ASTRAZENECA PLC
Form 6-K
October 17, 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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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-_____

17 October 2017 07:00 BST

US FDA ACCEPTS SUPPLEMENTAL BIOLOGICS LICENSE APPLICATION FOR IMFINZI IN LOCALLY ADVANCED UNRESECTABLE NON-SMALL CELL LUNG CANCER

Imfinzi granted Priority Review

Acceptance follows FDA's Breakthrough Therapy Designation

AstraZeneca and MedImmune, its global biologics research and development arm, today announced that the US Food and Drug Administration (FDA) has accepted a supplemental Biologics License Application (sBLA) for Imfinzi (durvalumab) for the treatment of patients with locally advanced (Stage III) unresectable non-small cell lung cancer (NSCLC) whose disease has not progressed following platinum-based chemoradiation therapy. The FDA has granted Imfinzi Priority Review status.

The US FDA sBLA submission acceptance is an important milestone for Imfinzi in a disease state where patients need better treatment options and outcomes. Currently, the standard of care for patients with this earlier stage of lung disease is active monitoring following concurrent chemoradiation.

The sBLA submission is based on positive progression-free survival (PFS) data from the Phase III PACIFIC trial. The trial continues to evaluate overall survival (OS), its other primary endpoint. Detailed results of the PACIFIC trial, including additional safety information, were published online in the New England Journal of Medicine.

On 28 September 2017, the US NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines) were updated to include Imfinzi for the treatment of patients with locally-advanced unresectable NSCLC with no disease progression after two or more cycles of definitive chemoradiation, based on the data from the PACIFIC Phase III trial. This indication is not yet FDA-approved.

About Locally Advanced (Stage III) NSCLC
Locally advanced (Stage III) lung cancer is commonly divided into two stages (IIIA and IIIB), which are defined by how much the cancer has spread locally and the possibility of surgery. This differentiates it from Stage IV disease, when the cancer has spread (metastasised) to distant organs.

Stage III lung cancer represents approximately one-third of NSCLC incidence and was estimated to affect around 105,000 patients in the top-7 countries in 20161. More than 70% of these patients have tumours that are unresectable. The current standard of care is chemotherapy and radiation followed by active surveillance to monitor for progression. The prognosis remains poor and long-term survival rates are low.

About PACIFIC
The PACIFIC trial is a randomised, double-blinded, placebo-controlled, multi-centre trial of Imfinzi as treatment in unselected patients with locally-advanced, unresectable (Stage III) NSCLC who have not progressed following platinum-based chemotherapy concurrent with radiation therapy.

The trial is being conducted in 235 centres across 26 countries involving approximately 700 patients. The primary endpoints of the trial are progression-free survival (PFS) and overall survival (OS), and secondary endpoints include landmark PFS and OS, objective response rate (ORR) and duration of response.

About Imfinzi
Imfinzi (durvalumab), a human monoclonal antibody directed against PD-L1, blocks PD-L1 interaction with PD-1 and CD80 on T cells, countering the tumour's immune-evading tactics and inducing an immune response.

Imfinzi has already received accelerated approval in the US for the treatment of patients with locally advanced or metastatic urothelial carcinoma, who have disease progression during or following platinum-containing chemotherapy, or whose disease has progressed within 12 months of receiving platinum-containing chemotherapy before (neoadjuvant) or after (adjuvant) surgery.

As part of a broad development programme, Imfinzi is also being investigated for the adjuvant treatment of patients with NSCLC in the CCTG (Canadian Cancer Trials Group) trial ADJUVANT (BR31). In the MYSTIC, NEPTUNE, and PEARL Phase III trials, Imfinzi is being studied for 1st-line treatment as monotherapy and/or in combination with tremelimumab, an anti-CTLA-4 monoclonal antibody, for the treatment of metastatic NSCLC. The POSEIDON trial is investigating Imfinzi with and without tremelimumab in combination with chemotherapy in the same population.

About AstraZeneca in Lung Cancer
AstraZeneca is committed to developing medicines to help every patient with lung cancer. We have two approved medicines and a growing pipeline that targets genetic changes in tumour cells and boosts the power of the immune response against cancer. Our unrelenting pursuit of science aims to deliver more breakthrough therapies with the goal of extending and improving the lives of patients across all stages of disease and lines of therapy.

About AstraZeneca's Approach to Immuno-Oncology (IO)
Immuno-Oncology (IO) is a therapeutic approach designed to stimulate the body's immune system to attack 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 Imfinzi (anti-PD-L1) monotherapy and in combination with tremelimumab (anti-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 research 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 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 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 commercialisation of small molecule and biologic prescription medicines. MedImmune is pioneering innovative research and exploring novel pathways across Oncology; Respiratory, Cardiovascular & Metabolic Diseases; 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

1France, Germany, Italy, Japan, Spain, United Kingdom, United States

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: 17 October 2017

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