



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 SANOVO Phase III Data for ORPATHYS® plus TAGRISSO® in First-Line EGFR-Mutated Lung Cancer Presented at ESMO Congress 2026

- *ORPATHYS® plus TAGRISSO® reduced the risk of disease progression or death by 44% in the overall population and 55% in the high MET overexpression population in the first-line setting —*
- *Robust PFS gains alongside very encouraging OS clinical benefit in this treatment-naïve biomarker-selected patient population —*
- *Offers a potential new standard of care through an all-oral, biomarker-driven frontline strategy for MET-overexpressing, EGFR-mutated lung cancer patients —*

HUTCHMED (China) Limited ("[HUTCHMED](#)") today announces positive results from the SANOVO Phase III trial in China. ORPATHYS® (savolitinib) plus TAGRISSO® (osimertinib) demonstrated a statistically significant and highly clinically meaningful improvement in the primary endpoint 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 combination also demonstrated very encouraging clinical benefit in overall survival ("OS"), a secondary endpoint of the trial.

These results have been presented in a Proffered Paper session at the 2026 European Society for Medical Oncology ("ESMO") Congress in Madrid, Spain (abstract #LBA69). ¹

PFS benefits were demonstrated in both the high MET (IHC 3+) and the intention-to-treat ("ITT") trial populations (IHC 2+, IHC 3+). ORPATHYS® plus TAGRISSO® reduced the risk of disease progression or death by 44% compared to TAGRISSO® alone in the ITT population (based on a PFS hazard ratio ["HR"] of 0.56; 95% confidence interval ["CI"] 0.43-0.74; $p < 0.0001$). The combination demonstrated a median PFS of more than two years (24.9 months) compared to approximately a year (13.8 months) for TAGRISSO® alone.

In the high MET population, ORPATHYS® plus TAGRISSO® reduced the risk of disease progression or death by 55% compared to TAGRISSO® alone (PFS HR of 0.45; 95% CI 0.31-0.66; $p < 0.0001$). ORPATHYS® plus TAGRISSO® extended median PFS by 13.7 months versus the comparator arm (24.8 versus 11.1 months).

For the secondary endpoint of OS in the ITT population, ORPATHYS® plus TAGRISSO® showed a clinically meaningful improvement in OS (OS HR of 0.48; 95% CI 0.33-0.68) versus TAGRISSO® alone. ORPATHYS® plus TAGRISSO® extended median OS by 9.6 months versus the comparator arm (44.5 versus 34.9 months). An estimated 67.4% of patients treated with the combination were alive at three years compared to 47.4% in the comparator arm. With longer follow-up, the OS curves showed continued separation, signaling a greater magnitude of benefit over time for the ORPATHYS® plus TAGRISSO® combination. Importantly, the PFS and OS benefit observed was consistent across all prespecified ITT subgroups.

Professor Yi-Long Wu of the Guangdong Provincial People's Hospital, and the leading principal investigator of the trial, said: "The SANOVO results mark a pivotal evolution in how we approach first-line EGFR-mutated lung cancer. Historically, co-occurring MET alterations have been associated with poor outcomes on EGFR-TKI treatment, increasing the motivation to test for MET alterations at diagnosis and upon progression. These potentially practice-changing results showed that adding savolitinib to osimertinib extended median PFS by more than a year in the high MET population, and 11 months overall, in first-line MET-overexpressing EGFR-mutated lung cancer. Coupled with highly encouraging clinical benefit in OS, these data reinforce the transformative potential of this all-oral, biomarker-directed treatment approach for a patient population where co-occurring MET overexpression may limit the long-term benefits of EGFR-TKI monotherapy."

Mr Johnny Cheng, Acting Chief Executive Officer and Chief Financial Officer of HUTCHMED, said: "SANOVO, alongside the SAFFRON and SACHI studies, establishes a comprehensive treatment continuum for the ORPATHYS® plus TAGRISSO® combination — spanning frontline intervention to post-EGFR-TKI resistance. SANOVO demonstrates that by identifying MET overexpression at diagnosis and initiating an all-oral, dual-targeted combination upfront, we can meaningfully extend PFS and OS while preserving patient quality of life. SANOVO reinforces our strategy to improve long-term clinical outcomes for patients by advancing precision oncology into earlier lines of therapy."

Dr Jing He, Senior Vice President and Head of R&D China of AstraZeneca, said: "The SANOVO results build on the proven efficacy seen in SAFFRON and SACHI, bringing the benefit of ORPATHYS® plus backbone TAGRISSO® to first-line patients with EGFR-mutated lung cancer with co-occurring MET overexpression. By targeting both EGFR and MET pathways, this all-oral, biomarker-directed combination improved both progression-free and overall survival in this setting. These results allow us to further advance our strategy to redefine standards of care for patients with EGFR-mutated lung cancer by delivering novel, targeted combinations."

Summary of PFS and OS results: SANOVO ⁱ

	ORPATHYS® + TAGRISSO® (n=162)	Placebo + TAGRISSO® (n=164)
PFS (ITT) ⁱⁱ		
Number of patients with event, n (%)	101 (62.3)	124 (75.6)
Median PFS (95% CI) (in months)	24.9 (22.1-27.6)	13.8 (10.9-16.6)
HR (95% CI)	0.56 (0.43-0.74)	
p-value	p<0.0001	
PFS (IHC3+>90%)		
Number of patients, n	98	98
Median PFS (95% CI) (in months)	24.8 (19.4-27.6)	11.1 (8.3-16.6)
HR (95% CI)	0.45 (0.31-0.66)	
p-value	p<0.0001	
OS (ITT) ⁱⁱ		
Number of deaths, n (%)	49 (30.2)	83 (50.6)
Median OS (95% CI) (in months)	44.5 (41.3-NE ⁱⁱⁱ)	34.9 (26.3-41.1)
HR (95% CI)	0.48 (0.33-0.68)	
ⁱ PFS data cut-off was 31 July 2026.		
ⁱⁱ ITT = intention-to-treat (IHC 2+, IHC 3+)		
ⁱⁱⁱ NE = not estimable		

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. Demonstrating strong long-term tolerability, treatment discontinuation due to adverse events occurred in only 14.8% of patients receiving ORPATHYS® plus TAGRISSO®. Most adverse events were manageable with dose adjustments, and fatal adverse event rates (excluding disease progression) were low and balanced across treatment arms (4.3% versus 4.8%).

By simultaneously targeting EGFR and co-occurring MET pathway alterations at initial diagnosis, this chemotherapy-free, all-oral regimen intercepts bypass activation mechanisms before primary or early resistance emerges, offering robust clinical efficacy and sustained disease control while maintaining patient quality of life.

An additional presentation featured during a Presidential Symposium at the ESMO Congress highlighted data from the SAFFRON Phase III trial of ORPATHYS® plus TAGRISSO® in MET-driven EGFRm NSCLC after progression on TAGRISSO® (abstract #LBA6).²

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-tyrosine kinase inhibitor (“TKI”) therapy based on the SACHI Phase III trial. Based on data from the SANOVO Phase III trial, HUTCHMED plans to submit a supplemental New Drug Application in China for this first-line setting.

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}

About 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® compared 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® 80 mg once daily plus either ORPATHYS® or placebo at 300/200 mg 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, duration of response, disease control rate, time to response and safety.

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 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 SANOVO Study. Presented at the European Society for Medical Oncology Congress 2026, 26 October at 08:30 CET.
- ² 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.
- 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.

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