

1 September 2026

Tagrisso plus Orpathys demonstrated statistically significant and highly clinically meaningful improvement in progression-free survival in 1st-line MET-overexpressing EGFR-mutated lung cancer

Results of SANOVO Phase III trial in China build on established success of global SAFFRON and China SACHI trials, extending clinical value of the all-oral combination into the 1st-line setting

Results reinforce Tagrisso as the backbone therapy across EGFRm lung cancer

Positive high-level results from the SANOVO Phase III trial showed *Tagrisso* (osimertinib) plus *Orpathys* (savolitinib) demonstrated a statistically significant and highly clinically meaningful improvement in progression-free survival (PFS) versus *Tagrisso* alone in treatment-naïve patients with epidermal growth factor receptor-mutated (EGFRm) locally advanced or metastatic non-small cell lung cancer (NSCLC) and MET overexpression. The PFS benefit was demonstrated in both the high MET (IHC 3+) and the intention-to-treat (ITT) trial populations (IHC 2+, IHC 3+).

In both patient populations, the combination also demonstrated very encouraging clinical benefit in overall survival (OS), a secondary endpoint of the trial. The trial will continue to follow up on these results.

Professor Yi-Long Wu of the Guangdong Provincial People's Hospital, and the leading principal investigator of the trial, said: "Co-occurring MET overexpression in treatment-naïve EGFR-mutated non-small cell lung cancer often compromises the long-term durability of EGFR-TKI monotherapy. The positive findings from SANOVO demonstrate that addressing both pathways upfront with an all-oral, biomarker-directed regimen offers a powerful new approach for these patients whose tumours have MET overexpression. By combining *Orpathys* with *Tagrisso*, we have observed a clear clinical benefit that could reshape primary treatment strategy for this distinct patient population."

Leora Horn, Senior Vice President, Late Development, Oncology R&D, AstraZeneca, said: "These positive data from the SANOVO trial build on the growing body of evidence demonstrating the benefit of adding *Orpathys* to backbone *Tagrisso* to intercept MET-driven resistance, delay progression and improve outcomes for these patients. By developing novel, biomarker-directed combinations that improve upon established standards of care, AstraZeneca continues to raise the bar for patients with EGFR-mutated lung cancer."

Weiguo Su, Chief Executive Officer and Chief Scientific Officer of HUTCHMED, said: "We are thrilled by the positive results from SANOVO, which validate our strategy of addressing MET-driven disease across multiple stages of lung cancer. Building on the strong foundations of our Phase III SAFFRON global study and SACHI study in China in pre-treated patients, SANOVO data further validate the therapeutic strength and versatility of the *Orpathys* and *Tagrisso* combination in first-line patients. We are deeply grateful to all patients and investigators who participated in the trial, and we look forward to sharing the data with regulatory authorities to bring this innovative all-oral combination to the first-line setting in China."

The safety profile for *Tagrisso* plus *Orpathys* was consistent with the known profiles of each medicine, and there were no new safety findings. These data will be presented at a forthcoming medical meeting and shared with regulatory authorities.

Tagrisso plus *Orpathys* is approved in China for patients with locally advanced or metastatic EGFRm NSCLC with MET amplification after disease progression on EGFR-TKI therapy based on the SACHI Phase III trial. The combination also recently reported positive high-level results in the [SAFFRON global Phase III trial](#) in EGFRm NSCLC with MET overexpression or amplification after disease progression on *Tagrisso*, demonstrating a statistically significant and clinically meaningful improvement in both PFS and OS.

Orpathys is being jointly developed by AstraZeneca and HUTCHMED and commercialised by AstraZeneca.

Notes

NSCLC and MET aberrations

Lung cancer is the leading cause of cancer death globally, accounting for almost one in four (23%) cancer deaths.¹ Lung cancer is broadly split into NSCLC and small cell lung cancer, with 80-85% of patients diagnosed with NSCLC.² Approximately 75% of NSCLC patients are diagnosed with advanced disease.³ Additionally, about 10-15% of NSCLC patients in the US and Europe, and 30-40% of patients in Asia, have EGFRm NSCLC.⁴⁻⁶

MET is a tyrosine kinase receptor that has an essential role in normal cell development.⁷ MET overexpression or amplification can lead to tumour growth and the metastatic progression of cancer cells.⁷⁻⁸

SANOVO

SANOVO is a blinded, randomized, controlled Phase III trial in previously untreated patients with locally advanced or metastatic NSCLC with activating EGFR mutations and MET overexpression in China conducted by HUTCHMED. The study evaluates the efficacy and safety of *Orpathys* in combination with *Tagrisso* comparing to *Tagrisso* alone, a standard-of-care treatment option for these patients. A total of 326 treatment-naïve patients with locally advanced or metastatic NSCLC harbouring EGFR mutations (exon 19 deletion or L858R) and MET overexpression were randomized in a 1:1 ratio to receive *Tagrisso* 80mg once daily plus either *Orpathys* or placebo at 300/200mg twice daily (dosed based on body weight).

