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**_Tagrisso_ approved in the EU for patients with unresectable _EGFR_-mutated lung cancer**

***First and only EGFR inhibitor and targeted treatment approved in the EU in unresectable NSCLC***

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

AstraZeneca's *Tagrisso* (osimertinib) has been approved in the European Union (EU) for the treatment of adult patients with locally advanced, unresectable non-small cell lung cancer (NSCLC) whose tumours have epidermal growth factor receptor (*EGFR*) exon 19 deletions or exon 21 (L858R) substitution mutations and whose disease has not progressed during or following platinum-based chemoradiation therapy (CRT).

The approval by the European Commission follows the positive opinion of the Committee for Medicinal Products for Human Use and is based on results from the LAURA Phase III trial, which were published in *The New England Journal of Medicine*.

In the trial, *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, and the trial is continuing to assess OS as a secondary endpoint.

Each year in Europe, there are more than 450,000 people diagnosed with lung cancer, and approximately 80-85% have NSCLC.[1-3] Among those with NSCLC in Europe, about 10-15% have tumours with an *EGFR* mutation.[4-6]

Manuel Cobo, MD, Specialist Physician of the Medical Oncology Service at the Carlos Haya University Hospital, Malaga, Spain, and investigator for the trial, said: "Today's approval marks a major breakthrough for patients in the EU with unresectable, *EGFR*-mutated non-small cell lung cancer, delivering the first targeted treatment in this setting. Osimertinib reduced the risk of disease progression or death by an unprecedented 84 per cent in the LAURA trial, setting a new benchmark for outcomes and underscoring the importance of testing for *EGFR* mutations upon diagnosis."

Dave Fredrickson, Executive Vice President, Oncology Business Unit, AstraZeneca, said: "*Tagrisso* is now the first and only *EGFR* inhibitor and targeted treatment approved in the EU for locally advanced, unresectable lung cancer, providing a new standard of care to patients who have historically experienced early progression after chemoradiation therapy. The powerful results from the LAURA trial show *Tagrisso* improves outcomes for patients in the unresectable setting, reinforces the importance of timely EGFR testing and solidifies *Tagrisso* as the backbone therapy in *EGFR*-mutated non-small cell lung cancer."

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

This is the fifth major approval for *Tagrisso* based on the LAURA trial following recent approvals in the US, Switzerland, South Korea and Australia. Regulatory applications are also currently under review in China, Japan and several other countries.

*Tagrisso* is approved as monotherapy in more than 100 countries including in the US, EU, China and Japan. Approved indications include 1st-line treatment of patients with locally advanced or metastatic *EGFR*m NSCLC, locally advanced or metastatic *EGFR* T790M mutation-positive NSCLC, and adjuvant treatment of early-stage *EGFR*m NSCLC. *Tagrisso* is also approved in combination with chemotherapy in the US, China and several other countries for 1st-line treatment of patients with locally advanced or metastatic *EGFR*m NSCLC.

## Notes

**Lung cancer**

Each year, an estimated 2.4 million people are diagnosed with lung cancer globally.[7] Lung cancer is the leading cause of cancer death among both men and women, accounting for about one-fifth of all cancer deaths.[7] Lung cancer is broadly split into NSCLC and small cell lung cancer, with 80-85% of patients diagnosed with NSCLC, the most common form of lung cancer.[2,3] The majority of all NSCLC patients are diagnosed with advanced disease.[8]

Approximately 10-15% of NSCLC patients in the US and Europe, and 30-40% of patients in Asia have *EGFR*m NSCLC.[4-6] Patients with *EGFR*m 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.[9]

**LAURA**
LAURA is a randomised, double-blind, placebo-controlled, multi-centre, global Phase III trial in patients with unresectable, Stage III *EGFR*m 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. The primary endpoint is 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 metastases. *Tagrisso* (40mg and 80mg once-daily oral tablets) has been used to treat patients across its indications worldwide and AstraZeneca continues to explore *Tagrisso* as a treatment for patients across multiple stages of *EGFR*m NSCLC.

There is an extensive body of evidence supporting the use of *Tagrisso* as standard of care in *EGFR*m NSCLC. *Tagrisso* improved patient outcomes in early-stage disease in the ADAURA Phase III trial, Stage III, unresectable 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 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 savolitinib 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; *Orpathys* (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 and follow the Company on social media @AstraZeneca.

**Contacts**
For details on how to contact the Investor Relations Team, please click here. For Media contacts, click here.

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