ASTRAZENECA PLC
Form 6-K
October 31, 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 October 2017

Commission File Number: 001-11960

AstraZeneca PLC

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This announcement contains inside information
31 October 2017 17:00 GMT

US FDA APPROVES ASTRAZENECA'S CALQUENCE (ACALABRUTINIB) FOR ADULT PATIENTS WITH PREVIOUSLY-TREATED MANTLE CELL LYMPHOMA

Accelerated approval of the selective Bruton tyrosine kinase
(BTK) inhibitor in MCL marks AstraZeneca's entry into the treatment of blood cancers

80% of patients receiving Calquence achieved an overall response,
with 40% achieving a complete response

AstraZeneca and its haematology research and development centre of excellence, Acerta Pharma, today announced that the US Food and Drug Administration (FDA) has granted accelerated approval to Calquence (acalabrutinib). Calquence is a kinase inhibitor indicated for the treatment of adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy.1

Calquence is approved under the FDA's accelerated approval pathway, based on overall response rate, which allows for earlier approval of medicines that treat serious conditions and that fill an unmet medical need based on a surrogate endpoint.2 Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.1

Pascal Soriot, Chief Executive Officer of AstraZeneca, said: "The accelerated approval of Calquence is a landmark moment for our company. It provides an exciting new treatment option for patients with mantle cell lymphoma and marks the first approval of a medicine that will be the cornerstone of our presence in haematology. Furthermore, today's approval demonstrates our commitment to scientific leadership in Oncology and reinforces our progress towards returning to growth."

Michael L. Wang, MD, Professor, Department of Lymphoma/Myeloma, The University of Texas MD Anderson Cancer Center, and Principal Investigator of the ACE-LY-004 MCL clinical trial, said: "The acalabrutinib approval represents an important development for patients currently battling mantle cell lymphoma, an aggressive type of blood cancer that is typically diagnosed at an advanced stage and associated with a high relapse rate. In addition to the overall response rate, the high complete response rate of 40% seen in this trial illustrates the potential of acalabrutinib to help patients achieve a deep response."

Summary of key efficacy results as assessed by Independent Review Committee (IRC) from the ACE-LY-004 trial,1 a Phase II open-label, single-arm clinical trial in 124 adult patients with relapsed or refractory MCL:

Efficacy Measure	IRC Results
Overall Response Rate	80% (95% CI: 72, 87)
Complete Response	40% (95% CI: 31, 49)
Partial Response	40% (95% CI: 32, 50)

Per 2014 Lugano classification, CI = Confidence interval

In the ACE-LY-004 trial, the most common adverse reactions (≥20%) of any grade were anaemia (46%), thrombocytopoenia (44%), headache (39%), neutropoenia (36%), diarrhoea (31%), fatigue (28%), myalgia (21%) and bruising (21%). Haematological events were based on laboratory measurements and adverse reactions.1

Dosage reductions or discontinuation due to any adverse reaction were reported in 1.6% and 6.5% of patients, respectively.1 Increases in creatinine 1.5 to 3 times the upper limit of normal occurred in 4.8% of patients.1

These data demonstrate the potential impact that Calquence could have on the management of previously-treated MCL. Calquence is not approved for use outside this labelled indication in the US.

Meghan Gutierrez, Chief Executive Officer, Lymphoma Research Foundation, said: "Relapse is common in mantle cell lymphoma patients and represents disease progression.3 When patients learn there is a new treatment option available for their disease, it brings great hope and an opportunity to participate in shared decision making with their healthcare team."

Full results from the ACE-LY-004 clinical trial have been submitted for presentation at a forthcoming medical meeting. This will be the first MCL trial data to be presented from the Calquence development programme, which includes both monotherapy and combination therapies in a broad range of blood cancers and solid tumours. Calquence is also being evaluated in combination with bendamustine and rituximab as a potential 1st-line treatment for patients with MCL in the Phase III ACE-LY-308 clinical trial.4

About Calquence
Calquence (acalabrutinib; previously known as ACP-196) is a selective inhibitor of BTK. Calquence binds covalently to BTK, thereby inhibiting its activity, and has demonstrated this with minimal interactions with other immune cells in pre-clinical studies.1,5,6 In B cells, BTK signalling results in activation of pathways necessary for B cell proliferation, trafficking, chemotaxis and adhesion.1

The recommended dose of Calquence is one 100mg capsule taken orally approximately every twelve hours until disease progression or unacceptable toxicity.1 Calquence may be taken with or without food.1

Calquence is also in development for the treatment of multiple B-cell malignancies and other cancers including chronic lymphocytic leukaemia (CLL), MCL, Waldenström macroglobulinaemia (WM), follicular lymphoma, diffuse large B-cell lymphoma, and multiple myeloma. It is also being studied as a monotherapy and in combination trials for solid tumours. More than 35 clinical trials across 40 countries with more than 2,500 patients are underway or have been completed.7

Calquence was granted Orphan Drug Designation by the US FDA for the treatment of adult patients with MCL in September 2015 and by the European Commission in March 2016 for the treatment of adult patients with CLL, MCL and WM. Calquence was granted Breakthrough Therapy Designation by the FDA in August 2017 for the treatment of adult patients with MCL who have received at least one prior therapy.

About Mantle Cell Lymphoma (MCL)
MCL is an aggressive B-cell non-Hodgkin lymphoma (NHL) with poor prognosis.8,9,10,11 MCL accounts for approximately 3% to 6% of new NHL cases in Western countries each year; in the US, approximately 3,300 new cases of MCL are diagnosed each year.9,13 The median age at diagnosis is 68 years, with a 3:1 male predominance.10 While MCL patients initially respond to treatment, there is a high relapse rate.9

About the ACE-LY-004 trial
ACE-LY-004 is a Phase II open-label, single-arm clinical trial in 124 adult patients with relapsed or refractory MCL. The trial showed that 80% (95% CI: 72, 87) of patients treated with Calquence achieved an overall response; 40% (95% CI: 31, 49) achieved a complete response and 40% (95% CI: 32, 50) achieved a partial response1 per 2014 Lugano classification as assessed by Independent Review Committee.1

About Acerta Pharma
Acerta Pharma, a member of the AstraZeneca Group, is creating novel 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 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

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3 Lymphoma Research Foundation. Getting the Facts Mantle Cell Lymphoma: Relapsed/Refractory. http://www.lymphoma.org/atf/cf/%7BAAF3B4E5-2C43-404C-AFE5-FD903C87B254%7D/LRF_FACTSHEET_MCL_RR_2
Accessed July 2017
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10 Hoster 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.
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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: 31 October 2017

By: /s/ Adrian Kemp

Name: Adrian Kemp

Title: Company Secretary