ASTRAZENECA PLC
Form 6-K
September 24, 2018

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 September 2018
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-_____

AstraZeneca PLC

INDEX TO EXHIBITS

1.
EMA approves AZ's Imfinzi for Stage III NSCLC

24 September 2018 16:10 BST

European Commission approves Imfinzi
for locally-advanced, unresectable NSCLC

Phase III PACIFIC trial demonstrated compelling overall survival
benefit and progression-free survival of more than 11 months

Imfinzi is the only immunotherapy medicine approved for
the treatment of locally-advanced, unresectable NSCLC

AstraZeneca and MedImmune, its global biologics research and development arm, today announced that the European Commission has granted marketing authorisation for Imfinzi (durvalumab) as monotherapy for the treatment of locally-advanced, unresectable non-small cell lung cancer (NSCLC) in adults whose tumours express PD-L1 on ≥1% of tumour cells and whose disease has not progressed following platinum-based chemotherapy and radiation therapy (CRT). The approval is based on results from the Phase III PACIFIC trial.

Dave Fredrickson, Executive Vice President, Head of the Oncology Business, said: "Patients in Europe diagnosed with locally-advanced, unresectable non-small cell lung cancer now have a new treatment option. Imfinzi is the only immunotherapy to be approved in this curative-intent setting, and we are proud to bring a new standard of care for this difficult disease."

Dr. Luis Paz-Ares, co-principal investigator of the PACIFIC trial, from the Hospital Universitario Doce de Octubre, Madrid, Spain, said: "Lung cancer is the leading cause of cancer-related death in Europe and approximately a third of European patients with NSCLC present with locally-advanced disease. For decades, the standard of care for these patients has been chemotherapy and radiation therapy followed by active surveillance, after which the majority of patients progress to advanced disease. Imfinzi has demonstrated a compelling survival benefit for these patients in this area of significant unmet need."

The approval follows the positive opinion on 27 July 2018 from the CHMP of the European Medicines Agency.

The most common adverse reactions (greater than or equal to 20% of patients) of Imfinzi versus placebo were cough (40.2% vs. 30.3%), upper respiratory tract infections (26.1% vs 11.5%) and rash (21.7% vs 12.0%). 12.8% of patients experienced a grade 3 or 4 AE with Imfinzi vs 9.8% with placebo.

Imfinzi is approved for the treatment of patients with unresectable, Stage III (locally-advanced) NSCLC in the US, Canada, Switzerland, India, Japan and Brazil. Other global health authority reviews and submissions are ongoing.

About Stage III NSCLC

Stage III (locally-advanced) NSCLC is divided into three sub-categories (IIIA, IIIB and IIIC), defined by how much the cancer has spread locally and the possibility of surgery. Stage III disease is different from Stage IV disease, when the cancer has spread (metastasised) to distant organs, as Stage III is currently treated with curative intent.

Stage III NSCLC represents approximately one-third of NSCLC incidence and was estimated to affect around 105,000 patients in the top-eight countries (China, France, Germany, Italy, Japan, Spain, UK, US) in 2017. The majority of Stage III NSCLC patients are diagnosed with unresectable tumours. No new treatments beyond chemoradiation therapy, followed by active surveillance to monitor for progression, have been available to patients for decades.

About PACIFIC

The PACIFIC trial is a Phase III, randomised, double-blinded, placebo-controlled, multi-centre trial of Imfinzias treatment in 'all-comer' patients (i.e. regardless of PD-L1 status) with unresectable, Stage III (locally-advanced) NSCLC whose disease has not progressed following platinum-based chemotherapy and radiation therapy (CRT).

The trial is being conducted in 235 centres across 26 countries involving 713 patients. The primary endpoints of the trial are PFS and OS, and secondary endpoints include landmark PFS and OS, objective response rate, and duration of response.

About Imfinzi

Imfinzi (durvalumab) is a human monoclonal antibody that binds to PD-L1 and blocks the interaction of PD-L1 with PD-1 and CD80, countering the tumour's immune-evading tactics and releasing the inhibition of immune responses.

Imfinzi is approved for unresectable, Stage III NSCLC in the US, Canada, Switzerland, India, Japan, and Brazil based on the Phase III PACIFIC trial. Imfinzi is also approved for the treatment of patients with locally-advanced or metastatic urothelial carcinoma in the US, Canada, Brazil, Israel, Hong Kong, and India.

As part of a broad development programme, Imfinzi is also being tested as a monotherapy and in combination with chemotherapy, radiation therapy, small molecules, and tremelimumab, an anti-CTLA4 monoclonal antibody, as a first or second-line treatment for patients with NSCLC, small-cell lung cancer, locally-advanced or metastatic urothelial carcinoma, head and neck cancer and other solid tumours.

About AstraZeneca in Lung Cancer

Lung cancer is the leading cause of cancer death among both men and women, accounting for about one-third of all cancer deaths.

AstraZeneca has a comprehensive portfolio of approved and potential new medicines in late-stage clinical development for the treatment of different forms of lung cancer across all stages of disease and lines of therapy. We aim to address the unmet needs of patients with EGFR-mutated tumours as a genetic driver of disease, which occur in 10-15% of NSCLC patients in the US and EU and 30-40% of NSCLC patients in Asia, with our approved medicines Iressa and Tagrisso and ongoing FLAURA, ADAURA and LAURA Phase III trials. Our extensive late-stage immuno-oncology programme focuses on 75-80% of patients with lung cancer without a known genetic mutation. Imfinzi, an anti-PDL1 antibody is in development as monotherapy (ADJUVANT BR.31, PACIFIC2, MYSTIC and PEARL Phase III trials) and in combination with tremelimumab and/or chemotherapy (MYSTIC, NEPTUNE, POSEIDON and CASPIAN Phase III trials).

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 clear majority of patients.

We are pursuing a comprehensive clinical trial programme that includes Imfinzi (anti-PDL1) as monotherapy and in combination with tremelimumab (anti-CTLA4) 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 advancing Oncology as a growth driver for AstraZeneca, 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, Renal & 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 therapy areas - Oncology, Cardiovascular, Renal & Metabolism and Respiratory. 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: 24 September 2018

By: /s/ Adrian Kemp

Name: Adrian Kemp

Title: Company Secretary