-dose inhaler or pMDI) demonstrated a statistically significant improvement compared with dual combination therapies in six out of seven lung function primary endpoints based on forced expiratory volume in one second (FEV1) assessments in patients with moderate t six out of seveno very severe chronic obstructive pulmonary disease (COPD). In total, eight of the nine primary endpoints in the KRONOS trial were met, including two non-inferiority endpoints to qualify PT009, one of the comparators.

KRONOS is a randomised, double-blind, parallel-group, 24-week, chronic-dosing, multi-centre trial to assess the efficacy and safety of PT010. The trial compared PT010 to Bevespi Aerosphere (glycopyrronium/formoterol fumarate 14.4/9.6µg pMDI), Symbicort Turbuhaler (budesonide/formoterol fumarate 400/12µg) and PT009 (budesonide/formoterol fumarate 320/9.6µg using Aerosphere Delivery Technology in a pMDI, being characterised to qualify as a relevant comparator in clinical trials for PT010).1 Patients were given two inhalations twice a day of PT010, PT009, Bevespi Aerosphere or Symbicort Turbuhaler.

There were no unexpected safety or tolerability signals for PT010 identified in the trial.

Summary of trial results:

Primary endpoint results assessed by FEV1	
PT010 vs Symbicort	
Over 24 weeks (post-dose*)	Met
PT010 vs Bevespi Aerosphere	
Over 24 weeks (trough)	Met
Over 12-24 weeks (trough)	Met
At 24 weeks (trough)	Not met; favourable trend
PT010 vs PT009	
Over 24 weeks (post-dose*)	Met
Over 12-24 weeks (trough)	Met
At 24 weeks (post-dose*)	Met
PT009 vs Symbicort (non-inferiority comparison)	

Over 24 weeks (trough)	Met
Over 12-24 weeks (trough)	Met

* Post-dose assessments FEV1 area under the curve 0-4 hours

Dr. Sean Bohen, Executive Vice President, Global Medicines Development and Chief Medical Officer, said: "We are encouraged by the results of the KRONOS trial that has demonstrated PT010's efficacy in improving lung function and look forward to the ETHOS exacerbation trial results in 2019 that will further characterise the role of this potential treatment for patients with COPD."

Klaus Rabe, Professor of Pulmonary Medicine at the University of Kiel, Director of the Department of Pneumology at Clinic Grosshansdorf, Germany, and National Co-ordinating Investigator of the KRONOS trial, said: "With the KRONOS trial, we are seeing the potential of PT010 as a triple combination therapy for COPD. I expect the triple class of medicines to play an increasingly important role in addressing the needs of the many COPD patients who are currently undertreated or are receiving triple combination therapy as separate medicines in multiple devices."

The KRONOS trial results will be presented at a forthcoming medical meeting. AstraZeneca anticipates making regulatory submissions in Japan and China in the second half of 2018, followed by potential submissions in the US and Europe in 2019.

About COPD
COPD is a progressive disease which can cause obstruction of airflow in the lungs resulting in debilitating bouts of breathlessness.2 It affects an estimated 329 million people worldwide3 and is predicted to be the third-leading cause of death by 2020.2 Improving lung function, reducing exacerbations and managing daily symptoms such as breathlessness are important to the management of COPD. Today, approximately one quarter of patients in Europe and the US are taking triple combination therapy (inhaled corticosteroid (ICS)/long-acting muscarinic antagonist (LAMA)/long-acting beta2-agonist (LABA)), but delivered as separate medicines in multiple devices.4,5

About PT010 and the Aerosphere portfolio
PT010 is a single inhaler, fixed-dose triple combination therapy of budesonide, an ICS with glycopyrronium, a LAMA, and formoterol fumarate, a LABA. It is being developed using AstraZeneca's Aerosphere Delivery Technology. Aerosphere Delivery Technology is also the platform for the approved medicine Bevespi Aerosphere.

About the ATHENA clinical trial programme
ATHENA is AstraZeneca's Phase III clinical trial programme for PT010, which includes more than 15,500 patients globally across 11 trials.1,6,7,8 The four key trials are ETHOS, KRONOS, TELOS and SOPHOS. ETHOS and TELOS include low and high doses of ICS and stratification of patients by eosinophil levels as part of randomisation, for PT010 and PT009 respectively.6,7

About Symbicort
Symbicort is a combination formulation containing budesonide, an ICS, and formoterol, a LABA, in a single inhaler. Symbicort is approved in approximately 120 countries to treat COPD either as Symbicort Turbuhaler or Symbicort pMDI.

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), which is now approved in the US, EU and Japan respectively, and is under regulatory review in other jurisdictions, 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 & Metabolic Diseases and Respiratory. The Company also is selectively active in the areas of autoimmunity, neuroscience and infection. 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.

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Adrian Kemp
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AstraZeneca PLC

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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 January 2018
By: /s/ Adrian Kemp
Name: Adrian Kemp
Title: Company Secretary