ASTRAZENECA PLC
Form 6-K
March 18, 2019

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 March 2019

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.
US FDA grants saracatinib ODD for IPF

18 March 2019 07:00 GMT

US FDA grants saracatinib Orphan Drug Designation
for idiopathic pulmonary fibrosis

The US Food and Drug Administration (FDA) has granted Orphan Drug Designation (ODD) for saracatinib, a potential new medicine for the treatment of idiopathic pulmonary fibrosis (IPF), a type of lung disease that results in scarring (fibrosis) of the lungs. Saracatinib is an inhibitor of src kinase which regulates broad cell functions including cell growth and cell differentiation.1Saracatinib has completed Phase I development.

IPF is a chronic, progressive, irreversible and usually fatal interstitial lung disease1 which affects approximately 100,000 people in the US.2 On average, patients who are diagnosed with IPF live between two and five years from diagnosis, given the limited medicines available to treat the disease.1 The FDA grants ODD status to medicines intended for the treatment, diagnosis or prevention of rare diseases or disorders that affect fewer than 200,000 people in the US.

Mene Pangalos, Executive Vice President, R&D BioPharmaceuticals, said: "Idiopathic pulmonary fibrosis has a significant impact on patients' lives and new therapies are urgently needed. IPF is a recent addition to our respiratory research strategy and we are interested to see whether saracatinib could be a useful approach for the treatment of this intractable disease."

IPF is characterised by thickening and scarring of the connective (interstitial) tissue in the lungs. The cause is thought to be due to an abnormal wound-healing process that results in excessive tissue build-up in the lung.1 Pre-clinical trials of saracatinib showed that it inhibits fibroblast activity and collagen deposition, which are key features of lung fibrosis.3

About IPF
IPF causes shortness of breath and progressive damage of the lung, resulting in life-threatening complications such as respiratory failure. IPF progression varies greatly between patients but over time, most experience increasing respiratory symptoms, increased scarring of the lungs and a gradual decline in lung function. 'Idiopathic' refers to the unknown cause of disease, however there is proof of genetic predisposition in some patients.1

About saracatinib
Saracatinib is a small molecule, highly-potent and selective inhibitor of src tyrosine kinase.3 The potential new medicine was discovered by AstraZeneca and has previously been in clinical development in oncology. Phase II trials for saracatinib in IPF have not yet commenced.

About AstraZeneca in Respiratory Disease
Respiratory is one of AstraZeneca's main therapy areas, and our medicines reached more than 18 million patients as maintenance therapy in 2018. 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 also has a growing portfolio of respiratory biologics, including Fasenra (anti-eosinophil, anti-IL-5r), now approved for severe, eosinophilic asthma and in development for severe nasal polyposis, and tezepelumab (anti-TSLP), which has been granted Breakthrough Therapy designation by the US Food and Drug Administration in patients with severe asthma, and is in Phase III trials. AstraZeneca's research is focused on addressing underlying disease drivers focusing on the lung epithelium, lung immunity and lung regeneration.

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, Renal & Metabolism and Respiratory. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. For more information, please visit astrazeneca.com and follow us on Twitter@AstraZeneca.

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Adrian Kemp
Company Secretary

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References

1. Lederer, D J and Martinez F J. Idiopathic Pulmonary Fibrosis. N Engl J Med. 2018;378:1811-23.
2. Genetic Home Reference of the National Institutes of Health National Library of Medicine, accessed on 16 October 2018.
3. Hu, M et al. Therapeutic targeting of src kinase in myofibroblast differentiation and pulmonary fibrosis. J Pharmacol Exp Ther 2014; 351:87-95.

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: 18 March 2019

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