ASTRAZENECA PLC
Form 6-K
February 20, 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 February 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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AstraZeneca's IMFINZI approved for Stage III nsclc

This announcement contains inside information

19 February 2018 07:00 GMT

US FDA APPROVES IMFINZI FOR UNRESECTABLE STAGE III NON-SMALL CELL LUNG CANCER

Imfinzi is the only immunotherapy approved for patients with unresectable Stage III non-small cell lung cancer

Imfinzi showed an 11.2 month improvement in median progression-free survival (16.8 months compared to 5.6 months on placebo)

AstraZeneca and MedImmune, its global biologics research and development arm, today announced that the US Food and Drug Administration (FDA) has approved Imfinzi for the treatment of patients with unresectable Stage III non-small cell lung cancer (NSCLC) whose disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy (CRT).

Dave Fredrickson, Executive Vice President, Head of the Oncology Business Unit at AstraZeneca, said: "The approval of Imfinzi in this earlier stage of non-small cell lung cancer is a truly meaningful milestone for patients who, until now, had no FDA-approved treatment options following chemoradiation therapy. Globally, approximately 30% of patients with NSCLC present with Stage III disease and we are excited to launch the first immunotherapy into this setting."

Scott J. Antonia, MD, Ph.D., Chair of the Thoracic Oncology Department at the H. Lee Moffitt Cancer Center and Research Institute in Tampa and investigator in the PACIFIC trial, said: "Until now, treatment guidelines have recommended that patients with unresectable Stage III lung cancer undergo a period of active surveillance following chemoradiation therapy until disease progression. Given that up to 89% of patients will progress to metastatic disease, it is important that there is now a new option that can give patients more time without disease progression. The PACIFIC trial data supporting today's approval of Imfinzi will change how we treat these patients."

The approval of Imfinzi is based on the positive PFS data from the Phase III PACIFIC trial in which Imfinzi demonstrated an improvement in median PFS of 11.2 months compared to placebo, representing a 48% reduction in relative risk of progression or death vs. placebo in all patients, regardless of PD-L1 status. The PACIFIC trial is ongoing to evaluate overall survival (OS) in unresectable Stage III NSCLC. Detailed interim results of the PACIFIC trial were published online in the New England Journal of Medicine (NEJM).

PFS (co-primary endpoint)1	Imfinzi (N=476)2	Placebo (N=237)2
Number (%) of patients with event	214 (45%)	157 (66%)
Median in months (95% CI)	16.8 (13, 18.1)	5.6 (4.6, 7.8)
Hazard Ratio (95% CI)3, 4	0.52 (0.42, 0.65)	
p-value3, 5	<0.0001	

1 Blinded Independent Central Review (BICR)
2 Among the ITT population, 7% in the IMFINZI arm and 10% in the placebo arm had non-measurable disease as assessed by BICR according to RECIST v1.1
3 Stratified by sex, age, and smoking history
4 Pike estimator
5 Compared with allocated a of 0.0104 (Lan DeMets spending function approximating O'Brien Fleming boundary) for interim analysis

Overall, the incidence and severity of adverse events were comparable for patients receiving Imfinzi and the patients receiving placebo. In patients receiving Imfinzi, the most common adverse reactions (greater than or equal to 20% of patients) were cough (40%), fatigue (34%), pneumonitis or radiation pneumonitis (34%), upper respiratory tract infections (26%), dyspnoea (25%), and rash (23%). Discontinuation after concurrent CRT due to adverse reactions, regardless of causality, occurred in 15% of patients receiving Imfinzi vs. 10% of patients receiving placebo.

On 28 September 2017, the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology were updated to include Imfinzi for the treatment of patients with unresectable Stage III NSCLC with no disease progression after two or more cycles of concurrent CRT.

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 France, Germany, Italy, Japan, Spain, the UK and the US in 2016. The majority of Stage III NSCLC patients are diagnosed with unresectable tumours. Until now, the current standard of care has been chemotherapy and radiation therapy, followed by active surveillance to monitor for progression. The prognosis remains poor and long-term survival rates are low.

About Imfinzi
Imfinzi (durvalumab), 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 has already received accelerated approval in the US for the treatment of patients with locally-advanced or metastatic urothelial carcinoma, who have disease progression during or following platinum-containing chemotherapy, or whose disease has progressed within 12 months of receiving platinum-containing chemotherapy before (neoadjuvant) or after (adjuvant) surgery.

As part of a broad development programme, Imfinzi is also being investigated for the adjuvant treatment of patients with NSCLC in the Canadian Cancer Trials Group BR31 trial (ADJUVANT). In the MYSTIC, NEPTUNE and PEARL Phase III trials, Imfinzi is being studied for 1st-line treatment as monotherapy and/or in combination with tremelimumab, an anti-CTLA-4 monoclonal antibody and potential new medicine, for the treatment of metastatic NSCLC. The POSEIDON trial is investigating Imfinzi with and without tremelimumab in combination with chemotherapy in a similar patient population.

About AstraZeneca in Lung Cancer
AstraZeneca is committed to developing medicines to help every patient with lung cancer. We have three approved medicines 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
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 durvalumab (anti-PD-L1) as 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 Oncology as a growth platform 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 & 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 & 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: 19 FEBRUARY 2018

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