ASTRAZENECA PLC
Form 6-K
December 07, 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 December 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.
Update on the Phase III EAGLE trial of Imfinzi

7 December 2018 07:00 GMT

Update on the Phase III EAGLE trial of Imfinzi and
tremelimumab in advanced head and neck cancer

AstraZeneca and MedImmune, its global biologics research and development arm, today announced overall survival (OS) results for the Phase III EAGLE trial. EAGLE is a randomised, open-label, multi-centre trial evaluating Imfinzi (durvalumab) monotherapy or Imfinzi in combination with tremelimumab, an anti-CTLA4 antibody, versus standard-of-care (SoC) chemotherapy in patients with recurrent or metastatic head and neck squamous cell carcinoma (HNSCC) who experienced disease progression following platinum-based chemotherapy, regardless of their PD-L1 tumour status.

Imfinzi monotherapy and the combination of Imfinzi plus tremelimumab did not meet the primary endpoints of improving OS compared to SoC chemotherapy in these hard-to-treat patients. The safety and tolerability profiles for Imfinzi and the combination with tremelimumab were consistent with previous experience.

Sean Bohen, Executive Vice President, Global Medicines Development and Chief Medical Officer, said: "The prognosis for recurrent or metastatic head and neck squamous cell cancer is very poor and new treatments for this group of cancers are urgently needed. While these results are disappointing, we remain committed to evaluating the potential of Imfinzi and other innovative medicines for patients with head and neck cancer. We look forward to seeing the results of the Phase III KESTREL trial of Imfinzi and tremelimumab in patients who have not received prior chemotherapy for recurrent or metastatic head and neck squamous cell carcinoma in the first half of 2019."

AstraZeneca will submit the results from the Phase III EAGLE trial for presentation at a forthcoming medical meeting.

About EAGLE
The EAGLE trial is a randomised, open-label, multi-centre, global, Phase III trial of Imfinzi (durvalumab) monotherapy or Imfinzi in combination with tremelimumab compared to standard-of-care chemotherapy in patients with recurrent or metastatic HNSCC who experienced progression following platinum-based chemotherapy, regardless of their PD-L1 tumour status.

The trial was conducted at 169 centres across 24 countries including the US, Europe, South America, Japan, Korea, Taiwan, Israel and Australia. The primary endpoint of the trial was OS, and secondary endpoints included progression-free survival, landmark OS, objective response rate and duration of response.

About HNSCC
Approximately 880,000 patients were diagnosed with head and neck cancer around the world in 2018. Two-thirds of patients diagnosed with head and neck cancer are in advanced stages (Stage III or IV), while the remaining one third are in the early stages of disease (Stage I or II). More than 90% of all head and neck cancers start in the squamous cells that line the mouth, nose and throat called head and neck squamous cell carcinomas (HNSCC).

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 non-small cell lung cancer (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, SCLC, bladder cancer, head and neck squamous cell carcinoma, liver cancer and blood cancers.

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: 07 December 2018

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