ASTRAZENECA PLC
Form 6-K
August 01, 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

1 Francis Crick Avenue

Cambridge Biomedical Campus

Cambridge CB2 0AA

United Kingdom

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

1 August 2017 07:00 BST

ACALABRUTINIB GRANTED BREAKTHROUGH THERAPY DESIGNATION BY US FDA FOR THE TREATMENT
OF PATIENTS WITH MANTLE CELL LYMPHOMA

AstraZeneca and its haematology research and development centre of excellence, Acerta Pharma, today announced that the US Food and Drug Administration (FDA) has granted Breakthrough Therapy Designation for acalabrutinib for the treatment of patients with mantle cell lymphoma (MCL) who have received at least one prior therapy. Acalabrutinib is a highly-selective, potent Bruton tyrosine kinase (BTK) inhibitor in development for the treatment of multiple B-cell cancers.

The Breakthrough Therapy Designation is designed to expedite the development and regulatory review of new medicines that are intended to treat a serious condition and that have shown encouraging early clinical results, which demonstrate substantial improvement on a clinically-significant endpoint over available medicines and when there is significant unmet medical need.

Sean Bohen, Executive Vice President, Global Medicines Development and Chief Medical Officer at AstraZeneca, said: "New treatments are urgently needed for people with mantle cell lymphoma who relapse or do not respond to current therapy. Breakthrough Therapy Designation for acalabrutinib will help us bring this potential new medicine to appropriate patients as quickly as possible."

The FDA granted Breakthrough Therapy Designation based on the totality of clinical data from the acalabrutinib development programme, including data from the Phase II ACE-LY-004 clinical trial in patients with relapsed or refractory MCL.

Flavia Borellini, PhD, Acerta Pharma Chief Executive Officer, said: "This is an exciting regulatory milestone for our work in haematology. Acalabrutinib is a potent, irreversible BTK inhibitor with a high degree of specificity for its target. If approved, it could be a clinically-meaningful treatment option for patients with this devastating disease."

This is the fifth Breakthrough Therapy Designation that AstraZeneca has received from the FDA for an oncology medicine since 2014 and the first for the Company in haematology. The acalabrutinib development programme includes both monotherapy and combination therapies for a broad range of blood cancers and solid tumours.

About mantle cell lymphoma (MCL)
Mantle cell lymphoma (MCL) is an aggressive B-cell non-Hodgkin lymphoma (NHL) with poor prognosis.1,2,3,4 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 3.5/100,000.2,5 The median age at diagnosis is 68 years, with a 3:1 male predominance.2

About a-calabrutinib
Acalabrutinib is a highly selective, potent, covalent inhibitor of Bruton tyrosine kinase (BTK) with minimal off-target activity observed in pre-clinical trials.6,7,8 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 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 interest 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.
Media Relations

Esra Erkal-Paler	UK/Global	+44 203 749 5638
Karen Birmingham	UK/Global	+44 203 749 5634
Rob Skelding	UK/Global	+44 203 749 5821
Matt Kent	UK/Global	+44 203 749 5906
Jacob Lund	Sweden	+46 8 553 260 20
Michele Meixell	US	+1 302 885 2677

Investor Relations

Thomas Kudsk Larsen		+44 203 749 5712
Craig Marks	Finance, Fixed Income, M&A	+44 7881 615 764

Henry Wheeler	Oncology	+44 203 749 5797
Mitchell Chan	Oncology	+1 240 477 3771
Lindsey Trickett	Cardiovascular & Metabolic Diseases	+1 240 543 7970
Nick Stone	Respiratory	+44 203 749 5716
Christer Gruvris	Autoimmunity, Neuroscience & Infection	+44 203 749 5711
US toll free		+1 866 381 7277

References

1Leukemia & Lymphoma Society. Mantle Cell Lymphoma Facts. https://www.lls.org/sites/default/files/file_assets/mantlecelllymphoma.pdf Accessed June 2017
2Cheah CY, Seymour JF, Wang M. Mantle Cell Lymphoma. Journal of Clinical Oncology 34, no. 11 (April 2016) 1256-1269.
3Hoster E, Klapper W et al. Confirmation of the Mantle-Cell Lymphoma International Prognostic Index in Randomized Trials of the European Mantle-Cell Lymphoma Network. Journal of Clinical Oncology 2014;32:1338-1346.
4Dreyling M, Ferrero S. The role of targeted treatment in mantle cell lymphoma: is transplant dead or alive? Haematologica 2016 Volume 101(2):104-114
5Orphanet Report Series. Prevalence and incidence of rare diseases: Bibilographic data. Number 2 March 2016.
6Covey T, Barf T, Gulrajani M, Krantz F, van Lith B, Bibikova E, et al. Abstract 2596: ACP-196: a novel covalent Bruton's tyrosine kinase (Btk) inhibitor with improved selectivity and in vivo target coverage in chronic lymphocytic leukemia (CLL) patients. Cancer Res. 2015;75(15 Supplement):2596.
7Byrd JC, Harrington B, O'Brien S, Jones JA, Schuh A, Devereux S, et al. Acalabrutinib (ACP-196) in relapsed chronic lymphocytic leukemia. N Engl J Med. 2016;374(4):323-32.
8Harrington BK, Gulrajani M, Covey T, Kaptein A, Van Lith B, Izumi R, et al. ACP-196 is a second generation inhibitor of Bruton tyrosine kinase (BTK) with enhanced target specificity. Blood. 2015;126(23):2908.

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: 01 August 2017 By: /s/ Adrian Kemp
Name: Adrian Kemp

Title: Company Secretary