ASTRAZENECA PLC
Form 6-K
May 30, 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 May 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.

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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-_____

INDEX TO EXHIBITS

1. Update on TERRANOVA PIII trial for Fasenra in COPD

30 May 2018 07:00 BST

Update on TERRANOVA Phase III trial for Fasenra
in chronic obstructive pulmonary disease

TERRANOVA trial did not meet the primary endpoint of a statistically-significant reduction of exacerbations in patients with chronic obstructive pulmonary disease

AstraZeneca and MedImmune, its global biologics research and development arm, today announced top-line results from TERRANOVA, the second of two pivotal Phase III trials for Fasenra (benralizumab) in patients with moderate to very severe chronic obstructive pulmonary disease (COPD). The trial did not meet the primary endpoint of a statistically-significant reduction of exacerbations. This news follows the announcement earlier this month that the first pivotal Phase III trial, GALATHEA, did not meet its primary endpoint.

Dr. Sean Bohen, Executive Vice President, Global Medicines Development and Chief Medical Officer, said: "These results are disappointing because uncontrolled COPD patients already on dual or triple inhaled therapy need new treatment options. We will now analyse the complete data sets from the GALATHEA and TERRANOVA trials to further understand these results."

The pivotal Phase III trials GALATHEA and TERRANOVA were randomised, double-blinded, 56-week placebo-controlled, multicentre trials assessing the safety and efficacy of Fasenra as an add-on to dual or triple inhaled therapy compared to placebo in patients with moderate to very severe COPD with a history of exacerbations across a range of baseline blood eosinophils.1,2

The safety and tolerability findings in TERRANOVA were consistent with those observed in previous trials with Fasenra. A full evaluation of the data is ongoing, and the results will be submitted for presentation at a forthcoming medical meeting. The Company does not currently intend to make a regulatory submission.

Fasenra is AstraZeneca's first respiratory biologic and is currently approved as an add-on treatment for severe eosinophilic asthma in the US, EU, Japan and several other countries. The results of the GALATHEA and TERRANOVA trials do not impact the approved indication in severe eosinophilic asthma.

About COPD
COPD is a progressive disease which can cause obstruction of airflow in the lungs resulting in debilitating bouts of breathlessness.3 It affects an estimated 384 million people worldwide and is predicted to be the third-leading cause of death by 2020.3,4 At initial diagnosis, approximately one-third of COPD patients have severe or very severe forms of this disease.5 Improving lung function, reducing exacerbations and managing daily symptoms such as breathlessness are important to the management of COPD.3

About 30-40% of moderate to severe COPD patients on triple inhaled therapy (ICS/LAMA/LABA) remain uncontrolled and continue to experience exacerbations.6,7 COPD exacerbations significantly impair quality of life and are linked to disease progression, accelerated decline in lung function, and increased hospitalisations and mortality.8,9,10

About Fasenra
Fasenra (benralizumab) is a monoclonal antibody that recruits natural killer cells to induce rapid and near-complete depletion of eosinophils, a type of white blood cell that are a normal part of the body's immune system.11,12 Depletion of circulating eosinophils is rapid, with an onset of action within 24 hours as confirmed in Phase I/II severe asthma trials.11,12,13

Fasenra is AstraZeneca's first respiratory biologic, now approved in severe eosinophilic asthma in the US, EU, Japan, Canada and Australia and under regulatory review in several other jurisdictions. Fasenra is also being tested in severe nasal polyposis.

Fasenra was developed by AstraZeneca with MedImmune, the company's global biologics research and development arm and is in-licensed from BioWa, Inc., a wholly-owned subsidiary of Kyowa Hakko Kirin Co., Ltd., Japan.

About the VOYAGER Programme
VOYAGER is AstraZeneca's Phase III Fasenra clinical trial programme in COPD and, with close to 4,000 patients, it is currently the largest COPD biologics development programme in the world.14 The VOYAGER programme includes two trials, GALATHEA and TERRANOVA, evaluating Fasenra in patients with moderate to very severe COPD with a history of exacerbations across a range of baseline blood eosinophils.14

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 MedImmune
MedImmune is the global biologics research and development arm of AstraZeneca, a global, innovation-driven biopharmaceutical business that focuses on the discovery, development and commercialisation of small molecule and biologic prescription medicines. MedImmune is pioneering innovative research and exploring novel pathways across Oncology, Respiratory, Cardiovascular & Metabolic Diseases, and Infection and Vaccines. The MedImmune headquarters is located in Gaithersburg, Md., one of AstraZeneca's three global R&D centres, with additional sites in Cambridge, UK and Mountain View, Calif. For more information, please visit www.medimmune.com

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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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: 30 May 2018

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