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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 NDA Acceptance in China for ORPATHYS® plus Osimertinib in First-Line EGFR-Mutated Lung Cancer with MET Overexpression

— Marks an important step forward in expanding this all-oral combination into first-line setting —

— Supported by Phase III SANOVO data showing a median PFS of 24.9 months, reducing the risk of disease progression or death by 44%, alongside an encouraging overall survival benefit —

HUTCHMED (China) Limited ("HUTCHMED") today announces that the New Drug Application ("NDA") for the combination of ORPATHYS® (savolitinib) and osimertinib has been accepted for review by the China National Medical Products Administration (NMPA) for the treatment of previously untreated, locally advanced or metastatic non-small cell lung cancer ("NSCLC") patients with epidermal growth factor receptor ("EGFR")-sensitizing mutations and MET overexpression.

The NDA is supported by data from SANOVO, a blinded, randomized, controlled Phase III trial in previously untreated patients with locally advanced or metastatic EGFR-mutated NSCLC and MET overexpression in China. Results were presented at the European Society for Medical Oncology (ESMO) Congress 2026 (abstract #LBA69). [1] In the intention-to-treat population, ORPATHYS® plus osimertinib demonstrated a median progression-free survival ("PFS") of 24.9 months compared to 13.8 months for osimertinib alone (hazard ratio ["HR"] 0.56; 95% confidence interval ["CI"] 0.43-0.74; p<0.0001). The combination also showed a clinically meaningful OS benefit (HR 0.48; 95% CI 0.33-0.68), extending median overall survival ("OS") by 9.6 months (44.5 versus 34.9 months). The safety profile was consistent with the known profiles of each medicine, and there were no new safety concerns.

Mr Johnny Cheng, Acting Chief Executive Officer and Chief Financial Officer of HUTCHMED, said: "This NDA acceptance marks an important step towards bringing the benefits of simultaneous EGFR and MET inhibition to patients early in their treatment journey. SANOVO has highlighted the pivotal role of addressing co-occurring MET alterations in first-line care, showing that targeting both pathways upfront can deliver meaningful improvements across both progression-free survival and overall survival. Together with AstraZeneca, we look forward to bringing this potential new all-oral, dual-targeting combination to patients in China as soon as possible."

In China, ORPATHYS® plus osimertinib is approved for patients with locally advanced or metastatic EGFR mutation-positive non-squamous NSCLC with MET amplification following disease progression on EGFR- tyrosine kinase inhibitor ("TKI") therapy, based on the SACHI Phase III trial. This NDA, supported by the SANOVO trial, seeks to expand the combination into the first-line setting for EGFR-mutated patients with MET overexpression.

In addition, regulatory processes for the combination are underway in the US, Europe and Japan for patients following prior EGFR-TKI therapy, supported by positive results from the global Phase III SAFFRON trial, which were presented in a Presidential Symposium at the ESMO Congress 2026 and simultaneously published in *The New England Journal of Medicine*.

ORPATHYS® is an oral, potent and highly selective MET-TKI, being jointly developed by AstraZeneca and HUTCHMED and commercialized by AstraZeneca. TAGRISSO® (osimertinib) is a third-generation irreversible EGFR-TKI developed by AstraZeneca.

About NSCLC and MET aberrations

Lung cancer is the leading cause of cancer death globally, accounting for almost one in five (19%) cancer deaths. [2,3] It is estimated that approximately 2.64 million new cases of lung cancer are diagnosed worldwide each year, including nearly 660,000 in China.[2,4] 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 EGFR-mutated 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 harboring 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 osimertinib 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 osimertinib. 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 EGFR-mutated NSCLC, locally advanced or metastatic EGFR T790M mutation-positive NSCLC, adjuvant treatment of early-stage EGFR-mutated 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 EGFR-mutated NSCLC.

About HUTCHMED

HUTCHMED (Nasdaq/AIM:HCM; HKEX:13) is an innovative, commercial-stage, biopharmaceutical company. It is committed to the discovery, 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 five 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 osimertinib 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 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.

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3 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 November 2026.

4 World Health Organization. International Agency for Research on Cancer. China Fact Sheet. Available at: https://gco.iarc.who.int/media/globocan/factsheets/populations/160-china-fact-sheet.pdf. Accessed November 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, November 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