



HUTCHMED (China) Limited

和黃醫藥（中國）有限公司

(Incorporated in the Cayman Islands with limited liability)

(Stock Code: 13)

VOLUNTARY ANNOUNCEMENT

HUTCHMED Highlights SAFFRON Global Phase III Data Presented at ESMO Congress 2026 and Simultaneously Published in The New England Journal of Medicine

— ORPATHYS® plus TAGRISSO® reduced the risk of disease progression or death by 45% and the risk of death by 32% in MET-driven EGFR-mutated lung cancer after progression on TAGRISSO® —

— ORPATHYS® plus TAGRISSO® extended median OS by nearly 5 months —

— SAFFRON is the first global Phase III trial to show significant progression-free and overall survival benefit in this setting —

— Establishes ORPATHYS® plus TAGRISSO® as an important targeted strategy to address MET-driven resistance following progression on prior EGFR TKI treatment —

HUTCHMED (China) Limited ([“HUTCHMED”](#)) today announces positive results from the SAFFRON global Phase III trial. 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®.

These results have been presented during the Presidential Symposium at the European Society for Medical Oncology (“ESMO”) Congress in Madrid, Spain (abstract #LBA6).¹ They were also simultaneously published in The New England Journal of Medicine 2026. Featuring prominently on oncology’s premier stage and in a flagship journal underscores the pivotal nature of the SAFFRON trial in redefining the treatment paradigms for MET-driven EGFRm NSCLC. The data validate ORPATHYS® combined with TAGRISSO® as a landmark, all-oral strategy to address the major unmet need of MET-driven resistance after third-generation epidermal growth factor receptor (“EGFR”) tyrosine kinase inhibitor (“TKI”) therapy.

Results showed ORPATHYS® plus TAGRISSO® reduced the risk of disease progression or death by 45% compared to chemotherapy (based on a PFS hazard ratio [“HR”] of 0.55; 95% confidence interval [“CI”] 0.42-0.72; $p < 0.001$). Median PFS as assessed by blinded independent central review (“BICR”) was 7.6 months for ORPATHYS® plus TAGRISSO® versus 5.4 months for the comparator arm. An estimated 36% of patients treated with the combination were progression-free at one year compared to 10% in the comparator arm. Importantly, the PFS benefit observed was consistent across all prespecified subgroups, including patients whose tumor had MET-overexpression or MET-amplification.

Results for the key secondary endpoint of OS showed ORPATHYS® plus TAGRISSO® reduced the risk of death by 32% versus chemotherapy (OS HR 0.68; 95% CI 0.50-0.91; $p = 0.010$). ORPATHYS® plus TAGRISSO® extended median OS by 4.9 months versus the comparator arm (17.8 versus 12.9 months). An estimated 70% of patients treated with the combination were alive at one year compared to 53% in the comparator arm.

Professor Shun Lu, Director of Shanghai Lung Cancer Center, Shanghai Chest Hospital, Shanghai Jiao Tong University, School of Medicine and global leading principal investigator of the trial, said: “These results have the potential to establish a new global standard of care for the third of patients with EGFR-mutated non-small cell lung cancer experiencing MET-driven resistance after osimertinib. There are currently no well-tolerated, oral, biomarker-directed treatment options to

address this frequent driver of disease progression. Savolitinib plus osimertinib significantly extended median overall survival by nearly five months in this later-line setting, establishing a new clinical benchmark and reinforcing the critical need for MET testing to guide patient care.”

Mr Johnny Cheng, Acting Chief Executive Officer and Chief Financial Officer of HUTCHMED, said: “These data from SAFFRON mark a decisive step forward in targeting MET-driven resistance — a longstanding challenge in EGFR-mutated lung cancer. Precision inhibition with ORPATHYS® alongside TAGRISSO® offers a meaningful, all-oral option for patients with disease progression. We are delighted to see that our partnership with AstraZeneca continues to deliver impactful innovations that have the potential to redefine standard of care and improve outcomes for patients globally.”

Dr Susan Galbraith, Executive Vice President, Oncology Haematology R&D, AstraZeneca, said: “These data show combining ORPATHYS® with backbone therapy TAGRISSO® directly addresses MET-driven resistance while maintaining EGFR suppression, building on the established efficacy, safety and central nervous system protection of TAGRISSO®. With the potential to become the first biomarker-directed, all-oral treatment option in this setting, this combination further strengthens our leadership in EGFR-mutated lung cancer and reflects our strategy of matching the right therapy to the underlying drivers of disease at every stage.”

Summary of PFS and OS results: SAFFRON ⁱ

	ORPATHYS® + TAGRISSO® (n=171)	Chemotherapy (n=167)
PFS by BICR: Full Analysis Set (FAS)		
Number of patients with event, n (%)	117 (68.4)	113 (67.7)
Median PFS (95% CI) (in months)	7.6 (5.6-9.7)	5.4 (4.2-5.8)
HR (95% CI)	0.55 (0.42-0.72)	
p-value	p<0.001	
PFS rate at 12 months (%)	36	10
OS: FAS		
Number of deaths, n (%)	87 (50.9)	93 (55.7)
Median OS (95% CI) (in months)	17.8 (15.6-23.7)	12.9 (10.6-16.8)
HR (95% CI)	0.68 (0.50-0.91)	
p-value	p=0.010	
OS rate at 12 months (%)	70	53
PFS by BICR: MET-overexpressed analysis set		
Number of patients, n	127	118
Number of patients with event, n (%)	77 (60.6)	80 (67.8)
Median PFS (95% CI) (in months)	8.5 (5.7-11.1)	5.6 (4.4-6.7)
HR (95% CI)	0.51 (0.37-0.71)	
p-value	p<0.001	
PFS rate at 12 months (%)	40	11
PFS by BICR: MET-amplified analysis set ⁱⁱ		
Number of patients, n	129	116
Number of patients with event, n (%)	89 (68.9)	79 (68.1)
Median PFS (95% CI) (in months)	7.64 (5.6-9.7)	4.2 (3.1-5.5)
HR (95% CI)	0.487 (0.35-0.66)	
PFS rate at 12 months (%)	33	8
ⁱ OS and PFS data cut-off was 6 July 2026.		
ⁱⁱ No formal statistical testing was carried out for the MET-amplified analysis set		

