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Press Release

HUTCHMED Completes Patient Enrollment of SANOVO Phase III Trial of ORPATHYS® and TAGRISSO® Combination as a First-Line Therapy for Certain Lung Cancer Patients in China

Hong Kong, Shanghai & Florham Park, NJ - Wednesday, August 20, 2025: HUTCHMED (China) Limited ("HUTCHMED") (Nasdaq/AIM:HCM; HKEX:13) today announces the completion of patient enrollment of SANOVO, a China Phase III study of ORPATHYS® (savolitinib) and TAGRISSO® (osimertinib) as a first-line treatment in certain non-small cell lung cancer ("NSCLC") patients whose tumors harbor epidermal growth factor receptor ("EGFR") mutation and MET overexpression. The last patient was enrolled on August 18, 2025.

This Phase III trial is a blinded, randomized, controlled study in previously untreated patients with locally advanced or metastatic NSCLC with activating EGFR mutations and MET overexpression. The study will evaluate the efficacy and safety of TAGRISSO® in combination with ORPATHYS® comparing to TAGRISSO® alone, a standard-of-care treatment option for these patients. The primary endpoint of the study is progression free survival ("PFS") as assessed by investigators. Other endpoints include PFS assessed by an independent review committee, overall survival (OS), objective response rate ("ORR"), duration of response (DoR), disease control rate (DCR), time to response (TTR), and safety. Additional details may be found at clinicaltrials.gov, using identifier NCT05009836.

Topline results from the SANOVO study are estimated to be reported in the second half of 2026, followed by submission of results for presentation at an appropriate medical congress. If favorable, the results would enable a supplementary New Drug Application submission to China's National Medical Products Administration ("NMPA").

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

About NSCLC and MET aberrations

Lung cancer is the leading cause of cancer death, accounting for about one-fifth of all cancer deaths.[1] Lung cancer is broadly split into NSCLC and small cell lung cancer, with 80-85% classified as NSCLC.[2] The majority of NSCLC patients (approximately 75%) are diagnosed with advanced disease, and approximately 10-15% of NSCLC patients in the US and Europe and up to 40-50% of patients in Asia have EGFR-mutated ("EGFRm") NSCLC.[3],[4],[5],[6],[7]

MET is a tyrosine kinase receptor that has an essential role in normal cell development. MET overexpression and/or amplification can lead to tumor growth and the metastatic progression of cancer cells, and is one of the mechanisms of *de novo* or acquired resistance to EGFR TKI for metastatic EGFRm NSCLC.[8],[9]

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 and is marketed by AstraZeneca 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® is also approved in China for the treatment of patients with locally advanced or metastatic EGFRm-positive non-squamous NSCLC with MET amplification after disease progression on EGFR tyrosine kinase inhibitor therapy, in combination with TAGRISSO®.

It is currently under clinical development for multiple tumor types, including lung, kidney, and gastric cancers as a single treatment and in combination with other medicines.

About TAGRISSO®

TAGRISSO® (osimertinib) is a third-generation, irreversible EGFR-TKI with proven clinical activity in NSCLC, including against central nervous system (CNS) metastases. TAGRISSO® (40mg and 80mg once-daily oral tablets) has been used to treat more than one million patients across its indications worldwide and AstraZeneca continues to explore TAGRISSO® as a treatment for patients across multiple stages of EGFRm NSCLC.

There is an extensive body of evidence supporting the use of TAGRISSO® in EGFRm NSCLC, and it is the only targeted therapy shown to improve patient outcomes across all stages of the disease.

In late stage disease, TAGRISSO® demonstrated improved outcomes as monotherapy in the FLAURA Phase III trial

in late-stage disease, TAGRISSO® demonstrated improved outcomes as monotherapy in the FLAURA Phase III trial and in combination with chemotherapy in the FLAURA2 Phase III trial. TAGRISSO® is also being investigated in this setting in combination with ORPATHYS® (savolitinib) in the SAFFRON Phase III trial and in combination with DATROWAY® (datopotamab deruxtecan or Dato-DXd) in the TROPION-Lung14 and TROPION-Lung15 Phase III trials.

TAGRISSO® also showed improved outcomes in early-stage disease in the NeoADAURA and ADAURA Phase III trials and in locally advanced stages in the LAURA Phase III trial. As part of AstraZeneca's ongoing commitment to treating patients as early as possible in lung cancer, TAGRISSO® is also being investigated in the early-stage adjuvant resectable setting in the ADAURA2 Phase III trial.

About ORPATHYS® and TAGRISSO® Combination Development in EGFR-mutated NSCLC

Among patients who experience disease progression following treatment with a third-generation EGFR TKI, approximately 15-50% present with MET aberration, depending on the sample type, detection method and assay cut-off used. TAGRISSO® is a third-generation, irreversible EGFR-TKI with proven clinical activity in NSCLC, including against central nervous system metastases. Treatment with ORPATHYS® in combination with TAGRISSO® has been studied extensively in these patients in the TATTON (NCT02143466) and SAVANNAH (NCT03778229) studies. The encouraging results led to the initiation of several Phase III trials in this setting including the SACHI trial in China (NCT05015608) and the global SAFFRON trial (NCT05261399), as well as the SANOVO trial in China (NCT05009836).

This combination represents a promising chemotherapy-free oral treatment strategy to address mechanisms of resistance in this advanced setting. Positive data from the SACHI randomized Phase III trial led to the filing of a third NDA in China. Strong data from the SAVANNAH single-arm Phase II study was recently presented at the European Lung Cancer Congress (ELCC) in March 2025 demonstrated high, clinically meaningful and durable ORR, with consistent safety results. The SAFFRON randomized Phase III trial is progressing. Following AstraZeneca's consultation with the US Food and Drug Administration ("FDA"), we look forward to completing the SAFFRON trial as soon as possible to support potential US and other global registration filings.

SACHI: The SACHI China Phase III study evaluated the combination of ORPATHYS® and TAGRISSO® for the treatment of patients with EGFRm, MET-amplified locally advanced or metastatic NSCLC after progression on EGFR TKI compared to platinum-based doublet chemotherapy. Results were presented at the ASCO Annual Meeting in June 2025. Based on the data from the SACHI study, the combination of ORPATHYS® and TAGRISSO® received approval from the China NMPA for the treatment of patients with locally advanced or metastatic EGFR mutation-positive non-squamous NSCLC with MET amplification after disease progression on EGFR TKI therapy in June 2025.

SAFFRON: In 2023, ORPATHYS® and TAGRISSO® received Fast Track Designation from the US FDA in this setting. The global SAFFRON Phase III trial is currently ongoing to assess the ORPATHYS® plus TAGRISSO® combination versus platinum-based doublet chemotherapy in patients with EGFRm, MET-overexpressed and/or amplified, locally advanced or metastatic NSCLC following progression on treatment with TAGRISSO®. Patients are being prospectively selected using the high MET level cut-off identified in SAVANNAH.

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 three 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.hutchmed.com or follow us on LinkedIn.

Forward-Looking Statements

This press release 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 other jurisdictions and to gain commercial acceptance after obtaining regulatory approval; the potential market of ORPATHYS® for a targeted indication; and HUTCHMED and/or its partner's ability to fund, implement and complete its further clinical development and commercialization plans for ORPATHYS®, and the timing of these events. 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 press release, whether as a result of new information, future events or circumstances or otherwise.

Medical Information

This press release 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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