ASTRAZENECA PLC
Form 6-K
July 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 July 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-_____

31 July 2017 07:00 BST

IMFINZI GRANTED BREAKTHROUGH THERAPY DESIGNATION BY US FDA FOR PATIENTS WITH LOCALLY-ADVANCED UNRESECTABLE NON-SMALL CELL LUNG CANCER

Fourth Breakthrough Therapy Designation for an AstraZeneca New Oncology medicine in three years

AstraZeneca and MedImmune, its global biologics research and development arm, today announced that the US Food and Drug Administration (FDA) has granted Breakthrough Therapy Designation for Imfinzi (durvalumab) for the treatment of patients with locally-advanced, unresectable non-small cell lung cancer (NSCLC) whose disease has not progressed following platinum-based chemoradiation therapy.

Sean Bohen, Executive Vice President, Global Medicines Development and Chief Medical Officer at AstraZeneca, said: "For patients who have not progressed following chemoradiation therapy the only current option is active monitoring. Unfortunately, for the majority of patients, their cancer will progress to metastatic disease, typically within 12 months. Imfinzi is the first immuno-oncology medicine to show a clinically-significant benefit in this earlier, non-metastatic setting, so following the Breakthrough Designation we hope to bring it to patients as soon as possible."

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.

The Breakthrough Therapy Designation for Imfinzi was granted on the basis of interim results from the Phase III PACIFIC trial, a randomised, double-blinded, placebo-controlled multi-centre trial of Imfinzi as sequential treatment in patients with locally-advanced, unresectable (Stage III) NSCLC who had not progressed following standard platinum-based chemotherapy concurrent with radiation therapy. This achievement follows the recent accelerated approval from the US FDA for Imfinzi in previously-treated patients with advanced bladder cancer, and is the fourth Breakthrough Therapy Designation AstraZeneca has received from the FDA for a New Oncology cancer medicine over the past three years, the second for Imfinzi.

Data from the PACIFIC trial have been submitted for presentation at a forthcoming medical meeting.

Imfinzi is also being tested in the adjuvant NSCLC setting in the ADJUVANT Phase III trial. In the Stage IV 1st-line setting for patients with advanced NSCLC, Imfinzi as monotherapy and in combination with tremelimumab, an anti-CTLA4, is being tested in the MYSTIC, NEPTUNE, and PEARL Phase III trials. The POSEIDON trial is evaluating Imfinzi with and without tremelimumab in combination with chemotherapy.

About PACIFIC
The PACIFIC trial is a randomised, double-blinded, placebo-controlled multi-centre trial of Imfinzi as sequential 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, including the US, Canada, Europe, South and Central America, Japan, Korea, Taiwan, South Africa and Australia. 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), 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 continues to be studied in multiple monotherapy trials and combination trials with tremelimumab and other potential new medicines in immuno-oncology. Imfinzi is being assessed in Phase III trials as a monotherapy in various stages of NSCLC, in small-cell lung cancer (SCLC), in metastatic urothelial cancer (mUC) and in head and neck squamous cell carcinoma (HNSCC). The combination of Imfinzi and tremelimumab is being assessed in Phase III trials in NSCLC, SCLC, mUC and HNSCC and in Phase I/II trials in hepatocellular carcinoma (HCC) and haematological malignancies.

About Locally-Advanced (Stage III) NSCLC
Stage III lung cancer is 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 metastasised to other organs.

Stage III lung cancer represents approximately one third of NSCLC incidence and was estimated to affect around 100,000 patients in the G7 countries in 2016. About half 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 AstraZeneca in NSCLC
Lung cancer is the leading cause of cancer death among both men and women, accounting for about one-third of all cancer deaths and more than breast, prostate and colorectal cancers combined.

AstraZeneca has a comprehensive portfolio of approved and potential new medicines in late-stage clinical development for the treatment of NSCLC across all stages of disease and lines of therapy. We aim to address 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 on-going FLAURA and ADAURA trials for Tagrisso. Our extensive late-stage immuno-oncology programme focuses on 75-80% of patients with NSCLC without a known genetic mutation. Our portfolio includes Imfinzi, an anti-PD-L1 antibody, which is in development as monotherapy (ADJUVANT, PACIFIC, MYSTIC, PEARL and ARCTIC trials) and in combination with tremelimumab, an anti-CTLA-4 (MYSTIC, NEPTUNE, ARCTIC and POSEIDON 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 vast majority of patients.

We are pursuing a comprehensive clinical trial program 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

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 July 2017 By: /s/ Adrian Kemp
Name: Adrian Kemp
Title: Company Secretary