ASTRAZENECA PLC
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FORM 6-K

SECURITIES AND EXCHANGE COMMISSION
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Report of Foreign Issuer

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For the month of January 2018

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AstraZeneca PLC

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10 January 2018 15:10 GMT

FASENRA RECEIVES EU APPROVAL FOR SEVERE EOSINOPHILIC ASTHMA

Approval based on Phase III WINDWARD programme that demonstrated significant reductions in asthma exacerbations, improvements in lung function and reductions in oral corticosteroid use from baseline, versus placebo

Fasenra is the first-ever approved respiratory biologic medicine with an 8-week maintenance dosing schedule

AstraZeneca and its global biologics research and development arm, MedImmune, today announced that the European Commission (EC) has approved Fasenra (benralizumab) as an add-on maintenance treatment in adult patients with severe eosinophilic asthma inadequately controlled despite high-dose inhaled corticosteroids plus long-acting beta-agonists.1

The approval is based on the results from the WINDWARD programme, including the pivotal Phase III exacerbation trials, SIROCCO and CALIMA, and the Phase III OCS-sparing trial, ZONDA.1

Sean Bohen, Executive Vice President, Global Medicines Development and Chief Medical Officer at AstraZeneca, said: "Fasenra is our first respiratory biologic medicine. Today's decision from the EC follows the recent approval of Fasenra in the US and is another positive step towards our ambition to transform care for severe asthma patients whose disease is driven by eosinophilic inflammation."

Tim Harrison, Professor of Asthma and Respiratory Medicine, University of Nottingham, UK, and investigator in the WINDWARD trial programme, said: "Many patients with severe eosinophilic asthma experience debilitating symptoms and face increased risk of emergency room visits, hospitalisations and death, despite current treatments. I look forward to being able to offer Fasenra as a new anti-eosinophilic monoclonal antibody which has demonstrated efficacy versus placebo in pivotal clinical trials and has the convenience of an 8-week maintenance dosing regimen."

Eosinophils are a type of white blood cell that are a normal part of the body's immune system.2 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.3,4 Fasenra binds directly to the IL-5a receptor on an eosinophil and attracts natural killer cells to induce apoptosis (programmed cell death).5,6,7 Fasenra will be available as a fixed-dose subcutaneous injection via a prefilled syringe administered once every 4 weeks for the first 3 doses, and then once every 8 weeks thereafter.1

In November 2017, the US Food and Drug Administration (FDA) approved Fasenra for the add-on maintenance treatment of patients with severe asthma aged 12 years and older, and with an eosinophilic phenotype.8 Fasenra is also under regulatory review in Japan and several other countries, with expected regulatory decisions in H1 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.3,9,10

Severe, uncontrolled asthma is debilitating and potentially fatal with patients experiencing frequent exacerbations and significant limitations on lung function and quality of life.11,12,13 Severe, uncontrolled asthma has higher risk of mortality than severe asthma.12,14

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.10,15,16,17,18 There is also a significant physical and socio-economic burden of severe, uncontrolled asthma with these patients accounting for 50% of asthma-related costs.19

About Fasenra

Fasenra is a monoclonal antibody that recruits natural killer cells to induce direct, rapid and near-complete depletion of eosinophils.7,20 Depletion of circulating eosinophils is rapid, with an onset of action within 24 hours as confirmed in early Phase I/II trials.7,20,21 Eosinophils are the biological effector cells in approximately 50% of asthma patients, leading to frequent exacerbations, impaired lung function and asthma symptoms.3,4

Fasenra is now approved in the US and EU, and under regulatory review in Japan and several other countries.

Fasenra is the foundation of AstraZeneca's respiratory biologics portfolio of potential new medicines targeting underlying causes of respiratory disease. Fasenra is also being evaluated in chronic obstructive pulmonary disease (COPD).22

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 WINDWARD Programme
The WINDWARD programme in asthma is made up six Phase III trials, including SIROCCO, CALIMA, ZONDA, BISE, BORA and GREGALE.22 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.5,6

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.5,6,23

In SIROCCO and CALIMA, patients with severe, uncontrolled eosinophilic asthma receiving Fasenra experienced significant reduction in asthma exacerbations and improved lung function and asthma symptoms compared to patients receiving placebo, on top of their standard treatments.5,6 The most commonly reported adverse reactions during treatment were headache (8%) and pharyngitis (3%). Other common adverse reactions included fever, hypersensitivity reactions and injection site reactions.1,5,6

A 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.23

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. The results were published in the New England Journal of Medicine in May 2017.24

In addition to WINDWARD, the Phase III VOYAGER programme is currently underway, which is evaluating the efficacy and safety of Fasenra in patients with severe COPD.22

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 Aerosphere Delivery Technology. The company's biologics include Fasenra, (anti-eosinophil, anti-IL-5r), which is now approved in the US and EU and is under regulatory review in Japan and other countries, 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 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, 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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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 January 2018

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