ASTRAZENECA PLC
Form 6-K
November 16, 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 November 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

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1.
AstraZeneca provides update on Phase III MYSTIC

This announcement contains inside information

16 November 2018 07:00 GMT

AstraZeneca provides update on the Phase III MYSTIC trial of
Imfinzi and tremelimumab in Stage IV non-small cell lung cancer

AstraZeneca and MedImmune, its global biologics research and development arm, today announced final overall survival (OS) results for the Phase III MYSTIC trial, a randomised, open-label, multi-centre, global trial of Imfinzi (durvalumab) monotherapy and the combination of Imfinziand tremelimumab, an anti-CTLA4 antibody, versus standard-of-care (SoC) platinum-based chemotherapy in previously-untreated patients with Stage IV (metastatic) non-small cell lung cancer (NSCLC).

In the primary analysis population of patients, whose tumours express PD-L1 on 25% or more of their cancer cells as determined by the VENTANA PD-L1 (SP263) Assay, Imfinzi monotherapy and the combination of Imfinzi plus tremelimumab did not meet the primary endpoints of improving OS compared to SoC chemotherapy. While the OS result did not meet statistical significance, a hazard ratio (HR) of 0.76 (97.54% CI 0.564-1.019; nominal p=0.036) was observed with Imfinzimonotherapy. The combination therapy had an HR of 0.85 (98.77% CI 0.611-1.173; nominal p=0.202); the data support further analysis in exploratory subgroups.

The safety and tolerability profiles for Imfinzi and the Imfinzi plus tremelimumab combination were consistent with previous trials.

Sean Bohen, Executive Vice President, Global Medicines Development and Chief Medical Officer, said: "We are encouraged to see that Imfinzi monotherapy activity is in-line with that of the anti-PD-1 class in previously-untreated patients with Stage IV non-small cell lung cancer; however, we are disappointed that these results missed statistical significance. We remain confident in Imfinzias the cornerstone of our IO programme and continue to evaluate its potential in ongoing non-small cell lung cancer trials, including Imfinzi and Imfinzi plus tremelimumab in combination with chemotherapy."

Imfinzi is approved for unresectable, Stage III NSCLC in more than 40 countries, including the US, EU and Japan, based on the Phase III PACIFIC trial. Imfinzi is currently being tested in a range of Phase III trials for Stage IV NSCLC.

Immuno-oncology Phase III trials in Stage IV, 1st-line NSCLC

PEARL	Imfinzi monotherapy vs SoC chemotherapy
NEPTUNE	Imfinzi + tremelimumab vs SoC chemotherapy
POSEIDON	Imfinzi + chemotherapy or Imfinzi + tremelimumab + chemotherapy vs SoC chemotherapy

About MYSTIC
The MYSTIC trial is a randomised, open-label, multi-centre, global Phase III trial of Imfinzi(durvalumab) monotherapy or Imfinzi in combination with tremelimumab versus SoC chemotherapy in the 1st-line treatment of patients with epidermal growth factor receptor (EGFR) and anaplastic lymphoma kinase (ALK) wild-type, locally-advanced or metastatic (Stage IV) non-small cell lung cancer.

The trial was conducted in 167 centres across 17 countries, including the US, Canada, Europe, Russia, Australia and parts of Asia, including Japan, Korea, Thailand, Taiwan and Vietnam. Primary endpoints included progression-free survival (PFS) for the combination, and OS in monotherapy and in combination therapy. The combination of Imfinzi and tremelimumab did not meet the primary endpoint of improving PFS compared to SoC in patients whose tumours express PD-L1 on 25% or more of their cancer cells in July 2017.

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 more than 40 countries including the US, EU, and Japan based on the Phase III PACIFIC trial. Imfinzi is also approved for previously-treated patients with advanced bladder cancer in the US, Canada, Brazil, Israel, India, United Arab Emirates, Australia and Hong Kong.

As part of a broad development programme, Imfinzi is also being tested as a monotherapy and in combination with tremelimumab, an anti-CTLA4 monoclonal antibody and potential new medicine, as a treatment for patients with NSCLC, small-cell lung cancer (SCLC), bladder cancer, head and neck cancer and other solid tumours.

About tremelimumab
Tremelimumab is a human monoclonal antibody and potential new medicine that targets the activity of cytotoxic T-lymphocyte-associated protein 4 (CTLA-4). Tremelimumab blocks the activity of CTLA-4, contributing to T cell activation and boosting the immune response to cancer. Tremelimumab is being tested in a clinical trial programme in combination with Imfinzi in NSCLC, urothelial carcinoma, head and neck squamous cell carcinoma, hepatocellular carcinoma and blood cancers.

About Stage IV NSCLC
Lung cancer is the leading cause of cancer death among both men and women and accounts for about one-fifth of all cancer deaths: more than breast, prostate and colorectal cancers combined. Lung cancer is broadly split into NSCLC and SCLC, with 80-85% classified as NSCLC. Stage IV is the most advanced form of lung cancer and is often referred to as metastatic disease. Approximately 85% of Stage IV patients are diagnosed after the tumour has spread outside of the lung. For these patients, prognosis is particularly poor, as only 1 in 10 will be alive five years after diagnosis.

About AstraZeneca in lung cancer
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 spanning several 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, PACIFIC-2, PACIFIC-5, MYSTIC and PEARL Phase III trials) and in combination with tremelimumab and/or chemotherapy (MYSTIC, NEPTUNE, POSEIDON, ADRIATIC and CASPIAN Phase III trials).

About AstraZeneca's approach to 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 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 from 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 Oncology as a key 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 South San Francisco, 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: 16 November 2018

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