ASTRAZENECA PLC
Form 6-K
November 15, 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 November 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):

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): _____

Indicate by check mark whether the registrant by furnishing the information contained in this Form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

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 PLC

INDEX TO EXHIBITS

1.
AZ Fasenra receives FDA approval for severe asthma

This announcement contains inside information

14 November 2017 22:45 GMT

FASENRA (BENRALIZUMAB) RECEIVES US FDA APPROVAL
FOR SEVERE EOSINOPHILIC ASTHMA

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

FDA approval based on Phase III programme demonstrating up to 51% reduction in asthma exacerbations, significant improvement in lung function and a 75% reduction in daily oral steroid use

AstraZeneca and its global biologics research and development arm, MedImmune, today announced that the US Food and Drug Administration (FDA) has approved Fasenra (benralizumab) for the add-on maintenance treatment of patients with severe asthma aged 12 years and older, and with an eosinophilic phenotype.

Pascal Soriot, Chief Executive Officer of AstraZeneca, said: "We're excited to offer Fasenra as a new precision biologic to help improve the lives of severe asthma patients whose disease is driven by eosinophilic inflammation. This is the first approval from our respiratory biologics portfolio and the latest in a series of significant milestones for our company as we deliver on our pipeline-driven transformation."

The FDA approval is based on 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. Results for the 8-week benralizumab dosing regimen from these trials showed:

- Up to 51% reduction in the annual asthma exacerbation rate (AAER) versus placebo
- Significant improvement in lung function as measured by forced expiratory volume in one second (FEV1) of up to 159mL versus placebo. Differences were seen as early as 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 that of placebo

Eugene Bleecker, MD, Professor and Co-Director, Genetics, Genomics and Precision Medicine, University of Arizona Health Sciences, and lead investigator of the pivotal Phase III SIROCCO study, said: "This is an important day for severe, eosinophilic asthma patients who have had limited treatment options for far too long, with many relying on oral steroids to manage their symptoms. Fasenra has a strong clinical profile which includes the ability to show lung function improvement after the first dose, the potential to reduce - or even stop - oral steroid use, and the convenience of 8-week dosing. Fasenra also treats a distinct patient phenotype, helping physicians select the right patient in clinical practice with more confidence."

Fasenra 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.

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

On 10 November, 2017, the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) adopted a positive opinion recommending the marketing authorisation of benralizumab. Benralizumab is also under regulatory review in Japan and several other countries.

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 Fasenra (benralizumab)
Fasenra 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 an early Phase II trial. In the pivotal Phase III trials, SIROCCO and CALIMA, Fasenra 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. Fasenra will be available as a subcutaneous injection via a prefilled syringe administered once every 4 weeks for the first 3 doses, and then once every 8-weeks thereafter.

Fasenra is now approved in the US, and under regulatory review in the EU, 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).

Fasenra was developed by AstraZeneca with 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 of 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 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.

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 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.

A recent pooled post-hoc analysis of the SIROCCO and CALIMA studies demonstrated an association between enhanced Fasenra efficacy and certain easily identifiable clinical features of severe eosinophilic asthma, including higher 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 Fasenra. Patients treated with Fasenra 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 Fasenra 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 Fasenra (anti-eosinophil, anti-IL-5R), which is now approved in the US, received a positive CHMP opinion in the EU and is under regulatory review in 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: 14 November 2017

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