The primary endpoint of the trial is PFS as assessed by investigators. Other endpoints include PFS assessed by an independent review committee, OS, objective response rate (ORR), duration of response (DoR), disease control rate (DCR), time to response (TTR), and safety.

Orpathys

Orpathys (savolitinib) is an oral, potent and highly selective MET-TKI that has demonstrated clinical activity in advanced solid tumours. It blocks atypical activation of the MET receptor tyrosine kinase pathway that occurs because of mutations (such as exon 14 skipping alterations or other point mutations), gene amplification or protein overexpression.

Orpathys is approved in China for the treatment of adult patients with locally advanced or metastatic NSCLC with MET exon 14 skipping alteration, representing the first selective MET inhibitor approved in China. *Orpathys* also received a conditional approval in China for the treatment of patients with locally advanced or metastatic gastric cancer or gastroesophageal junction adenocarcinoma with MET amplification who have failed at least two prior systemic treatments.

Orpathys in combination with *Tagrisso* is approved in China for patients with locally advanced or metastatic EGFRm-positive non-squamous NSCLC with MET amplification after disease progression on EGFR-TKI therapy based on the SACHI Phase III trial. The combination was also granted a temporary authorisation in Switzerland for the treatment of patients with locally advanced or metastatic EGFRm NSCLC and high levels of MET overexpression or amplification who progressed on prior treatment with *Tagrisso*. This was based on results from the global SAVANNAH Phase II trial.

Tagrisso

Tagrisso (osimertinib) is a third-generation, irreversible EGFR-TKI with proven clinical activity in NSCLC, including the treatment of central nervous system metastases. *Tagrisso* (40mg and 80mg QD oral tablets) has been used to treat more than one million 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 120 countries including the US, EU, China and Japan. Approved indications include for 1st-line treatment of patients with locally advanced or metastatic EGFRm NSCLC, locally advanced or metastatic EGFR T790M mutation-positive NSCLC, adjuvant treatment of early-stage EGFRm NSCLC and locally advanced, unresectable NSCLC following platinum-based chemoradiation therapy. *Tagrisso* is also approved in combination with chemotherapy in more than 80 countries, including the US, EU, China and Japan, for 1st-line treatment of patients with locally advanced or metastatic EGFRm NSCLC.

There is an extensive body of evidence supporting the use of *Tagrisso* in EGFRm NSCLC, and it is the only targeted therapy shown to improve patient outcomes across all stages of the disease.

In late-stage disease, *Tagrisso* demonstrated improved outcomes as monotherapy in the [FLAURA](#) Phase III trial and in combination with chemotherapy in the [FLAURA2](#) Phase III trial. *Tagrisso* is also being investigated in this setting in combination with *Datroway* (datopotamab deruxtecan or Dato-DXd) in the [TROPION-Lung14](#) and [TROPION-Lung15](#) Phase III trials.

Tagrisso also showed improved outcomes in early-stage disease in the NeoADAURA and [ADAURA](#) Phase III trials and in locally advanced stages in the [LAURA](#) 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 early-stage adjuvant resectable setting in the ADAURA2 Phase III trial.

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); *Zegfrovy* (sunvozertinib); *Imfinzi* (durvalumab) and *Imjudo* (tremelimumab); *Enhertu* (trastuzumab deruxtecan) and *Datroway* in collaboration with Daiichi Sankyo; *Orpathys* 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/NYSE: AZN) is a global, science-led biopharmaceutical company that focuses on the discovery, development, and commercialisation of prescription medicines in Oncology, Rare Disease, 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](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 Organization. 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 August 2026.
2. American Cancer Society. What Is Lung Cancer? Available at: <https://www.cancer.org/cancer/types/lung-cancer/about/what-is.html>. Accessed August 2026.
3. Chen HJ, *et al.* Long-term survival of advanced lung adenocarcinoma by maintenance chemotherapy followed by EGFR-TKI. *Medicine*. 2021;100(6):e24688.
4. Szumera-Ciećkiewicz A, *et al.* EGFR Mutation Testing on Cytological and Histological Samples in Non-Small Cell Lung Cancer: a Polish, Single Institution Study and Systematic Review of European Incidence. *Int J Clin Exp Pathol*. 2013;6:2800-2812.
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;29:2121-2127.
6. 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.
7. Uchikawa E, *et al.* Structural basis of the activation of c-MET receptor. *Nat Commun*. 2021;12(4074)
8. Wang Q, *et al.* MET inhibitors for targeted therapy of EGFR TKI-resistant lung cancer. *J Hematol Oncol*. 2019;63.

Matthew Bowden
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 rns@lse.com or visit www.rns.com.