ASTRAZENECA PLC
Form 6-K
May 17, 2016

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 2016

Commission File Number: 001-11960

AstraZeneca PLC

2 Kingdom Street, London W2 6BD

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-_____

ASTRAZENECA ANNOUNCES POSITIVE RESULTS FROM BENRALIZUMAB PHASE III PROGRAMME IN SEVERE ASTHMA

Benralizumab first AstraZeneca respiratory biologic to complete Phase III

17 May 2016

AstraZeneca today announced that benralizumab, a potential new medicine and anti-eosinophil monoclonal antibody, was well tolerated and achieved the primary endpoint in two pivotal Phase III registrational trials (SIROCCO and CALIMA), demonstrating significant reductions in the annual asthma exacerbation rate compared to placebo.

Sean Bohen, Executive Vice President, Global Medicines Development and Chief Medical Officer, said: "
Severe asthma affects the health and quality of life of millions of people around the world, and exacerbations can be life threatening for these patients. We are pleased with the top-line results from these pivotal trials as they demonstrate the potential for benralizumab to improve outcomes for patients with severe asthma. Benralizumab is AstraZeneca's first respiratory biologic and its development underscores our commitment to transform the treatment of asthma and chronic respiratory disease with our next generation of respiratory medicines."

The trials evaluated the efficacy and safety of two dose regimens of benralizumab as an add-on therapy for severe uncontrolled asthma with eosinophilic inflammation in adults and adolescents 12 years of age and older.

In SIROCCO and CALIMA, the primary analysis population included patients on high-dose inhaled corticosteroids (ICS) plus long-acting 2-agonist (LABA) with a baseline blood eosinophil count ≥ 300 cells/microliter. Patients were randomised to receive benralizumab 30mg every 4 weeks; 30mg every 4 weeks for the first three doses followed by 30mg every 8 weeks; or placebo. The safety and tolerability findings for benralizumab were generally consistent with those reported in previous trials.

Mark FitzGerald, MD , director of the Centre for Heart and Lung Health at the Vancouver Coastal Health Research Institute and Principal Investigator in the CALIMA trial, said: "We are learning more about different sub-types of asthma, and these trials investigate a potential new treatment to address the underlying driver for some patients. Within the appropriate patient population, the anti-eosinophil effect of benralizumab has the potential to deliver uniquely-targeted treatment for patients whose asthma is driven by eosinophilic inflammation."

Eosinophils are the biological effector cells that drive inflammation and airways hyper-responsiveness in approximately 50% of asthma patients, leading to frequent exacerbations, impaired lung function and reduced quality of life. Benralizumab is an anti-eosinophil monoclonal antibody that depletes eosinophils via antibody dependent cell-mediated cytotoxicity (ADCC), the process by which natural killer cells are activated to target eosinophils. Benralizumab induces direct, rapid, and near complete depletion of eosinophils in the bone marrow, blood and target tissue. Benralizumab was developed by MedImmune, AstraZeneca's global biologics research and development arm.

Results from the SIROCCO and CALIMA trials will be presented at a future medical meeting. Regulatory submissions in the US and EU are anticipated in the second half of 2016.

About Asthma

Asthma is a common, chronic condition in which inflammation and narrowing of the airways may cause wheezing, breathlessness, chest tightness and coughing. Asthma currently affects the health and day-to-day lifestyles of 315 million individuals worldwide, and by 2020 will likely increase in numbers to as many as 400 million people.

Up to 10% of asthma cases are severe, of which approximately 40% are uncontrolled. Severe, uncontrolled asthma has eight times higher risk of mortality than severe asthma. Uncontrolled asthma can lead to a dependence on oral corticosteroid (OCS). Systemic steroid exposure leads to serious and irreversible adverse effects, including osteoporosis, anxiety, depression, weight gain, glaucoma and diabetes. There is also a significant physical and socio-economic burden of asthma with severe patients accounting for 50% of asthma-related costs.

