ASTRAZENECA PLC
Form 6-K
August 02, 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 August 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-_____

This announcement contains inside information

02 August 2017 07:00 BST

US FDA ACCEPTS REGULATORY SUBMISSION FOR ACALABRUTINIB AND GRANTS PRIORITY REVIEW

AstraZeneca and its haematology research and development centre of excellence, Acerta Pharma, today announced that the US Food and Drug Administration (FDA) has accepted and granted priority review for the New Drug Application (NDA) for acalabrutinib, a highly-selective, potent, Bruton tyrosine kinase (BTK) inhibitor.

The NDA is based on results from the Phase II ACE-LY-004 clinical trial, which evaluated the safety and efficacy of acalabrutinib in patients with relapsed/refractory mantle cell lymphoma (MCL) who have received at least one prior therapy. This follows the FDA's recent Breakthrough Therapy Designation for acalabrutinib.

Sean Bohen, Executive Vice President, Global Medicines Development and Chief Medical Officer, said: "FDA's acceptance of the acalabrutinib application and Priority Review illustrates the impact it could have on patients with relapsed or refractory mantle cell lymphoma as we work to bring this potential medicine to those in need as quickly as possible."

Priority Review is granted to applications for medicines that, if approved, would offer a significant improvement in the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions.[1] The Prescription Drug User Fee Act (PDUFA) date is during the first quarter of 2018.

Flavia Borellini, PhD, Acerta Pharma Chief Executive Officer, said: "We believe acalabrutinib has the potential to be a very important treatment option for patients with this life-threatening blood cancer. The FDA's NDA acceptance exemplifies our progress in the acalabrutinib development programme and continues our momentum as we seek to transform care for people with haematologic malignancies."

Results from the ACE-LY-004 clinical trial will be submitted for presentation at a forthcoming medical meeting. The acalabrutinib development programme includes both monotherapy and combination therapy strategies in a broad range of blood cancers and solid tumours. The programme includes the Phase III ACE-LY-308 clinical trial evaluating acalabrutinib as a 1st-line treatment for patients with MCL.[2]

About mantle cell lymphoma (MCL)
Mantle cell lymphoma (MCL) is an aggressive B-cell non-Hodgkin lymphoma (NHL) with poor prognosis.[3],[4],[5],[6] MCL accounts for approximately 3% to 6% of new NHL cases in Western countries each year, with an annual incidence of 0.5 per 100,000 persons and an estimated prevalence of 3.5/100,000.5,[7] The median age at diagnosis is 68 years, with a 3:1 male predominance.5
About acalabrutinib
Acalabrutinib is a highly-selective, potent, covalent inhibitor of Bruton tyrosine kinase (BTK) with minimal off-target activity observed in pre-clinical trials.[8],[9],[10] This potential new medicine is in development for the treatment of

multiple B-cell and other cancers. The acalabrutinib development programme includes both monotherapy and combination therapy strategies in chronic lymphocytic leukaemia (CLL), MCL, Waldenström macroglobulinemia (WM), follicular lymphoma, diffuse large B-cell lymphoma, and multiple myeloma, as well as monotherapy and combination trials in solid tumours. In total, more than 25 acalabrutinib clinical trials with more than 2,000 patients are underway or have completed. Acalabrutinib was granted Orphan Drug Designation by the FDA for the treatment of patients with MCL in September 2015 and by the European Commission in March 2016 for the treatment of patients with CLL, MCL and WM. Acalabrutinib was granted Breakthrough Therapy Designation by the FDA in August 2017 for the treatment of patients with MCL who have received at least one prior therapy. Acalabrutinib is a potential new medicine not approved for any current use.

About Acerta Pharma
Acerta Pharma, a member of the AstraZeneca Group, is creating novel selective therapies intended for the treatment of cancer and autoimmune diseases. AstraZeneca acquired a majority stake in Acerta Pharma, which serves as AstraZeneca's haematology research and development centre of excellence. For more information, please visit www.acerta-pharma.com.

About AstraZeneca in Oncology
AstraZeneca has a deep-rooted heritage in Oncology and offers a quickly growing portfolio of new medicines that have the potential to transform patients' lives and the Company's future. With at least six new medicines to be launched between 2014 and 2020 and a broad pipeline of small molecules and biologics in development, we are committed to advance New Oncology as one of AstraZeneca's five Growth Platforms focused on lung, ovarian, breast and blood cancers. In addition to our core capabilities, we actively pursue innovative partnerships and investments that accelerate the delivery of our strategy, as illustrated by our investment in Acerta Pharma in haematology.

By harnessing the power of four scientific platforms -- Immuno-Oncology, Tumour Drivers and Resistance, DNA Damage Response and Antibody Drug Conjugates -- and by championing the development of personalised combinations, AstraZeneca has the vision to redefine cancer treatment and one day eliminate cancer as a cause of death.

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 main 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

References

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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: 02 August 2017 By: /s/ Adrian Kemp
Name: Adrian Kemp
Title: Company Secretary