ASTRAZENECA PLC
Form 6-K
May 25, 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 May 2018

Commission File Number: 001-11960

AstraZeneca PLC

1 Francis Crick Avenue
Cambridge Biomedical Campus
Cambridge CB2 0AA
United Kingdom

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.
AZ's Imfinzi: significant OS in Stage III nsclc

This announcement contains inside information

25 May 2018 07:00 BST

Imfinzi significantly improves overall survival in the Phase III
PACIFIC trial for unresectable Stage III non-small cell lung cancer

Imfinzi met the second primary endpoint of overall survival which was both statistically-significant and clinically-meaningful at a planned interim analysis

AstraZeneca and MedImmune, its global biologics research and development arm, today announced positive overall survival (OS) results for the Phase III PACIFIC trial, a randomised, double-blinded, placebo-controlled, multi-centre trial of Imfinzi (durvalumab) in patients with unresectable Stage III non-small cell lung cancer (NSCLC) whose disease had not progressed following platinum-based chemotherapy concurrent with radiation therapy (CRT).

A planned interim analysis conducted by an Independent Data Monitoring Committee concluded that the trial has met its second of two primary endpoints by showing statistically-significant OS benefit with clinically-meaningful improvement in patients receiving Imfinzi compared to placebo. The safety and tolerability profile for Imfinzi was consistent with that reported at the time of the progression-free survival (PFS) analysis. AstraZeneca plans to present results from the PACIFIC trial at a forthcoming medical meeting.

Sean Bohen, Executive Vice President, Global Medicines Development and Chief Medical Officer at AstraZeneca, said: "The readout of positive overall survival data at the interim analysis of the PACIFIC trial provides additional compelling evidence of the clinical benefit that Imfinzi can offer patients in this earlier stage of lung cancer. We look forward to sharing these results with Health Authorities to support ongoing regulatory interactions and to update the Imfinzi label with these important data."

In May 2017, AstraZeneca announced that the PACIFIC trial met its first primary endpoint of PFS by demonstrating a median improvement of 11.2 months vs. placebo, as assessed by blinded independent central review.

Imfinzi is currently approved in the US and Canada for the treatment of patients with unresectable Stage III NSCLC who had not progressed following platinum-based chemoradiation therapy and under regulatory review in the EU, Japan and other jurisdictions with expected decisions in the second half of 2018.

About Stage III NSCLC
Stage III (locally-advanced) NSCLC is commonly divided into three sub-categories (IIIA, IIIB and IIIC), 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 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. Before the PACIFIC trial, the standard of care was chemotherapy and radiation therapy, followed by active surveillance to monitor for progression.

About PACIFIC
The PACIFIC trial is a randomised, double-blinded, placebo-controlled, multi-centre trial of Imfinzi as treatment in patients with Stage III unresectable NSCLC whose disease has not progressed following platinum-based chemoradiation 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, overall 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.

Earlier this month, Imfinzi received approval in Canada for the treatment of patients with unresectable Stage III NSCLC following chemoradiation therapy (CRT). In February 2018, Imfinzi received regulatory approval from the US FDA for the treatment of patients with unresectable Stage III NSCLC who had not progressed following concurrent platinum-based CRT.

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-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. The portfolio includes Imfinzi, an anti-PDL1 antibody, which is in development as monotherapy (ADJUVANT BR.31, MYSTIC and PEARL trials) and in combination with tremelimumab and/or chemotherapy (MYSTIC, NEPTUNE, CASPIAN, 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 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. 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.

Media Relations		
Karen Birmingham	UK/Global	+44 203 749 5634
Rob Skelding	UK/Global	+44 203 749 5821
Matt Kent	UK/Global	+44 203 749 5906
Gonzalo Viña	UK/Global	+44 203 749 5916
Jacob Lund	Sweden	+46 8 553 260 20
Michele Meixell	US	+1 302 885 2677

Investor Relations		
Thomas Kudsk Larsen		+44 203 749 5712
Craig Marks	Finance; Fixed Income; M&A	+44 7881 615 764
Henry Wheeler	Oncology	+44 203 749 5797
Mitchell Chan	Oncology; Other	+1 240 477 3771
Christer Gruvris	Brilinta; Diabetes	+44 203 749 5711
Nick Stone	Respiratory; Renal	+44 203 749 5716

US toll free +1 866 381 7277

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: 25 May 2018

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