

ASTRAZENECA PLC  
Form 6-K  
February 03, 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-\_\_\_\_\_

TAGRISSTO™ (OSIMERTINIB) APPROVED IN EU AS FIRST-IN-CLASS TREATMENT FOR PATIENTS WITH EGFR T790M MUTATION-POSITIVE METASTATIC NON-SMALL CELL LUNG CANCER

TAGRISSO™ is the first new medicine to be approved under the European Commission's expedited process

Approval based on studies showing objective response rate of 66% and median progression-free survival of 9.7 months

Tumour sample or blood test can determine patients likely to benefit from osimertinib

AstraZeneca today announced that the European Commission (EC) has granted conditional marketing authorisation for TAGRISSO™ (AZD9291, osimertinib) 80mg once-daily tablets for the treatment of adult patients with locally advanced or metastatic epidermal growth factor receptor (EGFR) T790M mutation-positive non-small cell lung cancer (NSCLC).

Osimertinib is indicated for patients with T790M mutation-positive NSCLC, irrespective of previous treatment with an EGFR tyrosine kinase inhibitor (TKI). Eligibility for treatment with osimertinib will be dependent on mutation status, to be determined through a validated diagnostic test based on a tumour tissue sample or plasma. Availability of a blood-based test for circulating tumour DNA (ctDNA) means that physicians and patients have multiple options to test for a T790M mutation.

Sean Bohan, Executive Vice President, Global Medicines Development and Chief Medical Officer at AstraZeneca, said: "Osimertinib defines a new generation of targeted EGFR-TKI treatments, and the European Commission's expedited approval reflects the importance of this innovative medicine for addressing the needs of patients with lung cancer who have the T790M mutation. We are now building on our understanding of the clinical activity of osimertinib to explore its full potential in patients with EGFRm lung cancer in multiple treatment settings."

Dr Matthew Peters, Chair of the Global Lung Cancer Coalition, added: "It is an exciting time in the care of patients with lung cancer. The ability to precisely characterise patients who have different types of lung cancer based on genetic mutations, and predict their response to targeted treatments, offers a more accurate and efficient approach to lung cancer care. Patients with common sensitising EGFR mutations and the separate T790M have disappointing responses to standard treatments. Testing for the T790M status of lung cancer patients, using either a tumour sample or a simple blood test, and directing patients towards a medication such as osimertinib that is specifically designed for their pattern of mutations, offers greater prospects for durable treatment outcomes."

Mutations in the EGFR receptor can lead to uncontrolled cell growth and tumour formation. Osimertinib targets both the EGFR mutation that triggers cancer development and T790M, a mutation that makes tumours resistant to existing treatment with EGFR-TKIs. Nearly two out of three patients with NSCLC whose disease progresses after treatment with an EGFR inhibitor develop the T790M mutation, for which treatment options are limited. A small number of patients (approximately 3-5%) have the T790M mutation at NSCLC diagnosis.

The EU approval for osimertinib is based on data from two Phase II studies (AURA extension and AURA2) and the AURA Phase I expansion study, which demonstrated efficacy in 474 patients with EGFRm T790M NSCLC who had progressed on or after an EGFR-TKI. In the combined Phase II studies, the objective response rate (ORR, a measurement of tumour shrinkage) was 66%, and in the Phase I study it was 62%. Progression-free survival (PFS) was 9.7 months in the combined Phase II studies and 11 months in the Phase I trial. Median duration of response (DOR) in the Phase I study was 9.7 months, and in the combined Phase II studies, median DOR was not reached.

The most common adverse events based on data from the two AURA Phase II studies were generally mild to moderate and included diarrhoea (42% all grades; 1.0% Grade 3/4), rash (41% all grades; 0.5% Grade 3/4), dry skin (31% all grades; 0% Grade 3/4) and nail toxicity (25% all grades; 0% Grade 3/4). Warnings and precautions include interstitial lung disease and QT interval prolongation.

The EU marketing authorisation was received through the Accelerated Assessment procedure of the European Medicines Agency (EMA). This approval follows US Accelerated Approval granted in November 2015 and availability in the UK under the Early Access to Medicines Scheme in December 2015. In Japan, osimertinib was granted Priority Review by the Pharmaceuticals and Medical Devices Agency (PMDA). Interactions with regulatory authorities in the rest of the world are ongoing.

## NOTES TO EDITORS

### About Non-Small Cell Lung Cancer (NSCLC)

Lung cancer is the leading cause of cancer death among both men and women, accounting for about one-third of all cancer deaths, and more than breast, prostate and colorectal cancers combined. Patients who have the EGFR<sup>m</sup> form of NSCLC, which occurs in 10-15% of NSCLC patients in Europe and 30-40% of NSCLC patients in Asia, are particularly sensitive to treatment with currently available EGFR-TKIs, which block the cell signalling pathways that drive the growth of tumour cells. However, tumours almost always develop resistance to treatment, leading to disease progression. In approximately two-thirds of patients treated with the approved EGFR-TKIs, gefitinib, erlotinib or afatinib, this resistance is caused by the secondary mutation, T790M.

### About osimertinib

Osimertinib 80mg once-daily tablet is the first medicine indicated for the treatment of adult patients with metastatic EGFR T790M mutation-positive NSCLC. Non-clinical in vitro studies have demonstrated that osimertinib has high potency and inhibitory activity against mutant EGFR phosphorylation across the range of clinically relevant EGFR<sup>m</sup> and T790M mutant NSCLC cell lines with significantly less activity against EGFR in wild-type cell lines.

Osimertinib is being compared with platinum-based doublet chemotherapy in the confirmatory AURA3 Phase III study in patients with EGFR T790M-positive, locally advanced or metastatic NSCLC who have progressed after EGFR-TKI therapy. It is also being investigated in the adjuvant and metastatic first-line settings, including in patients with brain metastases, and in combination with other compounds.

### 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 -

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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

03 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: 03 February 2016

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