ASTRAZENECA PLC
Form 6-K
January 19, 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 January 2018

Commission File Number: 001-11960

AstraZeneca PLC

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AstraZeneca PLC

INDEX TO EXHIBITS

ASTRAZENECA'S FASENRA RECEIVES APPROVAL IN JAPAN

19 January 2018 07:00 GMT

FASENRA RECEIVES APPROVAL IN JAPAN

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 approved respiratory biologic with an 8-week
maintenance dosing schedule

AstraZeneca and its global biologics research and development arm, MedImmune, today announced that the Japanese Ministry of Health, Labour and Welfare has approved Fasenra (benralizumab) as an add-on treatment for bronchial asthma in patients who continue to experience asthma exacerbations despite treatment with high-dose inhaled corticosteroid and other asthma controllers.

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 oral corticosteroid (OCS)-sparing trial, ZONDA.1 Fasenra will be available as a fixed-dose subcutaneous injection in a prefilled syringe administered once every four weeks for the first three doses, and then once every eight weeks thereafter.1

Sean Bohen, Executive Vice President, Global Medicines Development and Chief Medical Officer at AstraZeneca, said: "The approval of Fasenra, our first respiratory biologic medicine, in Japan closely follows the recent US and EU decisions and brings us another step closer to achieving our ambition of transforming care for severe asthma patients around the world."

Fasenra binds directly to the IL-5a receptor on eosinophils, a type of white blood cell that are a normal part of the body's immune system,2 and attracts natural killer cells to induce direct, rapid and near-complete depletion of eosinophils via apoptosis (programmed cell death).5,6,7 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

The Japanese approval follows US FDA approval in November 2017 and European Commission marketing authorisation in January 2018. Interactions with regulatory authorities in the rest of the world are on-going.

About Severe Asthma
Asthma affects approximately 315 million individuals worldwide. 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 (benralizumab)
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, EU and Japan, and under regulatory review in several other jurisdictions.

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) with data readout expected in the second half of 2018.22

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 Fasenra (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 medicines (including high-dosage inhaled corticosteroids and long-acting beta2-agonists) and were randomised globally to receive either Fasenra 30mg every 4-weeks; Fasenra 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 a significant reduction in asthma exacerbations and improvement in their lung function and asthma symptoms compared to patients receiving placebo, on top of their standard medicines.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 trials, demonstrated an association between enhanced Fasenra 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 Fasenra. 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 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's biologics include Fasenra, (anti-eosinophil, anti-IL-5r), which is now approved in the US, EU, Japan, and is under regulatory review in other jurisdictions, and tezepelumab (anti-TSLP), which successfully achieved its Phase IIb primary and secondary endpoints and has initiated Phase III. 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: 19 January 2018

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