ASTRAZENECA PLC
Form 6-K
September 11, 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 September 2017

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-_____

11 September 2017 07:00 BST

ASTRAZENECA PRESENTS SUPERIOR PROGRESSION-FREE SURVIVAL FOR IMFINZI IN THE PACIFIC TRIAL OF PATIENTS WITH LOCALLY-ADVANCED UNRESECTABLE LUNG CANCER AT ESMO 2017 CONGRESS

Imfinzi improves progression-free survival (PFS) by more than 11 months compared to standard of care and is the first medicine to show superior PFS in this setting

Data presented at the ESMO 2017 Congress follows FDA's recent Breakthrough Therapy Designation for Imfinzi in locally advanced, unresectable lung cancer

The PACIFIC trial continues to evaluate the other primary endpoint, overall survival

AstraZeneca and MedImmune, its global biologics research and development arm, have presented the full PFS data from a planned interim analysis of the Phase III PACIFIC trial. Results show that Imfinzi (durvalumab) demonstrated a statistically-significant and clinically-meaningful improvement in PFS compared to current standard of care with active surveillance in patients with locally-advanced (Stage III), unresectable non-small cell lung cancer (NSCLC) who had not progressed following standard platinum-based chemotherapy concurrent with radiation therapy (CRT).

Results of the Phase III PACIFIC trial, included at the Presidential Symposium I of the European Society of Medical Oncology (ESMO) 2017 Congress in Madrid, Spain, show an improvement in PFS of more than 11 months in patients treated with Imfinzi compared to placebo (full details in table below). The PFS improvement with Imfinzi was observed across all pre-specified subgroups, including PD-L1 expression status. Patients receiving Imfinzi also had a lower incidence of metastases than those receiving placebo. The PACIFIC trial continues to evaluate overall survival (OS), the other primary endpoint. Detailed results of the PACIFIC trial are published online in the New England Journal of Medicine.

Sean Bohen, Executive Vice President, Global Medicines Development and Chief Medical Officer at AstraZeneca, said: "The Phase III PACIFIC results are incredibly encouraging for a patient population that until now has been without treatment options. As the first Immuno-Oncology medicine to achieve improvement in progression-free survival in this setting, Imfinzi is showing clear potential to become a new standard of care for patients with locally-advanced, unresectable NSCLC who have not progressed following chemoradiation."

Dr. Luis Paz-Ares, Principal Investigator of the PACIFIC trial, from the Hospital Universitario Doce de Octubre, Madrid, Spain, said: "For patients with locally-advanced unresectable NSCLC who have completed chemoradiation therapy, Imfinzi represents a potential new treatment option in the context of clear unmet clinical need. Durvalumab overtly prolongs the period in which the disease is controlled with reasonable side effects. In addition, it offers hope to increase the cure rate in this setting, but more mature follow-up is needed to assess its impact on survival."

Summary of key efficacy results:

| Endpoint | Medicine | Value | Hazard ratio (HR)/Confidence interval (CI) |
|---|---|---|---|
| PFS*(first primary endpoint) | Imfinzi | 16.8 months (median) | HR 0.5295% CI, 0.42-0.65, p<0.0001 |
| | Placebo | 5.6 months(median) | |
| Duration of response (DoR) | Imfinzi | Not reached | N/A |
| | Placebo | 13.8 months | |
| Objective Response Rate (ORR) as measured from baseline scan post-CRT completion | Imfinzi | 28.4% | 95% CI, 24.28-32.89, p<0.001 |
| | Placebo | 16.0% | 95% CI, 11.31-21.59, p<0.001 |

* Time from randomisation to the first documented tumour progression, or death in the absence of progression. Randomisation in the PACIFIC trial occurred up to 6 weeks after completion of concurrent chemoradiation therapy (cCRT) and cCRT typically lasted at least 6 weeks. If the PFS had been measured prior to cCRT, it would add approximately 3 months or longer to the PFS value for each arm.

Among patients receiving Imfinzi, the most frequent treatment-related adverse events (AEs) vs. placebo were cough (35.4% vs 25.2%), pneumonitis/radiation pneumonitis (33.9% vs 24.8%), fatigue (23.8% vs 20.5%), dyspnoea (22.3% vs 23.9%) and diarrhoea (18.3% vs 18.8%). 29.9% of patients experienced a grade 3 or 4 AE vs. 26.1% for placebo, and 15.4% of patients discontinued treatment due to AEs compared to 9.8% of patients on placebo.

On 31 July 2017, Imfinzi received Breakthrough Therapy Designation from the US Food and Drug Administration (FDA) as a potential treatment for patients with locally advanced, unresectable NSCLC whose disease has not progressed following platinum-based chemoradiation therapy.

AstraZeneca is in discussions with global health authorities regarding regulatory submissions for Imfinzi based on the PACIFIC data. A status of regulatory submissions is usually provided with the Company's quarterly results announcement.

Imfinzi received accelerated approval from the US Food and Drug Administration for previously treated patients with advanced bladder cancer and is under review in Canada and Australia for similar use.

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 spread (metastasised) to other organs.

Stage III lung cancer represents approximately one-third of NSCLC incidence and was estimated to affect around 105,000 patients in the G7 countries in 2016. More than 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 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 involving approximately 700 patients. The primary endpoints of the trial are progression-free survival (PFS) and overall survival (OS), and secondary endpoints include landmark PFS and OS, objective response rate (ORR) 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 and haematological malignancies.

About AstraZeneca in Lung Cancer
AstraZeneca is committed to developing therapies to help every patient with lung cancer. We have two approved therapies and a growing pipeline that targets genetic changes in tumour cells and boosts the power of the immune response against cancer. Our unrelenting pursuit of science aims to deliver more breakthrough therapies with the goal of extending and improving the lives of patients across all stages of disease and lines of therapy.

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 programme 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.


| Media Relations | | |
|---|---|---|
| Esra Erkal-Paler | UK/Global | +44 203 749 5638 |
| Karen Birmingham | UK/Global | +44 203 749 5634 |
| Rob Skelding | UK/Global | +44 203 749 5821 |
| Matt Kent | UK/Global | +44 203 749 5906 |
| 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 | +1 240 477 3771 |
| Christer Gruvris | Diabetes; Autoimmunity, Neuroscience & Infection | +44 203 749 5711 |
| Nick Stone | Respiratory; Brilinta | +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: 11th September 2017
By: /s/ Adrian Kemp
Name: Adrian Kemp
Title: Company Secretary