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**Tagrisso approved in the US for patients with
unresectable, Stage III EGFR-mutated lung cancer**

**Based on LAURA Phase III trial results which showed Tagrisso
extended median progression-free survival by more than three years**

AstraZeneca's *Tagrisso* (osimertinib) has been approved in the US for the treatment of adult patients with unresectable, Stage III epidermal growth factor receptor-mutated (EGFRm) non-small cell lung cancer (NSCLC) whose disease has not progressed during or following concurrent or sequential platinum-based chemoradiation therapy (CRT). *Tagrisso* is indicated for patients with exon 19 deletions or exon 21 (L858R) mutations, as detected by a FDA-approved test.

The approval follows a [Priority Review](#) by the Food and Drug Administration (FDA) that was based on results from the LAURA Phase III trial, which were presented during the Plenary Session at the 2024 American Society of Clinical Oncology (ASCO) Annual Meeting and simultaneously published in [The New England Journal of Medicine](#).

Tagrisso reduced the risk of disease progression or death by 84% compared to placebo (hazard ratio 0.16; 95% confidence interval 0.10-0.24; p<0.001) as assessed by blinded independent central review. Median progression-free survival (PFS) was 39.1 months in patients treated with *Tagrisso* versus 5.6 months for placebo.

Overall survival (OS) results remain immature at this current analysis. The trial continues to assess OS as a secondary endpoint.

Each year in the US, there are more than 200,000 people diagnosed with lung cancer, and 80-85% of these patients are diagnosed with NSCLC, the most common form of lung cancer.¹⁻³ Approximately 15% of NSCLC patients in the US have EGFR mutations.⁴ Nearly one in five people diagnosed with NSCLC has an unresectable tumour.⁵

Suresh Ramalingam, MD, Executive Director of Winship Cancer Institute of Emory University, Atlanta, US, and principal investigator in the trial, said: "This approval represents a major breakthrough for patients with Stage III, EGFR-mutated lung cancer who will now have the opportunity to benefit from osimertinib. Patients treated with osimertinib lived without disease progression by more than three years in the LAURA trial, and this impressive benefit underscores the importance of diagnosing and testing lung cancer patients as early as possible."

Dave Fredrickson, Executive Vice President, Oncology Business Unit, AstraZeneca, said: "The approval of *Tagrisso* for patients with Stage III, unresectable EGFR-mutated non-small cell lung cancer addresses a critical need for patients with these mutations who have never had the option of targeted therapy before. The results of the LAURA trial show the powerful impact *Tagrisso* can make as backbone therapy in this disease, and with this approval, patients across all stages of EGFR-mutated non-small cell lung cancer can now benefit."

The safety and tolerability of *Tagrisso* in the LAURA trial was consistent with its established profile and no new safety concerns were identified.

Tagrisso is approved for patients with EGFR mutations in the 1st-line metastatic setting as a monotherapy and in combination with chemotherapy, and as an adjuvant treatment for early-stage disease. *Tagrisso* is currently under review with regulatory authorities in other countries around the world for this indication.

Notes

Lung cancer

Each year, an estimated 2.4 million people are diagnosed with lung cancer globally.⁶ Lung cancer is the leading cause of cancer death among both men and women, accounting for about one-fifth of all cancer deaths.⁶ Lung cancer is broadly split into NSCLC and small cell lung cancer.² The majority of all NSCLC patients are diagnosed with advanced disease.⁷

Approximately 10-15% of NSCLC patients in the US and Europe, and 30-40% of patients in Asia have EGFRm NSCLC.^{4,8-9} Patients with EGFRm NSCLC are particularly sensitive to treatment with an EGFR-tyrosine kinase inhibitor (EGFR-TKI) which blocks the cell-signalling pathways that drive the growth of tumour cells.¹⁰

LAURA

LAURA is a randomised, double-blind, placebo-controlled, multi-centre, global Phase III trial in patients

with unresectable, Stage III EGFRm NSCLC whose disease has not progressed following definitive platinum-based CRT. Patients were treated with *Tagrisso* 80mg once-daily oral tablets until disease progression, unacceptable toxicity or other discontinuation criteria were met. Upon progression, patients in the placebo arm were offered treatment with *Tagrisso*.

