

ASTRAZENECA PLC
Form 6-K
July 02, 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 July 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 ☒ 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 ☒

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.
Imfinzi approved in Japan for Stage III nscLc

02 July 2018 07:00 BST

Imfinzi approved in Japan for unresectable Stage III non-small cell lung cancer

Imfinzi is the only immunotherapy approved for unresectable Stage III NSCLC

Approval is based on the Phase III PACIFIC trial

AstraZeneca and MedImmune, its global biologics research and development arm, today announced that the Japanese Ministry of Health, Labour and Welfare approved Imfinzi (durvalumab) as maintenance therapy after definitive chemoradiation therapy (CRT) in locally-advanced (Stage III), unresectable non-small cell lung cancer (NSCLC).

Dave Fredrickson, Executive Vice President, Head of the Oncology Business Unit said: "Non-small cell lung cancer is a leading cause of death in Japan, and we are dedicated to bringing new treatment options to patients as quickly as possible. As the only immunotherapy approved in the curative-intent, Stage III lung cancer setting, Imfinzi has the potential to change the treatment paradigm for patients diagnosed with this disease."

The approval of Imfinzi is based on positive progression-free survival (PFS) data from the Phase III PACIFIC trial in unresectable Stage III NSCLC. In the trial, Imfinzi demonstrated an improvement in median PFS of 11.2 months compared to placebo. Imfinzi improved other meaningful outcomes such as time to distant metastasis or death and overall response rates. Detailed results of the PACIFIC trial were published in the New England Journal of Medicine (NEJM).

PFS (first primary endpoint) ¹	Imfinzi (N=476) ²	Placebo (N=237) ²
Median in months	16.8	5.6
(95% CI)	(13, 18.1)	(4.6, 7.8)
Hazard ratio	0.52 (0.42, 0.65)	
(95% CI) ^{3, 4}		
p-value ^{3, 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.

The incidence and severity of adverse events were comparable for patients receiving Imfinzi vs. patients receiving placebo. The most frequent adverse reactions were rash which occurred in 73 subjects (15.4%), hypothyroidism which occurred in 50 subjects (10.5%), diarrhoea which occurred in 46 subjects (9.7%) and interstitial lung disease which occurred in 46 subjects (9.7%).

In May 2018, AstraZeneca announced that the PACIFIC trial met its second primary endpoint, showing statistically-significant and clinically-meaningful overall survival (OS) in patients receiving Imfinzi compared to placebo. Full results will be presented at a forthcoming medical meeting.

Imfinzi is also approved in the US, Canada, Switzerland and India based on the Phase III PACIFIC trial. Regulatory reviews in the EU and other jurisdictions are ongoing with an EU decision expected in the second half of 2018.

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. Stage III disease is different from Stage IV disease, when the cancer has spread (metastasised) to distant organs, as Stage III is currently treated with curative intent.

Stage III NSCLC represents approximately one-third of NSCLC incidence and was estimated to affect around 105,000 patients in the top-eight countries (China, France, Germany, Italy, Japan, Spain, UK, US) in 2017. The majority of Stage III NSCLC patients are diagnosed with unresectable tumours. Before the PACIFIC trial, the standard of care was chemotherapy and radiation therapy, followed by active surveillance to monitor for progression.

About PACIFIC

The PACIFIC trial is a randomised, double-blinded, placebo-controlled, multi-centre trial of Imfinzi as treatment in patients with Stage III unresectable NSCLC whose disease has not progressed following platinum-based chemoradiation therapy (CRT).

The trial has been conducted in 235 centres across 26 countries involving 713 patients. The primary endpoints of the trial are PFS and OS, and secondary endpoints include landmark PFS and OS, objective response rate, and duration of response.

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.

As part of a broad development programme, Imfinzi is also being tested as a monotherapy and in combination with chemotherapy, radiation therapy, small molecules, and tremelimumab, an anti-CTLA4 monoclonal antibody, as a 1st-line treatment for patients with NSCLC, small cell lung cancer, locally-advanced or metastatic urothelial carcinoma, head and neck cancer and other solid tumours.

About AstraZeneca in Lung Cancer

Lung cancer is the leading cause of cancer death among both men and women, accounting for about one-third of all cancer deaths.

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 across all 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. The portfolio includes Imfinzi, an anti-PDL1 antibody, which is in development as monotherapy (ADJUVANT BR.31, PACIFIC-2, MYSTIC and PEARL trials) and in combination with tremelimumab and/or chemotherapy (MYSTIC, NEPTUNE, CASPIAN, and POSEIDON trials).

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 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 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 advancing Oncology as a 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. 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: 02 July 2018

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