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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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

TEZEPELUMAB SIGNIFICANTLY REDUCED ASTHMA EXACERBATIONS FOR A BROAD POPULATION OF PATIENTS WITH SEVERE UNCONTROLLED ASTHMA

First-in-class treatment that blocks thymic stromal lymphopoietin (TSLP) -

an upstream driver of inflammation in asthma

Results published today in New England Journal of Medicine

Late-breaking abstract at European Respiratory Society International Congress highlights results from the PATHWAY Phase IIb trial of tezepelumab in patients with severe, uncontrolled asthma

7 September 2017

AstraZeneca and Amgen Inc. (Amgen) today announced results from the PATHWAY Phase IIb trial of tezepelumab that showed a significant reduction in the annual asthma exacerbation rate compared with placebo in patients with severe, uncontrolled asthma. Tezepelumab is a first-in-class anti-TSLP monoclonal antibody being developed by MedImmune, AstraZeneca's global biologics research and development arm, in collaboration with Amgen.

The trial results were published today in the New England Journal of Medicine, and will be followed by an oral presentation on 12 September at the ERS International Congress 2017 in Milan.

The PATHWAY trial achieved its primary efficacy endpoint, showing annual asthma exacerbation rate reductions of 61%, 71% and 66% in the tezepelumab arms receiving either 70mg or 210mg every four weeks or 280mg every two weeks, respectively ($p<0.001$ for all comparisons to placebo). In the trial, tezepelumab was given as an add-on therapy to patients with a history of asthma exacerbations and uncontrolled asthma despite receiving inhaled corticosteroids/long-acting beta-agonists with or without oral corticosteroids and additional asthma controllers.

Significant and clinically-meaningful reductions in the exacerbation rate were observed independent of baseline blood eosinophil count or other type 2 (T2) inflammatory biomarkers. Tezepelumab also demonstrated improvements in lung function at all doses and in asthma control at the two higher doses ($p<0.05$ for all comparisons to placebo). The incidence of adverse events was similar between the tezepelumab and placebo groups. The most common adverse events (≥5%) in tezepelumab-treated patients were asthma, nasopharyngitis, headaches and bronchitis.

Dr Jonathan Corren, David Geffen School of Medicine, UCLA and Principal Investigator of the PATHWAY trial, said: "These efficacy results strongly confirm that TSLP is an important mediator of inflammation in severe asthma. Due to its activity early in the inflammatory cascade, tezepelumab may be suitable for patients with both T2 and non-T2 driven asthma, including those ineligible for current biologic therapies which only target the T2 pathway."

Bahija Jallal, Executive Vice President, Head of MedImmune, said: "In asthma patients, TSLP functions as an upstream epithelial 'master-switch' right at the start of the inflammation cascade. By binding to TSLP, tezepelumab impacts multiple downstream inflammatory pathways associated with asthma, as shown by striking reductions in the level of multiple biomarkers in the PATHWAY trial, including blood eosinophils, IgE and FeNO. This broad biomarker response is unprecedented among respiratory biologics and reflects our commitment to leading respiratory science for unmet medical needs."

TSLP is an epithelial cytokine produced in response to pro-inflammatory stimuli such as allergens, viruses and other pathogens in the lung. It drives the release of downstream T2 cytokines including IL-4, IL-5 and IL-13, leading to inflammation and asthma symptoms. TSLP also activates many types of cells involved in non T2 driven

inflammation. Therefore, the early, upstream activity of TSLP in the inflammation cascade has been identified as a potential target across a broad asthma population.

- ENDS -

NOTES TO EDITORS

About Severe Asthma

Asthma affects 315 million individuals worldwide, and up to 10% of asthma patients have severe asthma, which may be uncontrolled despite high doses of standard-of-care asthma controller medicines and can require the use of chronic oral corticosteroids (OCS).

Severe, uncontrolled asthma is debilitating and potentially fatal with patients experiencing frequent exacerbations and significant limitations on lung function and quality of life.

Severe, uncontrolled asthma can lead to a dependence on OCS, with systemic steroid exposure potentially leading to serious short- and long-term adverse effects, including weight gain, diabetes, osteoporosis, glaucoma, anxiety, depression, cardiovascular disease and immunosuppression. There is also a significant physical and socio-economic burden of severe, uncontrolled asthma with these patients accounting for 50% of asthma-related costs.

T2 inflammation driven (T2 high) asthma is present in over two-thirds of patients with severe asthma and is typically characterised by elevated levels of T2 inflammatory biomarkers, including blood eosinophils, serum IgE and fractional exhaled nitric oxide (FeNO). Conversely, approximately one-third of patients with severe asthma do not present with features of an activated T2 inflammatory pathway, and no biologic treatment options currently exist for these patients whose non-T2 driven disease is uncontrolled on established standard of care therapies.

About Tezepelumab

Tezepelumab is the first of a new kind of potential new medicines targeting TSLP. Tezepelumab is a human anti-TSLP monoclonal antibody that specifically binds human TSLP and prevents interaction with its receptor complex. Blocking TSLP with tezepelumab may prevent the release of pro-inflammatory cytokines by immune cells targeted by TSLP, and thus prevent asthma exacerbations and improve asthma control. Due to its activity early in the inflammation cascade, tezepelumab may be suitable for a broad population of patients with severe, uncontrolled asthma, including those whose asthma is not T2 driven. A previous proof-of-concept inhaled allergen challenge study in patients with mild, atopic asthma, demonstrated that tezepelumab inhibits early and late asthmatic responses and suppresses biomarkers of type 2 inflammation. The results were published in the New England Journal of Medicine in 2014. Tezepelumab is being developed in collaboration with Amgen.

About the PATHWAY Trial

The PATHWAY trial was a Phase IIb 52-week, randomised, double-blind, parallel group, placebo-controlled trial designed to evaluate the efficacy and safety of three dose regimens of tezepelumab, 70mg and 210mg every four weeks and 280mg every two weeks, as an add-on therapy in patients with a history of asthma exacerbations and uncontrolled asthma receiving inhaled corticosteroids/long-acting beta-agonist with or without oral corticosteroids and additional asthma controllers.

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 2016. 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 both pMDIs and dry powder inhalers, as well as the innovative Co-SuspensionTM Delivery Technology. The company's biologics include benralizumab (anti-eosinophil, anti-IL-5r), which has been accepted for regulatory review in the US, EU and Japan, tralokinumab (anti-IL-13), which is currently in Phase III, and tezepelumab (anti-TSLP). 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 commercialization of small molecule and biologic prescription medicines. MedImmune is pioneering innovative research and exploring novel pathways across Respiratory & Autoimmunity, Cardiovascular & Metabolic Diseases, Oncology, 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, CA. 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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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