



HUTCHMED (China) Limited

和黃醫藥（中國）有限公司

(Incorporated in the Cayman Islands with limited liability)

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INSIDE INFORMATION

HUTCHMED Announces ORPATHYS® Plus TAGRISSO® Demonstrated Statistically Significant and Clinically Meaningful Improvements in Progression-Free and Overall Survival in MET-Driven EGFR-Mutated Lung Cancer After Progression on TAGRISSO®

— First global Phase III trial to show significant progression-free and overall survival benefits in this setting —

— SAFFRON trial results reinforce TAGRISSO® as the backbone therapy across EGFRm lung cancer —

This announcement is made by HUTCHMED (China) Limited ([“HUTCHMED”](#)) pursuant to Rule 13.09(2)(a) of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited and the Inside Information Provisions under Part XIVa of the Securities and Futures Ordinance (Cap. 571).

HUTCHMED today announces that positive high-level results from the SAFFRON Phase III trial showed ORPATHYS® (savolitinib) plus TAGRISSO® (osimertinib) demonstrated a statistically significant and clinically meaningful improvement in both progression-free survival (“PFS”) and overall survival (“OS”) versus doublet platinum-based chemotherapy in patients with epidermal growth factor receptor-mutated (“EGFRm”) non-small cell lung cancer (“NSCLC”). Patients in the trial had tumors with high levels of MET overexpression or amplification and had progressed on prior treatment with TAGRISSO®.

Third-generation EGFR-tyrosine kinase inhibitors (“TKIs”) have significantly improved outcomes for patients with EGFRm NSCLC.¹ However, one in three patients’ tumors will develop MET overexpression or amplification, one of the most common mechanisms of resistance on third-generation EGFR-TKIs.^{1,2} MET-driven resistance is associated with poor prognosis, and there is a significant unmet need for effective and well-tolerated treatment options in later-line settings.²

Professor Shun Lu, Director of Shanghai Lung Cancer Center, Shanghai Chest Hospital, Shanghai Jiao Tong University, School of Medicine and principal investigator of the trial, said: “These exciting results from SAFFRON represent a critical advance for patients with EGFR-mutated non-small cell lung cancer experiencing MET-driven resistance after osimertinib, a population with poor outcomes and no biomarker-directed treatment options available that are oral and well-tolerated. MET is one of the most common drivers of progression on targeted therapy in this setting, and these data underscore the potential impact of this novel osimertinib plus savolitinib combination and the urgency of MET testing to inform treatment decisions.”

Dr Weiguo Su, Chief Executive Officer* and Chief Scientific Officer of HUTCHMED, said: “Overcoming MET-driven resistance after EGFR TKI therapy has been a long-standing challenge in clinical practice. The SAFFRON global study further reinforces the robust efficacy previously demonstrated in the SACHI Phase III trial that supported approval in China, with the results providing clear evidence to support global registrations of the TAGRISSO® and ORPATHYS® combination. We are grateful to everyone who supported this trial. Together with AstraZeneca, we look forward to potentially bringing this landmark treatment to patients around the world.”

* currently on leave of absence.

Dr Susan Galbraith, Executive Vice President, Oncology Hematology R&D, AstraZeneca, said: “These data demonstrate the clear benefit of adding ORPATHYS® to backbone therapy TAGRISSO® to address MET overexpression or amplification while maintaining EGFR suppression. By combining ORPATHYS® and TAGRISSO®, with its established efficacy, safety profile and central nervous system protection, we aim to deliver the first biomarker-directed, all-oral option in this setting to patients across the globe. This further strengthens our leadership in EGFR-mutated lung cancer, reinforcing our strategy to improve patient outcomes across stages and through lines of therapy with novel combinations.”

The safety profile for ORPATHYS® plus TAGRISSO® 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 global regulatory authorities.

ORPATHYS® plus TAGRISSO® 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.

ORPATHYS® is being jointly developed by AstraZeneca and HUTCHMED and commercialized by AstraZeneca.

About NSCLC and MET aberrations

Lung cancer is the leading cause of cancer death globally, accounting for almost one in four (23%) cancer deaths.³ Lung cancer is broadly split into NSCLC and small cell lung cancer, with 80-85% of patients diagnosed with NSCLC.⁴ Approximately 75% of NSCLC patients are diagnosed with advanced disease.⁵ Additionally, about 10-15% of NSCLC patients in the US and Europe, and 30-40% of patients in Asia, have EGFRm NSCLC.^{6,7,8}

MET is a tyrosine kinase receptor that has an essential role in normal cell development.⁹ MET overexpression or amplification can lead to tumor growth and the metastatic progression of cancer cells.^{9,10} An estimated 34% of tumors will develop high levels of MET overexpression or amplification after progression on a third-generation EGFR TKI.¹

About SAFFRON

SAFFRON is a randomized, open-label, multi-center, global Phase III trial studying the efficacy of ORPATHYS® (300mg twice daily) added to TAGRISSO® (80mg once daily) versus doublet platinum-based chemotherapy in 338 patients with EGFRm, locally advanced or metastatic NSCLC with MET overexpression or amplification whose disease progressed following first- or second-line treatment with TAGRISSO®. The trial enrolled patients in 230 centers across 29 countries, including in North America, Europe, South America and Asia. The primary endpoint is PFS and key secondary endpoints include OS and objective response rate (ORR).