The safety profile for ORPATHYS® plus TAGRISSO® was manageable and consistent with the known profiles of each medicine, and there were no new safety concerns. Grade 3 or higher treatment-emergent adverse events from all causes occurred in 64% of patients treated with ORPATHYS® plus TAGRISSO® and 63% of patients in the comparator arm. Median total duration of treatment exposure was more than twice as long for ORPATHYS® plus TAGRISSO® (8.5 months) compared with the comparator arm (3.5 months).

Based on the SAFFRON Phase III trial results, a New Drug Application (“NDA”) for ORPATHYS® plus TAGRISSO® were [submitted to the US Food and Drug Administration](#) for the treatment of patients with locally advanced or metastatic NSCLC whose tumors have high levels of MET overexpression or amplification and who had disease progression on or after an EGFR-TKI therapy. An NDA submission in Europe and Japan is also progressing as planned. ORPATHYS® plus 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.

Results from the SANOVO Phase III trial evaluating ORPATHYS® plus TAGRISSO® in treatment-naïve patients in China with EGFRm locally advanced or metastatic NSCLC and MET overexpression will be presented during a Proffered Paper session at the ESMO Congress (abstract #LBA69).²

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.^{3,4} Lung cancer is broadly split into NSCLC and small cell lung cancer, with 80-85% of patients diagnosed with NSCLC.⁵ Approximately 75% of NSCLC patients are diagnosed with advanced disease.⁶ Additionally, about 10-15% of NSCLC patients in the US and Europe, and 30-40% of patients in Asia, have EGFRm NSCLC.⁷

MET is a tyrosine kinase receptor that has an essential role in normal cell development.⁸ MET overexpression or amplification can lead to tumor growth and the metastatic progression of cancer cells.^{8,9} Approximately one in three patients’ tumors will develop high levels of MET overexpression or amplification (IHC3+>90% and FISH10+) after progression on a third-generation EGFR-TKI.¹⁰

About SAFFRON

SAFFRON is a randomized, open-label, multi-center, global Phase III trial studying the efficacy of ORPATHYS® (300 mg twice daily) added to TAGRISSO® (80 mg 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 in North America, Europe, South America and Asia. The primary endpoint is PFS and key secondary endpoint includes OS.

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 adult 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. The global, randomized, [SAFFRON](#) Phase III trial in the same treatment setting comparing the combination with doublet platinum-based chemotherapy reported positive high-level results, demonstrating a statistically significant and clinically meaningful improvement in PFS and OS in August 2026.

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® 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.

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 four 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.

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.

- ¹ Lu S, *et al.* Osimertinib [osi] + savolitinib [savo] vs platinum–pemetrexed [plat–pem] in EGFRm MET-overexpressed [OE] and/or -amplified [AMP] advanced NSCLC post-osi: SAFFRON Phase [Ph] 3 primary results. Presented in a Proffered Paper session during Presidential Symposium II the European Society for Medical Oncology Congress 2026, 25 October at 16:45 CET.
- ² Wu YL, *et al.* Savolitinib or Placebo Combined with Osimertinib in Treatment-Naïve Advanced NSCLC with EGFR Mutation and MET Overexpression: Results from the Phase 3 SANVO Study. Presented at the European Society for Medical Oncology Congress 2026, 26 October at 08:30 CET.
- 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 October 2026.
- ⁴ World Health Organization. International Agency for Research on Cancer. All Cancers Fact Sheet. Available at: <https://gco.iarc.who.int/media/globocan/factsheets/cancers/39-all-cancers-fact-sheet.pdf>. Accessed October 2026.
- ⁵ American Cancer Society. What Is Lung Cancer? Available at: <https://www.cancer.org/cancer/types/lung-cancer/about/what-is.html>. Accessed August 2026.
- ⁶ Chen HJ, *et al.* Long-term survival of advanced lung adenocarcinoma by maintenance chemotherapy followed by EGFR-TKI. *Medicine*. 2021;100(6):e24688.
- ⁷ Gao X, *et al.* The safety and efficacy of osimertinib for the treatment of EGFR T790M mutation positive non-small-cell lung cancer. *Expert Rev Anticancer Ther*. 2016;16(4):383-390.
- ⁸ Uchikawa E, *et al.* Structural basis of the activation of c-MET receptor. *Nat Commun*. 2021;12(4074)
- ⁹ Wang Q, *et al.* MET inhibitors for targeted therapy of EGFR TKI-resistant lung cancer. *J Hematol Oncol*. 2019;63.
- ¹⁰ 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.

By Order of the Board

Edith Shih

Non-executive Director and Company Secretary

Hong Kong, October 26, 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