ASTRAZENECA PLC
Form 6-K
December 09, 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 December 2016

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

9 December 2016 15:00

US FDA ACCEPTS FIRST BIOLOGICS LICENSE APPLICATION FOR ASTRAZENECA'S DURVALUMAB IN BLADDER CANCER

FDA grants priority review status with PDUFA set for Q2 2017

AstraZeneca and its global biologics research and development arm, MedImmune, today announced that the US Food and Drug Administration (FDA) has accepted the first Biologics License Application (BLA) for durvalumab, a PD-L1 human monoclonal antibody (mAb), and granted priority review status with a Prescription Drug User Fee Act (PDUFA) set for the second quarter of 2017.

The BLA submission, for the treatment of patients with locally advanced or metastatic urothelial carcinoma (UC) whose disease has progressed during or after one standard platinum based regimen, is based on the results of the UC cohort of Study 1108 and follows the FDA's February 2016 Breakthrough Therapy Designation for durvalumab.

Sean Bohen, Executive Vice President, Global Medicines Development and Chief Medical Officer at AstraZeneca, said: "The BLA acceptance of durvalumab in urothelial cancer is an important milestone for patients who still face considerable unmet medical need in this area. It also represents an exciting advance for our Immuno-Oncology medicines as we continue to develop chemotherapy-free treatments based on the potential clinical benefits of durvalumab, both as monotherapy and in combination."

As part of a broad development programme, durvalumab is being tested as monotherapy and in combination with tremelimumab (CTLA-4 mAb) in the Phase III DANUBE trial as 1st-line treatment for patients with metastatic UC, regardless of eligibility for cisplatin-based chemotherapy.

The combination of durvalumab and tremelimumab is also being studied in Phase III trials in non-small cell lung cancer (NSCLC), head and neck squamous cell carcinoma (HNSCC) and in Phase II and earlier trials in gastric cancer, pancreatic cancer, hepatocellular carcinoma (HCC) and blood cancers. AstraZeneca currently has more than 30 ongoing durvalumab clinical trials in combination with other IO agents and targeted therapies.

About Study 1108

Study 1108 is a Phase I/II multicentre, open-label dose-escalation and dose-expansion study investigating the safety and efficacy of durvalumab in adult patients with inoperable or metastatic solid tumours.

About Urothelial Cancer (UC)

Urothelial cancer develops in the cells of the bladder lining (urothelium) and is the most common type of bladder cancer. UC accounts for more than 90% of all cases of bladder cancer worldwide and is an area of significant unmet medical need. Current standard of care for UC patients with inoperable or advanced metastatic disease is systemic platinum-based chemotherapy, introduced nearly 30 years ago.

About Durvalumab

Durvalumab is an investigational human monoclonal antibody directed against programmed death ligand-1 (PD-L1). PD-L1 expression enables tumours to evade detection from the immune system through binding to PD-1 on cytotoxic T lymphocytes. Durvalumab blocks PD-L1 interaction with both PD-1 and CD80 on T cells, countering the tumour's immune- evading tactics and activating the patient's immune system to attack the cancer. Durvalumab received FDA Breakthrough Therapy Designation in patients with PD-L1 positive inoperable or metastatic UC in 2016 and Fast Track Designation in 2015 for the treatment of patients with PD-L1 positive metastatic head and neck squamous cell carcinoma.

AstraZeneca's Approach to Immuno-Oncology (IO)

Immuno-Oncology (IO) is a therapeutic approach designed to stimulate the body's immune system to destroy tumours. At AstraZeneca, and MedImmune, our biologics research and development arm, our IO portfolio is anchored by immunotherapies that have been designed to overcome anti-tumour immune suppression. We believe that IO-based therapies will offer the potential for life-changing cancer treatments for the vast majority of patients.

We are pursuing a comprehensive clinical trial programme that includes durvalumab (PD-L1) monotherapy and durvalumab in combination with tremelimumab (CTLA-4) in multiple tumour types, stages of disease, and lines of therapy, using the PD-L1 biomarker as a decision-making tool to define the best potential treatment path for a patient.

In addition, the ability to combine our IO portfolio with small targeted molecules from across our oncology pipeline, and with those of our partners, may provide new treatment options across a broad range of tumours.

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 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 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 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 MedImmune

MedImmune is the global biologics research and development arm of AstraZeneca, a global, innovation-driven biopharmaceutical business that focuses on the discovery, development and commercialization of small molecule and biologic prescription medicines. MedImmune is pioneering innovative research and exploring novel pathways across key therapeutic areas, including oncology; respiratory, inflammation and autoimmunity; cardiovascular and metabolic disease; and infection and vaccines. The MedImmune headquarters is located in Gaithersburg, MD., one of AstraZeneca's three global R&D centres, with additional sites in Cambridge, UK and Mountain View, CA. For more information, please visit www.medimmune.com.

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

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: 09 December 2016 By: /s/ Adrian Kemp
Name: Adrian Kemp
Title: Company Secretary