ASTRAZENECA PLC
Form 6-K
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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 January 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):
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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

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17 January 2017 07:00

ASTRAZENECA EXPANDS 1ST-LINE LUNG CANCER IMMUNO-ONCOLOGY PROGRAMME OPPORTUNITIES

Refined endpoints and statistical analysis plan in the Phase III MYSTIC trial

China regulatory submission opportunity strengthened with the expansion of the Phase III NEPTUNE trial and the initiation of the new Asia-focused Phase III PEARL trial

AstraZeneca today provides an update on its Immuno-Oncology (IO) late-stage clinical development programme in 1st-line non-small cell lung cancer (NSCLC), including a refinement of the Phase III MYSTIC trial.

The MYSTIC trial was initially designed to assess the benefit of durvalumab monotherapy and durvalumab and tremelimumab (durva + treme) combination therapy versus standard-of-care (SoC) chemotherapy, focused on progression-free survival (PFS).

The MYSTIC trial will now assess PFS and overall survival (OS) endpoints in patients with PDL1-expressing tumours for both durvalumab monotherapy and the combination of durva + treme, as well as in 'all comers' for the combination of durva + treme, versus SoC chemotherapy.

While the focus remains on exploring the benefit of durva + treme as combination therapy, the Company has updated the endpoints of the MYSTIC trial to include OS and PFS in durvalumab monotherapy. This is based on recent internal and external data, including durvalumab's strong efficacy in monotherapy presented at recent medical meetings, as well as significant opportunities in the competitive landscape.

The estimated primary completion date has been updated to reflect both an increase in patient recruitment (as reported in February 2016 with the inclusion of OS as a co-primary endpoint) and the event-based nature of the trial. As a result, the Company anticipates MYSTIC PFS data in mid-2017 and final OS data at the latest in 2018. MYSTIC also includes several undisclosed interim analyses for OS.

Additionally, the ongoing Phase III NEPTUNE trial will be expanded with local patients to support regulatory submission of durva + treme combination therapy in China for 1st-line NSCLC patients without delaying the anticipated OS data readout in 2018 from the global cohort, which is approaching full recruitment. The Company has also initiated the new Phase III PEARL trial of durvalumab monotherapy versus SoC chemotherapy in 1st-line NSCLC patients whose tumours express PD-L1. The PEARL trial focuses on Asian countries, primarily China, due to the high prevalence of NSCLC in the region.

All amendments will be reflected in updates to clinical trials websites, including clinicaltrials.gov.

Sean Bohen, Executive Vice President, Global Medicines Development and Chief Medical Officer at AstraZeneca, said: "The MYSTIC trial amendments, the NEPTUNE trial expansion and initiation of the new PEARL trial are all designed to enhance our options in 1st-line NSCLC for IO-IO combination as well as for IO monotherapy. We continue to follow the science through both internal and external sources for the benefit of patients and look forward to sharing our first pivotal data in mid-2017."

About MYSTIC

The MYSTIC trial is a randomised, open-label, multi-centre, global, Phase III trial of durvalumab in combination with tremelimumab or durvalumab monotherapy versus SoC platinum-based chemotherapy in 1st-line treatment of patients with epidermal growth factor receptor (EGFR) and anaplastic lymphoma kinase (ALK) wild-type advanced or metastatic NSCLC.

About NEPTUNE

The NEPTUNE trial is randomised, open-label, multi-centre, global, Phase III trial of durvalumab in combination with tremelimumab versus SoC platinum-based chemotherapy in 1st-line treatment of patients with epidermal growth factor receptor (EGFR) and anaplastic lymphoma kinase (ALK) wild-type advanced or metastatic NSCLC.

About PEARL

The PEARL trial is a randomised, open-label, multi-centre Phase III trial of durvalumab monotherapy versus SoC chemotherapy in 1st-line treatment of patients with epidermal growth factor receptor (EGFR) and anaplastic lymphoma kinase (ALK) wild-type advanced or metastatic PDL1-expressing NSCLC. The trial was initiated to determine the efficacy and safety of durvalumab in Asian countries, some of which have the highest current NSCLC burden, with over 1.1 million new cases projected for China alone in 2030.

About Durvalumab

Durvalumab is an investigational human monoclonal antibody directed against programmed death ligand-1 (PD-L1). PD-L1 expression enables tumours to evade detection from the immune system through binding to PD-1 on cytotoxic T lymphocytes. Durvalumab blocks PD-L1 interaction with both PD-1 and CD80 on T cells, countering the tumour's immune- evading tactics and activating the patient's immune system to attack the cancer. Durvalumab received FDA Breakthrough Therapy Designation in patients with PD-L1 positive inoperable or metastatic UC in 2016 and Fast Track Designation in 2015 for the treatment of patients with PD-L1 positive metastatic head and neck squamous cell carcinoma. The durvalumab biological license application (BLA) in second-line urothelial carcinoma (UC) has been accepted by the FDA with a PDUFA date in the second quarter of 2017.

AstraZeneca's Approach to Immuno-Oncology (IO)

IO is a therapeutic approach designed to stimulate the body's immune system to destroy 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 durvalumab (PD-L1) monotherapy and durvalumab in combination with tremelimumab (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 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 six 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, the genetic drivers of cancer 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 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: 17 January 2017 By: /s/ Adrian Kemp
Name: Adrian Kemp
Title: Company Secretary