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 Submission of US NDA for ORPATHYS® plus TAGRISSO® in MET-Driven EGFR-Mutated Lung Cancer

— Filing seeks approval for a biomarker-directed, all-oral treatment option for patients whose tumors have MET overexpression or amplification, after progression on an EGFR-TKI therapy —

— Application supported by SAFFRON, the first global Phase III trial to demonstrate statistically significant and clinically meaningful improvements in progression-free and overall survival in this setting —

— SAFFRON builds on evidence from the SACHI Phase III and SAVANNAH Phase II trials —

HUTCHMED (China) Limited ("HUTCHMED") today announces that AstraZeneca has submitted a New Drug Application ("NDA") to the US Food and Drug Administration ("FDA") for ORPATHYS® (savolitinib) plus TAGRISSO® (osimertinib) 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.

The NDA is supported by the global SAFFRON Phase III trial. SAFFRON showed 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®. The safety profile was consistent with the known profiles of each medicine, and there were no new safety concerns. These results will be presented in a Presidential Symposium at the upcoming European Society for Medical Oncology (ESMO) Congress 2026.

Third-generation EGFR tyrosine kinase inhibitors ("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.

Mr Johnny Cheng, Acting Chief Executive Officer and Chief Financial Officer of HUTCHMED, said: "This filing is an important step toward potentially bringing ORPATHYS® plus TAGRISSO® to patients in the US, after its approval in China based on the SACHI Phase III trial. The success of the global SAFFRON Phase III trial reflects the long-standing collaboration between HUTCHMED and AstraZeneca in addressing MET-driven progression in EGFR-mutated lung cancer. We remain committed to supporting the regulatory review and making this biomarker-directed, chemotherapy-free oral combination available to eligible patients."

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] 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.[4,5,6]

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

By Order of the Board

Edith Shih
Non-executive Director and Company Secretary

Hong Kong, September 29, 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