ASTRAZENECA PLC
Form 6-K
July 27, 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-_____

This announcement contains inside information

27 July 2017 07:10 BST

ASTRAZENECA REPORTS INITIAL RESULTS
FROM THE ONGOING MYSTIC TRIAL IN STAGE IV LUNG CANCER

Imfinzi plus tremelimumab combination did not meet a primary endpoint of progression-free survival compared to chemotherapy

The MYSTIC trial continues as planned to assess the additional primary endpoints of overall survival for Imfinzi monotherapy and for the Imfinzi plus tremelimumab combination

AstraZeneca and MedImmune, its global biologics research and development arm, today announced progression-free survival (PFS) results for the Phase III MYSTIC trial, a randomised, open-label, multi-centre, global trial of Imfinzi (durvalumab) monotherapy or Imfinzi in combination with tremelimumab versus platinum-based standard-of-care (SoC) chemotherapy in previously-untreated patients with metastatic (Stage IV) 1st-line non-small cell lung cancer (NSCLC).

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 (as determined by the VENTANA PD-L1 (SP263) assay).

As a secondary endpoint, although not formally tested, Imfinzi monotherapy would not have met a pre-specified threshold of PFS benefit over SoC in this disease setting.

The trial will continue to assess two additional primary endpoints of overall survival (OS) for Imfinzi monotherapy and OS for the Imfinzi plus tremelimumab combination. Final OS data from both primary endpoints are expected during the first half of 2018.

Sean Bohen, Executive Vice President, Global Medicines Development and Chief Medical Officer at AstraZeneca, said: “While the results from the MYSTIC trial for progression free survival in first-line Stage IV non-small cell lung cancer compared with standard of care are disappointing, the trial was designed to assess overall survival and we look forward to evaluating the remaining primary endpoints of overall survival for both mono- and combination therapy.”

AstraZeneca recently received accelerated approval from the US FDA for Imfinzi in previously-treated patients with locally advanced or metastatic urothelial carcinoma (mUC).

About MYSTIC

The MYSTIC trial is a randomised, open-label, multi-centre, global Phase III trial of Imfinzi monotherapy or Imfinzi in combination with tremelimumab versus SoC in treatment of patients with epidermal growth factor receptor (EGFR) and anaplastic lymphoma kinase (ALK) wild-type locally-advanced or metastatic (Stage IV) 1st-line NSCLC. Lung cancer is an unapproved use of Imfinzi.

The trial is being conducted in 167 centres across 17 countries, including the US, Canada, Europe, parts of Asia including Japan, Korea, Thailand, Taiwan and Vietnam, and in Russia and Australia. Primary endpoints include PFS and OS.

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 mUC and in head and neck squamous cell carcinoma (HNSCC). The combination of Imfinzi and tremelimumab is being assessed in Phase III trials in mUC, NSCLC, SCLC and HNSCC and in Phase I/II trials in hepatocellular carcinoma (HCC) and haematological malignancies.

About Tremelimumab

Tremelimumab is an investigational human monoclonal antibody 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 investigated in an extensive clinical trial programme in combination with Imfinzi, in NSCLC, mUC, HNSCC, HCC and blood cancers.

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 ongoing FLAURA and ADAURA trials. Our extensive late-stage immuno-oncology programme focuses on 75-80% of patients with NSCLC without a known genetic mutation. Our portfolio includes Imfinzi (durvalumab), an anti-PDL1 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 and POSEIDON trials).

About AstraZeneca’s approach to Immuno-Oncology

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-PDL1) 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 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: 27 July 2017 By: /s/ Adrian Kemp
Name: Adrian Kemp
Title: Company Secretary