

19 February 2024

## **Tagrisso demonstrated overwhelming efficacy benefit for patients with unresectable, Stage III EGFR-mutated lung cancer in LAURA Phase III trial**

### ***First EGFR inhibitor and targeted treatment to demonstrate progression-free survival benefit in Stage III setting***

Positive high-level results from the LAURA Phase III trial showed AstraZeneca's *Tagrisso* (osimertinib) demonstrated a statistically significant and highly clinically meaningful improvement in progression-free survival (PFS) for patients with unresectable, Stage III epidermal growth factor receptor-mutated (EGFRm) non-small cell lung cancer (NSCLC) after chemoradiotherapy (CRT) compared to placebo after CRT.

Overall survival (OS) data showed a favourable trend for *Tagrisso*, although data were not mature at the time of this analysis. The trial will continue to assess OS as a secondary endpoint.

Each year an estimated 2.4 million people are diagnosed with lung cancer globally with 80-85% of patients diagnosed with NSCLC, the most common form of lung cancer.<sup>1-3</sup> Approximately 10-15% of NSCLC patients in the US and Europe, and 30-40% of patients in Asia, have EGFR mutations.<sup>4-7</sup> More than one in six patients with NSCLC are diagnosed with unresectable Stage III disease (15%).<sup>8</sup>

Suresh Ramalingam, MD, Executive Director of Winship Cancer Institute of Emory University, Atlanta, US, and principal investigator in the trial, said: "These results represent a major advance for patients with Stage III EGFR-mutated lung cancer who have a high propensity for early progression and spread to the brain, and where no targeted therapy is available. LAURA shows osimertinib can provide impactful clinical benefit and could become the first targeted treatment option for patients with Stage III disease."

Susan Galbraith, Executive Vice President, Oncology R&D, AstraZeneca, said: "These highly impactful results for the LAURA trial in this potentially curative early lung cancer setting further entrench *Tagrisso* as the backbone therapy for EGFR-mutated lung cancer. These data together with the ADAURA data, reinforce the imperative to diagnose and treat patients with lung cancer as early as possible."

The safety and tolerability of *Tagrisso* in the LAURA trial was consistent with its established profile and no new safety concerns were reported with *Tagrisso* maintenance treatment following CRT.

The data will be presented at a forthcoming medical meeting and shared with global regulatory authorities.

In addition, *Tagrisso* plus chemotherapy was recently approved in the US based on 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.

### **Notes**

#### **Lung cancer**

Lung cancer is the leading cause of cancer death among both men and women, accounting for about one-fifth of all cancer deaths.<sup>1</sup> Lung cancer is broadly split into NSCLC and small cell lung cancer.<sup>2</sup> The majority of all NSCLC patients are diagnosed with advanced disease.<sup>6</sup>

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.<sup>10</sup>

#### **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 permitted to be treated 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 metastases. *Tagrisso* (40mg and 80mg once-daily oral tablets) has been used to treat more than 800,000 patients across its indications worldwide and AstraZeneca continues to explore *Tagrisso* as a treatment for patients across multiple stages of EGFRm NSCLC.

*Tagrisso* is approved as monotherapy in more than 100 countries including in the US, EU, China and Japan. These include for 1st-line treatment of patients with locally advanced or metastatic EGFRm

support. These include first-line treatment of patients with locally advanced or metastatic EGFRm NSCLC, locally advanced or metastatic EGFR T790M mutation-positive NSCLC, and adjuvant treatment of early-stage (IB, II and IIIA) EGFRm NSCLC, where *Tagrisso* recently demonstrated a statistically significant and clinically meaningful OS benefit.

There is an extensive body of evidence supporting the use of *Tagrisso* in EGFRm NSCLC. *Tagrisso* is the only targeted therapy to improve patient outcomes in both early-stage disease in the [ADAURA Phase III trial](#) and late-stage disease in the [FLAURA Phase III trial](#) and [FLAURA2 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, 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; *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 operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. Please visit [astrazeneca.com](https://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](#).

### **References**

1. World Health Organisation. International Agency for Research on Cancer. Lung Fact Sheet. Available at: <https://gco.iarc.who.int/media/globocan/factsheets/cancers/15-trachea-bronchus-and-lung-fact-sheet.pdf>. Accessed February 2024.
2. LUNGeVity Foundation. Types of Lung Cancer. Available at: <https://lungevity.org/for-patients-caregivers/lung-cancer-101/types-of-lung-cancer>. Accessed February 2024.
3. American Cancer Society. What Is Lung Cancer? Available at: [https://www.cancer.org/cancer/lung-cancer/about/what-is.html#:~:text=About%2080%25%20to%2085%25%20of,\(outlook\)%20are%20often%20similar](https://www.cancer.org/cancer/lung-cancer/about/what-is.html#:~:text=About%2080%25%20to%2085%25%20of,(outlook)%20are%20often%20similar). Accessed February 2024.
4. Knight SB, et al. Progress and prospects of early detection in lung cancer. *Open Biol.* 2017;7(9): 170070.
5. Keedy VL, et al. American Society of Clinical Oncology Provisional Clinical Opinion: Epidermal Growth Factor Receptor (EGFR) Mutation Testing for Patients with Advanced Non-Small-Cell Lung Cancer Considering First-Line EGFR Tyrosine Kinase Inhibitor Therapy. *J Clin Oncol.* 2011;29:2121-27.
6. Zhang Y, et al. The prevalence of EGFR mutation in patients with non-small cell lung cancer: a systematic review and meta-analysis. *Oncotarget.* 2016;7(48).
7. Szumera-Cieckiewicz A, et al. EGFR Mutation Testing on Cytological and Histological Samples in 11. Non-Small Cell Lung Cancer: a Polish, Single Institution Study and Systematic Review of European Incidence. *Int J Clin Exp Pathol.* 2013;6:2800-12.
8. Cerner CancerMPact database. Accessed October 2023.
9. Keedy VL, et al. American Society of Clinical Oncology Provisional Clinical Opinion: Epidermal Growth Factor Receptor (EGFR) Mutation Testing for Patients with Advanced Non-Small-Cell Lung Cancer Considering First-Line EGFR Tyrosine Kinase Inhibitor Therapy. *J Clin Oncol.* 2011;29:2121-27.
10. Ellison G, et al. EGFR Mutation Testing in Lung Cancer: a Review of Available Methods and Their Use for Analysis of Tumour Tissue and Cytology Samples. *J Clin Pathol.* 2013;66:79-89.
11. Cross DA, et al. AZD9291, an Irreversible EGFR TKI, Overcomes T790M-Mediated Resistance to EGFR Inhibitors in Lung Cancer. *Cancer Discov.* 2014;4(9):1046-1061.

### **Adrian Kemp**

Company Secretary

**Company Secretary**  
**AstraZeneca PLC**

This information is provided by RNS, the news service of the London Stock Exchange. RNS is approved by the Financial Conduct Authority to act as a Primary Information Provider in the United Kingdom. Terms and conditions relating to the use and distribution of this information may apply. For further information, please contact [ms@seg.com](mailto:ms@seg.com) or visit [www.ms.com](http://www.ms.com).

RNS may use your IP address to confirm compliance with the terms and conditions, to analyse how you engage with the information contained in this communication, and to share such analysis on an anonymised basis with others as part of our commercial services. For further information about how RNS and the London Stock Exchange use the personal data you provide us, please see our [Privacy Policy](#).

END

MSCQKFBBOBKDPBD