

ASTRAZENECA PLC  
Form 6-K  
February 29, 2016

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 2016

Commission File Number: 001-11960

AstraZeneca PLC

2 Kingdom Street, London W2 6BD

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 REPORTS TOP-LINE RESULT OF TREMELIMUMAB MONOTHERAPY TRIAL IN MESOTHELIOMA

Trial did not meet primary endpoint of improving overall survival in challenging to treat mesothelioma patients with no currently approved treatment options in the second-line setting

Tremelimumab remains key component of Immuno-Oncology combination strategy across multiple tumour types

AstraZeneca and MedImmune, its global biologics research and development arm, today announced that DETERMINE, the Phase IIb clinical trial of 10 mg/kg tremelimumab monotherapy in second or third-line treatment of unresectable malignant mesothelioma, did not meet its primary endpoint of overall survival.

Robert Iannone, Senior Vice President, Head of Immuno-Oncology, Global Medicines Development at AstraZeneca, said: "We are disappointed that tremelimumab monotherapy did not demonstrate a survival benefit in this patient population with no approved medicines beyond first-line treatment. However, we remain confident in tremelimumab's clinical activity in combination, as shown in our recently published Study 006 trial of tremelimumab and durvalumab in non-small cell lung cancer."

In addition to investigation as monotherapy for patients with mesothelioma, tremelimumab is being studied in combination with AstraZeneca's anti-PD-L1 investigational immunotherapy durvalumab in multiple tumour types, including non-small cell lung cancer (NSCLC), squamous cell carcinoma of the head and neck, bladder, pancreatic, gastric and liver cancers. Preclinical data have suggested that targeting both PD-L1 and CTLA-4 may have additive or synergistic effects.<sup>1</sup> In the recently published Study 006, combination treatment with durvalumab and tremelimumab demonstrated antitumour activity in patients with locally advanced or metastatic NSCLC, irrespective of PD-L1 status.<sup>2</sup>

The Company will complete a full evaluation of the final DETERMINE data, which will be submitted for presentation at an upcoming medical meeting in 2016.

<sup>1</sup>Stewart et al. Preclinical modeling of immune checkpoint blockade (P2012). J Immunol 2013: 190 (1 Meeting Abstracts): Abstract 214.7.

<sup>2</sup>Antonia S, et al. Safety and antitumour activity in a Phase 1b study of combined checkpoint blockade with anti-PD-L1 (durvalumab) and anti-CTLA-4 (tremelimumab) in non-small cell lung cancer. The Lancet Oncology. Available at [http://www.thelancet.com/pdfs/journals/lanonc/PIIS1470-2045\(15\)00544-6.pdf](http://www.thelancet.com/pdfs/journals/lanonc/PIIS1470-2045(15)00544-6.pdf). Accessed February 2016.

<sup>3</sup>Delgermaa V et al. Global mesothelioma deaths reported to the World Health Organization between 1994 and 2008. Bull World Health Organ. 2011 Oct 1;89(10):716-24, 724A-724C

<sup>4</sup>Driscoll T et al. The global burden of disease due to occupational carcinogens. Am J Ind Med. 2005 Dec;48(6):419-31.

#### About Mesothelioma

Mesothelioma is a rare and deadly form of cancer that affects the lining of the lungs or abdomen. There is a high unmet medical need for mesothelioma treatments, with median overall survival 9 to 12 months after initial diagnosis.<sup>3</sup> The disease causes approximately 43,000 deaths per year globally.<sup>4</sup> In 2015, tremelimumab was granted Orphan Drug Designation by the U.S. Food and Drug Administration.

#### About the DETERMINE trial

DETERMINE (NCT01843374) is a randomised, double-blind, placebo-controlled Phase IIb global trial with 571 patients across multiple countries. The trial evaluated the safety and efficacy of tremelimumab versus placebo in the treatment of unresectable pleural or peritoneal malignant mesothelioma.

#### About Tremelimumab

Tremelimumab is an investigational, selective human antibody directed against cytotoxic T- lymphocyte-associated protein 4 (CTLA-4). By blocking the activity of CTLA-4, tremelimumab "releases the brakes" on T cell activation and boosts the immune response against cancer cells. Tremelimumab is being investigated in an extensive clinical trial programme, as monotherapy or in combination with durvalumab, in NSCLC, bladder, head and neck, gastric, pancreatic, HCC and blood cancers. In 2015, the U.S. Food and Drug Administration granted tremelimumab Fast Track Designation and Orphan Drug Designation as a potential treatment for malignant mesothelioma, an aggressive, rare form of cancer that affects the lining of the lungs and abdomen.

#### 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. Durvalumab is being developed alongside other immunotherapies to activate the patient's immune system to attack the cancer. Durvalumab is being investigated in an extensive clinical trial programme, as monotherapy or in combination with tremelimumab, in NSCLC, bladder, head and neck, gastric, pancreatic, HCC and blood cancers. In 2015, durvalumab received Fast Track Designation for the treatment of patients with PD-L1-positive metastatic SCCHN, and in 2016, durvalumab was granted Breakthrough Designation by the U.S. Food and Drug Administration as a potential treatment for metastatic urothelial bladder cancer.

#### 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 6 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 repair 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, innovation-driven biopharmaceutical business that focuses on the discovery, development and commercialisation of prescription medicines, primarily for the treatment of diseases in three main therapy areas - respiratory, inflammation, autoimmune disease (RIA), cardiovascular and metabolic disease (CVMD) and oncology - as well as in infection and neuroscience. 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](http://www.astrazeneca.com)

#### CONTACTS

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Key: RIA - Respiratory, Inflammation and Autoimmunity, CVMD - Cardiovascular and Metabolic Disease, ING - Infection, Neuroscience and Gastrointestinal

29 February 2016

-ENDS-

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: 29 February 2016

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