ASTRAZENECA PLC
Form 6-K
February 25, 2016

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 February 2016

Commission File Number: 001-11960

AstraZeneca PLC

2 Kingdom Street, London W2 6BD

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-_____

ACALABRUTINIB RECOMMENDED FOR ORPHAN DRUG DESIGNATION IN EUROPE FOR THREE INDICATIONS

AstraZeneca and Acerta Pharma BV, a company in which AstraZeneca has a majority equity investment, today announced that the European Medicines Agency (EMA) Committee for Orphan Medicinal Products (COMP) adopted

three positive opinions recommending acalabrutinib (ACP-196) for designation as an orphan medicinal product. The three positive opinions are for the treatment of chronic lymphocytic leukaemia (CLL) / small lymphocytic lymphoma (SLL), mantle cell lymphoma (MCL) and lymphoplasmacytic lymphoma (Waldenström's macroglobulinaemia, MG).

Sean Bohen, Executive Vice-President of Global Medicines Development and Chief Medical Officer at AstraZeneca, said: "Today's three positive opinions recommending acalabrutinib for designation as an orphan medicinal product are important milestones. They reinforce the strategic rationale for our investment in Acerta, demonstrating clear progress in developing a potential best-in-class medicine that could transform treatment for patients across a range of blood cancers. The positive opinions underscore the continued need for the development of new therapies in these serious and life-threatening conditions and support our commitment to bring new medicines to patients as quickly as possible."

CLL is a slow-growing blood and bone marrow cancer that accounts for approximately one in four cases of leukaemia.i,ii Most CLL patients experience disease progression despite initial response to therapy and may require additional treatment. iii SLL is a clinically similar disease localized to the lymph nodes.iv

MCL is an aggressive non-Hodgkin's lymphoma (NHL) typically associated with very poor outcomes.v MCL represents around 5% of all NHLs.vi The name comes from the fact that the tumour cells originate in the mantle zone of the lymph node. vi
WG is a rare, slow-growing cancer predominantly affecting older individuals, with a mean age of 60 at diagnosis.vii, viii and median survival from five to nearly eleven years. vii, viii

The COMP adopts an opinion on Orphan Drug Designation, after which the opinion is submitted to the European Commission (EC) for endorsement. Orphan Drug Designation is a status assigned to a medicine intended for use in rare diseases.ix To be granted orphan status by the EC, a medicine must be intended for the treatment, prevention or diagnosis of a disease that is life threatening and has a prevalence of up to five in 10,000 in the European Union. Additionally, the intended medicine must aim to provide significant benefit to those affected by the condition. Orphan status provides companies with development and market exclusivity incentives for designated compounds and medicines.

In addition to ongoing Phase II/III trials in CLL, MCL and WG, acalabrutinib is currently being tested in Phase I/II trials in monotherapy as well as in combination with immunotherapy or chemotherapies in a range of other blood cancers and solid tumours.

i Chronic Lymphocytic Leukemia. Leukemia & Lymphoma Society Website.
http://www.lls.org/leukemia/chronic-lymphocytic-leukemia/ Accessed February 19, 2016.
ii What are the key statistics for chronic lymphocytic leukemia? American Cancer Society Website.
http://www.cancer.org/cancer/leukemia-chroniclymphocyticcll/detailedguide/leukemia-chronic-lymphocytic-key-statistics
. Accessed February 19, 2015.
iii Veliz M, Pinilla-Ibarz J. Treatment of relapsed or refractory chronic lymphocytic leukemia. Cancer Control. 2012; 19(1):37-53.
iv Chronic lymphocytic leukemia/Small lymphocytic lymphoma, National Cancer Institute Website.
http://www.cancer.gov/publications/dictionaries/cancer-terms?cdrid=641290 Accessed February 19, 2016.
v Campo E and Rule S. Mantle cell lymphoma: evolving management strategies. Blood. 2015 Jan 1;125(1):48-55.
vi Mantle Cell Lymphoma, Lymphoma.org Website.
http://www.lymphoma.org/site/pp.asp?c=bkLTKaOQLmK8E&b=6300157 Accessed February 19, 2016.
vi Lymphoplasmacytic lymphoma. National Cancer Institute. Surveillance, Epidemiology, and End Results program.
http://seer.cancer.gov/seertools/hemelymph/51f6cf57e3e27c3994bd5363/ Accessed February 19, 2016.
vii Dimopoulos MA, Kastritis E, Ghobrial IM. Waldenström's macroglobulinemia: a clinical perspective in the era of novel therapeutics. Ann Oncol. 2016 Feb;27(2):233-40.

viii Oza and Rajkumar. Waldenstrom macroglobulinemia: prognosis and management. Blood Cancer Journal (2015) 5, e394; doi:10.1038/bcj.2015.28
ix European Medicines Agency web site. "Orphan Designation." http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000029.jsp&mid=WC0b01ac058002 Accessed February 17, 2016.

About Acalabrutinib
Acalabrutinib is a highly selective, irreversible, second generation BTK inhibitor, with approximately 1,000 patients treated to date in clinical studies across the entire development programme. More than 600 patients have been treated with acalabrutinib monotherapy. Phase I/II data showing a favourable safety profile and efficacy in relapsed/refractory chronic lymphocytic leukaemia patients was presented at the American Society of Haematology Annual Meeting & Exposition in December 2015, with simultaneous publication in the New England Journal of Medicine.
Potentially registrational studies in haematological malignancies are ongoing. In addition, a head-to-head study versus ibrutinib in high risk chronic lymphocytic leukaemia patients is currently ongoing.
Acalabrutinib is also currently being tested in multiple Phase I/II studies in solid tumours, as monotherapy or in combination with immune checkpoint inhibitors or other standard of care regimens.

About Acerta Pharma
Acerta is a leader in the field of covalent binding technology and is applying this technology to create novel selective therapies intended for the treatment of cancer and autoimmune diseases. Acerta's lead molecule, acalabrutinib (ACP-196), is a selective and potent inhibitor of BTK. The company has operations in Oss, the Netherlands and multiple US sites. The US headquarters is in Redwood City, CA. AstraZeneca is the parent company of Acerta BV.

About AstraZeneca in Oncology
AstraZeneca has a deep-rooted heritage in Oncology and offers a quickly growing portfolio of new medicines that has the potential to transform patients' lives and the Company's future. With at least 6 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 six 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, the genetic drivers of cancer and resistance, DNA damage repair 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, innovation-driven biopharmaceutical business that focuses on the discovery, development and commercialisation of prescription medicines, primarily for the treatment of diseases in three main therapy areas - respiratory, inflammation, autoimmune disease (RIA), cardiovascular and metabolic disease (CVMD) and oncology - as well as in infection and neuroscience. 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

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Key: RIA - Respiratory, Inflammation and Autoimmunity, CVMD - Cardiovascular and Metabolic Disease, ING - Infection, Neuroscience and Gastrointestinal

25 February 2016

-ENDS-

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: 25 February 2016

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