Patients were prospectively selected for SAFFRON using the high MET level cut-offs identified in the SAVANNAH Phase II trial. In SAVANNAH, MET overexpression or amplification levels were determined by two tests: immunohistochemistry (IHC), which detects if cancer cells have a particular protein or marker on their surface, and fluorescence in situ hybridization (FISH), which detects a specific DNA sequence from cancer cells.

About ORPATHYS®

ORPATHYS® (savolitinib) is an oral, potent and highly selective MET TKI that has demonstrated clinical activity in advanced solid tumors. 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 ([GC/GEJ](#)) adenocarcinoma patients 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 [EGFR mutation-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 authorization 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.

About 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 first-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 first-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.

About HUTCHMED

HUTCHMED (Nasdaq/AIM:HCM; HKEX:13) is an innovative, commercial-stage, biopharmaceutical company. It is committed to the discovery and global development and commercialization of targeted therapies and immunotherapies for the treatment of cancer and immunological diseases. Since inception it has focused on bringing drug candidates from in-house discovery to patients around the world, with its first three medicines marketed in China, the first of which is also approved around the world including in the US, Europe and Japan. For more information, please visit: www.hutch-med.com or follow us on [LinkedIn](#).

Forward-Looking Statements

This announcement contains forward-looking statements within the meaning of the "safe harbor" provisions of the US Private Securities Litigation Reform Act of 1995. These forward-looking statements reflect HUTCHMED's current expectations regarding future events, including its expectations regarding the therapeutic potential of ORPATHYS®, the further clinical development for ORPATHYS®, its expectations as to whether any studies on ORPATHYS® would meet their primary or secondary endpoints, and its expectations as to the timing of the completion and the release of results from such studies. Forward-looking statements involve risks and uncertainties. Such risks and uncertainties include, among other things, assumptions regarding enrollment rates and the timing and availability of subjects meeting a study's inclusion and exclusion criteria; changes to clinical protocols or regulatory requirements; unexpected adverse events or safety issues; the ability of ORPATHYS®, including as a combination therapy, to meet the primary or secondary endpoint of a study, to obtain

regulatory approval in different jurisdictions and to gain commercial acceptance after obtaining regulatory approval; the potential market of ORPATHYS® for a targeted indication; the sufficiency of funding; HUTCHMED's and AstraZeneca's ability to successfully develop and commercialize ORPATHYS®. In addition, as certain studies rely on the use of other drug products such as TAGRISSO® as combination therapeutics with ORPATHYS®, such risks and uncertainties include assumptions regarding the safety, efficacy, supply and continued regulatory approval of these therapeutics. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. For further discussion of these and other risks, see HUTCHMED's filings with the US Securities and Exchange Commission, The Stock Exchange of Hong Kong Limited and on AIM. HUTCHMED undertakes no obligation to update or revise the information contained in this announcement, whether as a result of new information, future events or circumstances or otherwise.

Inside Information

This announcement contains inside information for the purposes of Article 7 of Regulation (EU) No 596/2014 (as it forms part of retained EU law as defined in the European Union (Withdrawal) Act 2018).

Medical Information

This announcement contains information about products that may not be available in all countries, or may be available under different trademarks, for different indications, in different dosages, or in different strengths. Nothing contained herein should be considered a solicitation, promotion or advertisement for any prescription drugs including the ones under development.

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- ¹ De Marinis F, et al. Savolitinib plus osimertinib in epidermal growth factor receptor (EGFR)-mutated advanced non-small cell lung cancer with MET overexpression and/or amplification following disease progression on osimertinib: primary results from the phase II SAVANNAH study. *Ann Oncol*. 2025;36(8):920-933.
 - ² Bar J, et al. Prevalence, molecular characterization, and prognosis of c-Met protein overexpression in a real-world cohort of patients with non-squamous non-small cell lung cancer. *Acta Oncol*. 2025;64:1544-1553.
 - ³ 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.
 - ⁴ American Cancer Society. What Is Lung Cancer? Available at: <https://www.cancer.org/cancer/types/lung-cancer/about/what-is.html>. Accessed August 2026.
 - ⁵ Chen HJ, et al. Long-term survival of advanced lung adenocarcinoma by maintenance chemotherapy followed by EGFR-TKI. *Medicine*. 2021;100(6):e24688.
 - ⁶ 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.
 - ⁷ 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.
 - ⁸ 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.
 - ⁹ Uchikawa E, et al. Structural basis of the activation of c-MET receptor. *Nat Commun*. 2021;12(4074)
 - ¹⁰ Wang Q, et al. MET inhibitors for targeted therapy of EGFR TKI-resistant lung cancer. *J Hematol Oncol*. 2019;63.

By Order of the Board

Edith Shih

Non-executive Director and Company Secretary

Hong Kong, August 17, 2026

As at the date of this announcement, the Directors of the Company are:

Chairman and Non-executive Director:

Dr Dan ELDAR

Executive Directors:

Dr Weiguo SU

*(Chief Executive Officer and
Chief Scientific Officer)*

Mr CHENG Chig Fung, Johnny

*(Acting Chief Executive Officer and
Chief Financial Officer)*

Non-executive Directors:

Ms Edith SHIH

Ms Ling YANG

Independent Non-executive Directors:

Dr Renu BHATIA

(Senior and Lead Independent Non-executive Director)

Dr Chaohong HU

Professor TAN Shao Weng, Daniel

Mr WONG Tak Wai