ASTRAZENECA PLC
Form 6-K
September 07, 2017

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 September 2017

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 __

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):

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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-_____

7 September 2017 07:00 BST

DUAKLIR SIGNIFICANTLY IMPROVES LUNG FUNCTION IN COPD PATIENTS

Phase III AMPLIFY trial demonstrated a statistically- significant improvement in lung function in patients with COPD

Study achieved the primary endpoints to support a New Drug Application (NDA) submission

AstraZeneca today announced positive top-line results from the Phase III AMPLIFY trial for Duaklir* (aclidinium bromide/formoterol 400µg/12µg twice-daily), which met its primary endpoints, demonstrating a statistically-significant improvement in lung function in patients with moderate to very severe stable chronic obstructive pulmonary disease (COPD) compared to each individual component (either aclidinium bromide or formoterol). In addition, aclidinium bromide achieved its primary bronchodilation endpoint of demonstrating non-inferiority to tiotropium bromide 18µg once-daily.

Dr. Sanjay Sethi, Professor and Chief, Pulmonary, Critical Care and Sleep Medicine at University at Buffalo, The State University of New York, USA and the lead investigator of the trial, said: "These results demonstrate the improvement in lung function achieved by the combination of aclidinium and formoterol compared to single LAMA bronchodilators tiotropium and aclidinium, with comparable safety."

The efficacy, safety and tolerability profiles for aclidinium bromide and formoterol were consistent with current experience. A full evaluation of the AMPLIFY data is ongoing and further results will be presented at a forthcoming medical meeting. AstraZeneca is expected to submit an NDA during H1 2018 to the US Food and Drug Administration (FDA) for Duaklir, based on the AMPLIFY data.

Steve Lewington, Global Medicine Leader, Respiratory, AstraZeneca said: "The AMPLIFY study top-line results provide further clinical evidence of Duaklir's efficacy and support making this LAMA/LABA combination treatment option available to COPD patients in the US."

In April 2017 AstraZeneca entered a strategic collaboration with Circassia Pharmaceuticals plc (Circassia) for the development and commercialisation of Tudorza and Duaklir in the US. Under the terms of the collaboration, Circassia was granted the rights to Duaklir in the US. Circassia is also leading the promotion of Tudorza in the US and was conferred an option to gain full commercial rights in the future.

- ENDS -

NOTES TO EDITORS

About COPD

Chronic obstructive pulmonary disease (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 329 million people worldwide and is predicted to be the third leading cause of death by 2020. Improving lung function, reducing exacerbations and managing daily symptoms such as breathlessness are important to the management of COPD.

About AMPLIFY

AMPLIFY is a 24-week treatment, multicentre, randomised, double-blind, double dummy, parallel-group trial to assess the efficacy and safety of aclidinium bromide/formoterol 400µg/12µg twice-daily compared to its component parts (aclidinium bromide 400µg twice-daily or formoterol fumarate 12µg twice-daily) and once-daily tiotropium 18µg in moderate to very severe stable COPD patients.

The primary outcome measures were to demonstrate;

- a change from base-line morning pre-dose (trough) FEV1 for aclidinium bromide/formoterol 400µg/12µg versus formoterol 12µg at week 24

- a change from base-line in morning one-hour post-dose FEV1 for aclidinium bromide/formoterol 400µg/12µg versus aclidinium bromide 400µg at week 24

- a change from baseline in morning pre-dose (trough) FEV1 at week 24 comparing aclidinium bromide 400µg versus tiotropium 18µg to demonstrate non-inferiority

Other objectives were to assess the safety of aclidinium bromide/formoterol fumarate 400µg/12µg, as well as to further characterise the effect of the combination on bronchodilation and health related quality of life.

About Duaklir

Duaklir (aclidinium bromide/formoterol fumarate 400µg/12µg twice-daily) is an approved fixed-dose LAMA/LABA combination of two long-acting bronchodilators - aclidinium bromide is a long-acting muscarinic antagonist (LAMA) and formoterol fumarate is a long-acting beta-agonist (LABA). The fixed-dose combination was approved by the European Medicines Agency (EMA) in November 2014 as a maintenance bronchodilator treatment to relieve symptoms in adult patients with COPD.

About Pressair

The Pressair is an easy-to-use, multi-dose, breath-activated inhaler with a unique patient feedback mechanism that is approved in the US for delivering Tudorza (aclidinium bromide). The Pressair inhaler is being used for the development of Duaklir in the US. Outside of the US the Pressair inhaler is marketed as Genuair.

About Circassia

In April 2017 AstraZeneca entered a strategic collaboration with Circassia Pharmaceuticals plc, for the development and commercialisation of Tudorza and Duaklir in the US. Under the terms of the collaboration Circassia was granted the rights to Duaklir in the US. Circassia is also leading the promotion of Tudorza in the US and was granted an option to gain the full commercial rights in the future. AstraZeneca has received a minority equity stake in Circassia. AstraZeneca will complete ongoing development activities and continue to manufacture and supply both medicines. AstraZeneca will receive $100 million at the approval of Duaklir in the US, or 30 June 2019, whichever is earliest, and Circassia will pay AstraZeneca tiered percentage royalties on potential future US sales of Duaklir.

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 is also 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 http://www.astrazeneca.com/ and follow us on Twitter @AstraZeneca

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*Duaklir, Pressair, Genuair and Tudorza are all registered trademarks of AstraZeneca. Duaklir is a registered trademark in Europe and other markets. The US trademark is subject to review and approval by the FDA.

Adrian Kemp
Company Secretary
AstraZeneca PLC

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: 7th September 2017

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