

ASTRAZENECA PLC ANNOUNCES TAGRISSO MET PRIMARY ENDPOINT IN PHASE III 2ND-LINE LUNG CANCER TRIAL

Tagrisso demonstrated superior progression-free survival compared to standard platinum-based chemotherapy, with a safety profile consistent with previous trials

First randomised trial to evaluate the clinical benefit of an EGFR T790M medicine, and data are consistent with those supporting Tagrisso approvals

This announcement contains inside information

AstraZeneca today announced that the Phase III AURA3 trial met its primary endpoint, demonstrating superior progression-free survival (PFS) compared to standard platinum-based doublet chemotherapy. The AURA3 randomised trial assessed the efficacy and safety of *Tagrisso* as a 2nd-line treatment in more than 400 patients with EGFR T790M mutation-positive, locally-advanced or metastatic NSCLC, whose disease had progressed following 1st-line EGFR tyrosine kinase inhibitor (TKI) therapy. *Tagrisso* also demonstrated a safety profile consistent with previous trials.

In addition to PFS, the objective response rate (ORR), disease control rate (DCR) and duration of response (DoR) also achieved clinically meaningful improvement versus chemotherapy. A full evaluation of AURA3 data, including an analysis of overall survival (OS), is ongoing, and results will be presented at an upcoming medical meeting.

Sean Bohan, Executive Vice President, Global Medicines Development and Chief Medical Officer at AstraZeneca, said: "These results confirm *Tagrisso* as a meaningful alternative to benefit EGFR T790M lung cancer patients. The AURA3 results demonstrate the benefits of our science-led approach that enabled the rapid development of *Tagrisso* as a targeted treatment to address the most common cause of resistance to a first-generation EGFR-TKI for patients with metastatic EGFR-mutant lung cancer. We remain committed to exploring the potential of *Tagrisso* to further extend its reach and help meet patient need."

Tagrisso is one of the fastest development programmes ever, from start of clinical trials to approval in just over two and a half years. It was approved in the US, EU, Japan, Canada, Switzerland, Israel and Mexico as the first treatment for patients with EGFR T790M mutation-positive advanced NSCLC. *Tagrisso* is also approved in South Korea in the same indication. Eligibility for treatment with *Tagrisso* is dependent on confirmation that the EGFR T790M mutation is present in the tumour.

AstraZeneca is committed to exploring the full potential of *Tagrisso* as monotherapy and in combination, for patients with lung cancer, including in adjuvant and locally-advanced/ metastatic 1st-line EGFRm settings. In addition, AstraZeneca is exploring *Tagrisso* in NSCLC patients with and without brain metastases, and has presented encouraging data in a small cohort of patients with leptomeningeal disease.

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 EGFRm form of NSCLC, which occurs in 10-15% of NSCLC patients in the US and 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 approved EGFR-TKIs such as gefitinib and erlotinib, this resistance is caused by the secondary mutation, T790M.

About Tagrisso

Tagrisso (osimertinib, AZD9291) 80mg once-daily tablet is the first medicine indicated for the treatment of adult patients with locally-advanced or metastatic EGFR T790M mutation-positive NSCLC. *Tagrisso* is an irreversible EGFR inhibitor, born out of scientific exploration and engineered to combat the mechanism of resistance by targeting the T790M resistance mutation.

Tagrisso is also being investigated in the adjuvant and metastatic 1st-line settings, including in patients with and without brain metastases, in leptomeningeal disease, and in combination with other treatments.

About AURA3

AURA3 compared the efficacy and safety of *Tagrisso* 80mg once daily and platinum-based doublet chemotherapy in 419 patients with EGFR T790M mutation-positive, locally-advanced or metastatic NSCLC whose disease had progressed on or after treatment with a previous EGFR-TKI. The trial was carried out in more than 130 locations worldwide, including the USA, Canada, Europe, China, Japan, Korea, Taiwan and Australia.

The primary endpoint of the trial was PFS, and secondary endpoints included OS, ORR, DoR, DCR, safety and measures of health-related quality of life (HRQoL).

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 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 therapy areas - Respiratory and Autoimmunity, Cardiovascular and Metabolic Diseases, and Oncology. The Company is also active in inflammation, infection and neuroscience through numerous collaborations. 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

CONTACTS

Media Enquiries

Neil Burrows	UK/Global	+44 203 749 5637
Vanessa Rhodes	UK/Global	+44 203 749 5736
Karen Birmingham	UK/Global	+44 203 749 5634
Rob Skelding	UK/Global	+44 203 749 5821
Jacob Lund	Sweden	+46 8 553 260 20
Michele Meixell	US	+1 302 885 2677

Investor Relations

UK

Thomas Kudsk Larsen		+44 203 749 5712
Craig Marks	Finance, Fixed Income, M&A	+44 7881 615 764
Nick Stone	Respiratory and Autoimmunity	+44 203 749 5716
Henry Wheeler	Oncology	+44 203 749 5797
Christer Gruvris	Infection and Neuroscience	+44 203 749 5711

US

Lindsey Trickett	Cardiovascular and Metabolic Diseases	+1 240 543 7970
Mitchell Chan	Oncology	+1 240 477 3771
Toll-free		+1 866 381 7277

Adrian Kemp
Company Secretary
AstraZeneca PLC

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