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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 Announces Regulatory Filings Accepted for Review for ORPATHYS® plus TAGRISSO® in MET-Driven EGFR-Mutated Lung Cancer in Europe and Japan

— Follows US FDA new drug application submission in September 2026, marking important global regulatory progress —

— Filings supported by positive SAFFRON global Phase III data demonstrating statistically significant and clinically meaningful PFS and OS improvements —

— Data selected for ESMO 2026 Presidential Symposium and simultaneously published in The New England Journal of Medicine —

HUTCHMED (China) Limited ("HUTCHMED") today announces that regulatory filings for ORPATHYS® (savolitinib) in combination with TAGRISSO® (osimertinib) have been accepted for review in Europe and Japan.

In Europe, the European Medicines Agency (EMA) has validated and accepted for regulatory review the Marketing Authorization Application (MAA) submitted by AstraZeneca, seeking approval for the combination for the treatment of patients with locally advanced or metastatic non-small cell lung cancer ("NSCLC") whose tumors have MET overexpression or amplification, and who had disease progression on or after an epidermal growth factor receptor ("EGFR") tyrosine kinase inhibitor ("TKI") therapy.

In Japan, AstraZeneca has submitted a New Drug Application ("NDA") to the Ministry of Health, Labour and Welfare (MHLW), which has also been accepted for review, seeking approval in patients with unresectable, advanced or recurrent NSCLC whose tumors have MET overexpression or amplification, and who had disease progression following EGFR-TKI therapy.

These filings in Europe and Japan follow the submission of an NDA for the same combination to the US Food and Drug Administration (FDA) in September 2026, marking further progress in expanding global access to this innovative targeted combination therapy.

The regulatory filings are supported by positive results from the SAFFRON global Phase III trial. These results have been presented in a Presidential Symposium at the European Society for Medical Oncology (ESMO) Congress 2026 and simultaneously published in *The New England Journal of Medicine*.

ORPATHYS® plus TAGRISSO® 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 who progressed on treatment with TAGRISSO®. 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. 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). The safety profile was consistent with the known profiles of each medicine, and there were no new safety concerns.

Third-generation EGFR-TKIs have significantly improved outcomes for patients with EGFRm NSCLC. However, MET overexpression or amplification is one of the most common mechanisms of resistance on third-generation EGFR-TKI treatment. MET-driven progression is associated with poor prognosis, and there remains a significant unmet need for effective and well-tolerated treatment options in this setting.

ORPATHYS® is being jointly developed by AstraZeneca and HUTCHMED and is 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.[1,2] Lung cancer is broadly split into NSCLC and small cell lung cancer, with 80-85% of patients diagnosed with NSCLC.[3] Approximately 75% of NSCLC patients are diagnosed with advanced disease.[4] Additionally, about 10-15% of NSCLC patients in the US and Europe, and 30-40% of patients in Asia, have EGFRm NSCLC.[5]

MET is a tyrosine kinase receptor that has an essential role in normal cell development.[6] MET overexpression or amplification can lead to tumor growth and the metastatic progression of cancer cells.[6,7] 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.[8]

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.

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[5] 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.

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[8] 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, November 2, 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