ASTRAZENECA PLC
Form 6-K
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FORM 6-K

SECURITIES AND EXCHANGE COMMISSION

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Report of Foreign Issuer

Pursuant to Rule 13a-16 or 15d-16 of

the Securities Exchange Act of 1934

For the month of November 2017

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AstraZeneca PLC

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This announcement contains inside information

10 November 2017 11:35 GMT

BENRALIZUMAB RECEIVES POSITIVE EU CHMP OPINION
FOR SEVERE, UNCONTROLLED EOSINOPHILIC ASTHMA

Benralizumab uniquely targets and rapidly depletes eosinophils and is the first respiratory biologic with an 8-week maintenance dosing schedule

Recommendation based on extensive Phase III programme demonstrating significant reductions in exacerbations, improvements in lung function and reductions in oral steroid use, respectively

AstraZeneca and its global biologics research and development arm, MedImmune, today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency has adopted a positive opinion, recommending the marketing authorisation of benralizumab as an add-on maintenance treatment in adult patients with severe eosinophilic asthma inadequately controlled despite high-dose inhaled corticosteroids plus long-acting -agonists.

Sean Bohen, Executive Vice President, Global Medicines Development and Chief Medical Officer at AstraZeneca, said: "This positive recommendation is an important step towards providing a next-generation treatment for severe, uncontrolled asthma patients with an eosinophilic phenotype. Benralizumab has the potential to make a real difference to patients with its combination of efficacy, speed of onset, convenience and the ability to reduce oral steroid use."

The CHMP recommendation is based on results from the WINDWARD programme, including the pivotal Phase III exacerbation trials, SIROCCO and CALIMA, and Phase III oral corticosteroid (OCS)-sparing trial, ZONDA. Results for the 8-week dosing benralizumab regimen from these trials showed:

- Up to 51% reduction in the annual asthma exacerbations rate (AERR) versus placebo
- Rapid improvement in lung function (290mL increase in forced expiratory volume in one second (FEV1) from baseline at 4 weeks) after the first dose, providing an early indication of effectiveness
- 75% median reduction in daily OCS use and discontinuation of OCS use in 52% of eligible patients
- An overall adverse event profile similar to placebo

Tim Harrison, Professor of Asthma and Respiratory Medicine, University of Nottingham, UK, and CALIMA trial investigator, said: "Severe, uncontrolled asthma affects millions of people around the world, and many patients experience debilitating symptoms and face increased risk of hospitalisations, emergency room visits and death despite current treatments. Benralizumab is a new kind of precision antibody with proven efficacy and ease of use which will help transform severe asthma care."

Benralizumab is the only respiratory biologic that provides direct, rapid and near-complete depletion of eosinophils within 24 hours. Eosinophils are a type of white blood cell that are a normal part of the body's immune system. Elevated levels of eosinophils, seen in about half of severe asthma patients, impact airway inflammation and airway hyper-responsiveness, resulting in increased asthma severity and symptoms, decreased lung function and increased risk of exacerbations.

Benralizumab binds directly to the IL-5a receptor on an eosinophil and uniquely attracts natural killer cells to induce apoptosis (programmed cell death). If approved, benralizumab will be available as a once every 8-week fixed-dose subcutaneous injection via a prefilled syringe.

A recent pooled analysis of the SIROCCO and CALIMA trials identified specific, well-defined characteristics of an eosinophilic phenotype that will allow clinicians to more precisely select the severe asthma patients most likely to receive maximum benefit from treatment with benralizumab.

The positive opinion from the CHMP will now be reviewed by the European Commission, which has the authority to approve medicines for the 28 EU member countries plus Iceland, Norway and Liechtenstein.

Benralizumab is also under regulatory review in the US, Japan and several other countries, with a US PDUFA date during the fourth quarter of 2017 and expected regulatory decisions elsewhere during the first half of 2018.

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 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 has higher risk of mortality than severe asthma.

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.

About Benralizumab
Benralizumab is a monoclonal antibody that recruits natural killer cells to induce direct, rapid and near-complete depletion of eosinophils. Depletion of circulating eosinophils is rapid, with an onset of action within 24 hours as confirmed in early Phase I/II trials. In the pivotal Phase III trials, SIROCCO and CALIMA, benralizumab demonstrated significant reduction in exacerbations and improved lung function and asthma symptoms in severe, uncontrolled eosinophilic asthma patients. Eosinophils are the biological effector cells in approximately 50% of asthma patients, leading to frequent exacerbations, impaired lung function and asthma symptoms. Benralizumab is not approved anywhere in the world, but is under regulatory review in the US, EU, Japan and several other countries.

Benralizumab is the foundation of AstraZeneca's respiratory biologics portfolio of potential new medicines targeting underlying causes of respiratory disease. Benralizumab is also being evaluated in chronic obstructive pulmonary

disease (COPD).

Benralizumab was developed by MedImmune, AstraZeneca'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 WINDWARD Programme
The WINDWARD programme in asthma is made up six Phase III trials, including SIROCCO, CALIMA, ZONDA, BISE, BORA and GREGALE. The two pivotal trials SIROCCO and CALIMA, are randomised, double-blinded, parallel-group, placebo-controlled trials designed to evaluate the efficacy and safety of a regular, subcutaneous administration of benralizumab (fixed 30mg dose) for up to 56-weeks in exacerbation-prone adult and adolescent patients 12 years of age and older.

A total of 2,510 patients (1,204 in SIROCCO and 1,306 in CALIMA) received standard-of-care medicine (including high-dosage inhaled corticosteroids and long-acting 2-agonists) and were randomised globally to receive either benralizumab 30mg every 4-weeks; benralizumab 30mg every 4-weeks for the first three doses followed by 30mg every 8-weeks; or placebo administered via subcutaneous injection using an accessorised pre-filled syringe.

A recent pooled post hoc analysis of the SIROCCO and CALIMA studies, demonstrated an association between enhanced benralizumab efficacy and certain easily identifiable clinical features of severe eosinophilic asthma, including baseline blood eosinophil counts, history of more frequent exacerbations, chronic OCS use and a history of nasal polyposis.

The third registrational trial, ZONDA, demonstrated a statistically-significant and clinically-meaningful reduction in daily-maintenance, OCS use compared with placebo for patients with severe, uncontrolled OCS-dependent eosinophilic asthma receiving benralizumab. Patients treated with benralizumab achieved a median reduction in OCS dose of 75%, and were more than four times as likely to reduce their OCS dose than those on placebo. The results were published in the New England Journal of Medicine in May 2017.

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

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 Aerosphere 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 has completed Phase III trials, and tezepelumab (anti-TSLP), which successfully achieved its Phase IIb primary and secondary endpoints. 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 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, 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: 10 November 2017

By: /s/ Adrian Kemp

Name: Adrian Kemp

Title: Company Secretary