The trial enrolled 216 patients in more than 145 centres across more than 15 countries, including in the US, Europe, South America and Asia. This is the analysis of the primary endpoint of PFS. The trial is ongoing and will continue to assess the secondary endpoint of OS.

Tagrisso

Tagrisso (osimertinib) is a third-generation, irreversible EGFR-TKI with proven clinical activity in NSCLC, including against central nervous system (CNS) metastases. *Tagrisso* (40mg and 80mg once-daily oral tablets) has been used to treat nearly 800,000 patients across its indications worldwide and AstraZeneca continues to explore *Tagrisso* as a treatment for patients across multiple stages of EGFRm NSCLC.

There is an extensive body of evidence supporting the use of *Tagrisso* as standard of care in EGFRm NSCLC. *Tagrisso* improved patient outcomes in early-stage disease in the [ADAURA Phase III trial](#), locally advanced disease in the [LAURA Phase III trial](#), late-stage disease in the [FLAURA Phase III trial](#), and with chemotherapy in the [FLAURA2 Phase III trial](#).

As part of AstraZeneca's ongoing commitment to treating patients as early as possible in lung cancer, *Tagrisso* is also being investigated in the neoadjuvant setting in the NeoADAURA Phase III trial with results expected later this year and in the early-stage adjuvant resectable setting in the ADAURA2 Phase III trial.

The Company is also researching ways to address tumour mechanisms of resistance through the SAVANNAH and ORCHARD Phase II trials, and the SAFFRON Phase III trial, which test *Tagrisso* plus *Orpathys* (savolitinib), an oral, potent and highly selective MET TKI, as well as other potential new medicines.

AstraZeneca in lung cancer

AstraZeneca is working to bring patients with lung cancer closer to cure through the detection and treatment of early-stage disease, while also pushing the boundaries of science to improve outcomes in the resistant and advanced settings. By defining new therapeutic targets and investigating innovative approaches, the Company aims to match medicines to the patients who can benefit most.

The Company's comprehensive portfolio includes leading lung cancer medicines and the next wave of innovations, including *Tagrisso* and *Iressa* (gefitinib); *Imfinzi* (durvalumab) and *Imjudo* (tremelimumab); *Enhertu* (trastuzumab deruxtecan) and datopotamab deruxtecan in collaboration with Daiichi Sankyo; savolitinib in collaboration with HUTCHMED; as well as a pipeline of potential new medicines and combinations across diverse mechanisms of action.

AstraZeneca is a founding member of the Lung Ambition Alliance, a global coalition working to accelerate innovation and deliver meaningful improvements for people with lung cancer, including and beyond treatment.

AstraZeneca in oncology

AstraZeneca is leading a revolution in oncology with the ambition to provide cures for cancer in every form, following the science to understand cancer and all its complexities to discover, develop and deliver life-changing medicines to patients.

The Company's focus is on some of the most challenging cancers. It is through persistent innovation that AstraZeneca has built one of the most diverse portfolios and pipelines in the industry, with the potential to catalyse changes in the practice of medicine and transform the patient experience.

AstraZeneca has the vision to redefine cancer care and, one day, eliminate cancer as a cause of death.

AstraZeneca

AstraZeneca (LSE/STO/Nasdaq: AZN) is a global, science-led biopharmaceutical company that focuses on the discovery, development, and commercialisation of prescription medicines in Oncology, Rare Diseases, and BioPharmaceuticals, including Cardiovascular, Renal & Metabolism, and Respiratory & Immunology. Based in Cambridge, UK, AstraZeneca's innovative medicines are sold in more than 125 countries and used by millions of patients worldwide. Please visit [astrazeneca.com](https://www.astrazeneca.com) and follow the Company on social media [@AstraZeneca](https://twitter.com/AstraZeneca).

Contacts

For details on how to contact the Investor Relations Team, please click [here](#). For Media contacts, click [here](#).

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Adrian Kemp
Company Secretary
AstraZeneca PLC

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