About the WINDWARD Programme
SIROCCO and CALIMA are both part of the comprehensive WINDWARD programme in asthma (comprised of six Phase III trials in 3,068 patients and 798 sites, across 26 countries), the largest Phase III development programme for a biologic in respiratory disease.

The two registrational trials, SIROCCO and CALIMA, are randomised, double-blind, parallel group, placebo-controlled trials designed to evaluate the efficacy and safety of a fixed 30 mg dose of benralizumab administered subcutaneously in patients with a history of asthma exacerbations and uncontrolled asthma receiving ICS/LABA with or without OCS and additional asthma controllers.

A total of 2,511 patients (1,205 in SIROCCO and 1,306 in CALIMA) were randomised globally and received benralizumab 30mg every 4 weeks; 30mg every 4 weeks for the first three doses followed by 30mg every 8 weeks; or placebo.

In addition to WINDWARD, the Phase III VOYAGER programme is currently underway, evaluating benralizumab in patients with severe chronic obstructive pulmonary disease (COPD).

About Benralizumab
Benralizumab is in-licensed from BioWa, Inc., a wholly-owned subsidiary of Kyowa Hakko Kirin Co., Ltd. Under the exclusive license agreement, Kyowa Hakko Kirin/BioWa have exclusive development and commercialisation rights for benralizumab in Japan and certain countries in Asia. AstraZeneca has exclusive rights for benralizumab in all other countries including the US and Europe. BioWa is eligible to milestone payments and royalties from AstraZeneca related to the development and commercialisation of benralizumab in those countries.

In July 2015 AstraZeneca entered an agreement with Kyowa Hakko Kirin Co. Ltd. (Kyowa Hakko Kirin) for an exclusive option to commercialise benralizumab for asthma and COPD in Japan.
Under the terms of the agreement, AstraZeneca paid Kyowa Hakko Kirin a $45 million up-front option fee and will make subsequent payments for regulatory filing, approval and commercial milestones, and sales royalties. Kyowa Hakko Kirin will continue to be responsible for the research and development of benralizumab in Japan. On exercising the option, AstraZeneca will be responsible for all sales and marketing in asthma and COPD in Japan. Kyowa Hakko Kirin will retain the rights to participate in certain commercial activities alongside AstraZeneca.

About Respiratory, Inflammation and Autoimmunity

Respiratory, Inflammation and Autoimmunity (RIA) is one of AstraZeneca's main therapy areas, and we have a growing portfolio of medicines that reached more than 17 million patients in 2015. Our strong pipeline has the potential to deliver up to seven launches between 2016 and 2020. In respiratory disease, our 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. We are building on a 40-year heritage in respiratory disease, and our capability in inhalation technology spans both pressurised metered-dose inhalers (pMDIs) and dry powder inhalers (DPIs), as well as our unique Co-SuspensionTM Technology.

In Inflammation and Autoimmunity, our aim is to develop innovative therapies for the treatment of autoimmune and rheumatoid diseases, with a lead programme in systemic lupus erythematosus. Across respiratory, inflammation and autoimmune diseases, our research is focused on four key biological pathways: eosinophilic disease, Th2-driven disease, epithelial-driven pathobiology, and autoimmunity.

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 key therapeutic areas, including respiratory, inflammation and autoimmunity; cardiovascular and metabolic disease; oncology; neuroscience; 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, innovation-driven biopharmaceutical business that focuses on the discovery, development and commercialisation of prescription medicines, primarily for the treatment of diseases in three main therapy areas - respiratory, inflammation, autoimmune disease (RIA), cardiovascular and metabolic disease (CVMD) and oncology - as well as in infection and neuroscience. 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.

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Key: RIA - Respiratory, Inflammation and Autoimmunity, CVMD - Cardiovascular and Metabolic Disease, ING - Infection, Neuroscience and Gastrointestinal

17 May 2016

-ENDS-

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: 17 May 2016

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