Press Release

HUTCHMED Announces NMPA Full Approval for ORPATHYS® (savolitinib) in China for Patients with Locally Advanced or Metastatic MET Exon 14 NSCLC

— Indication expands to include treatment-naïve patients —

— The 2021 conditional approval in previously treated patients converted to full approval —

Hong Kong, Shanghai & Florham Park, NJ — Tuesday, January 14, 2025: HUTCHMED (China) Limited ("HUTCHMED") (Nasdaq/AIM:HCM; HKEX:13) today announces that the supplemental New Drug Application for ORPATHYS® (savolitinib) has been granted approval by the China National Medical Products Administration ("NMPA") for the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer ("NSCLC") with MET exon 14 skipping alteration. The NMPA has also converted the prior conditional approval of ORPATHYS® in the previously treated patient population to full approval. The new label indication for ORPATHYS® will now include both treatment-naïve and previously treated patients in China.

The approval by the NMPA was based on data from the confirmatory Phase IIIb clinical trial in patients with MET exon 14 skipping alteration NSCLC (NCT04923945). Preliminary efficacy and safety data from the first-line cohort were presented during the IASLC World Conference on Lung Cancer (WCLC) in September 2023. Final data from the confirmatory Phase IIIb trial were presented at the European Lung Cancer Congress in March 2024.

In treatment-naïve patients, objective response rate ("ORR") was 62.1%, disease control rate ("DCR") was 92.0% and median duration of response ("DoR") was 12.5 months, as assessed by an independent review committee. Median progression free survival ("PFS") was 13.7 months and median overall survival ("OS") was not reached with median follow-up of 20.8 months. In previously treated patients, ORR was 39.2%, DCR was 92.4% and median DoR was 11.1 months, as assessed by an independent review committee. Median PFS was 11.0 months and median OS was not mature with median follow-up of 12.5 months. Responses occurred early (time to response 1.4-1.6 months) in both treatment-naïve and previously treated patients. The safety profile was tolerable and no new safety signals were observed. The most common drug-related treatment-emergent adverse events of Grade 3 or above (5% or more of patients) were abnormal hepatic function (16.9%), increased alanine aminotransferase (14.5%), increased aspartate aminotransferase (12.0%), peripheral oedema (6.0%) and increased gamma-glutamyltransferase (6.0%).

"This Phase IIIb confirmatory study of ORPATHYS® is one of the largest Phase III clinical trials conducted in China for this patient population to date. ORPATHYS® has demonstrated clear efficacy and tolerability in both first-line and second-line settings, underscoring its potential as a standard treatment option for NSCLC with MET exon 14 skipping alterations," said **Prof. Shun Lu, Chief of the Shanghai Lung Cancer Center at Shanghai Chest Hospital, School of Medicine, Shanghai Jiaotong University, and Principal Investigator of the confirmatory Phase IIIb study**. "By making ORPATHYS® available as a first-line treatment, we are able to provide our patients with an effective targeted therapy earlier in their treatment journey. We look forward to introducing this novel treatment and optimizing the treatment strategy for this challenging patient population to improve their outcomes and quality of life."

"The approval marks an exciting step forward in addressing the unmet needs of NSCLC patients with MET exon 14 skipping alteration. It not only validates our research but also emphasizes our dedication to addressing unmet medical needs through targeted drug development," said **Dr. Michael Shi, Head of R&D and Chief Medical Officer of HUTCHMED**. "We are focused on advancing our research and expanding access to ORPATHYS®, ultimately improving the treatment landscape for those affected by this challenging form of lung cancer. We also remain committed to further exploring ORPATHYS® in other MET driven diseases in order to help more patients who may benefit from this targeted treatment."

"Today's approval reinforces ORPATHYS® as a transformative option for the treatment of biomarker-driven lung cancer, and we are proud that we can now offer this therapy to both first-line and second-line patients in China with advanced NSCLC with MET exon 14 skipping alterations," said **Ms. Mary Guan, General Manager of AstraZeneca China Oncology Business**. "Through our partnership with HUTCHMED, we are advancing ORPATHYS® to address resistance to EGFR-TKIs[1], unlocking new possibilities for treating MET-altered and amplified cancers, and expanding the reach of this innovative therapy to even more patients with this form of lung cancer."

Savolitinib was launched and is marketed under the brand name ORPATHYS® by our partner, AstraZeneca, for this patient population, representing the first selective MET inhibitor approved in China.

About NSCLC and MET aberrations

Lung cancer is the leading cause of cancer death, accounting for about one-fifth of all cancer deaths.[2] More than a third of the world's lung cancer patients are in China. Lung cancer is broadly split into NSCLC and small cell lung cancer, with 80-85% classified as NSCLC.[3] 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 30-40% of patients in Asia have EGFR-mutated NSCLC. [4,5,6,7]

MET is a tyrosine kinase receptor that has an essential role in normal cell development.[8] MET overexpression and/or amplification can lead to tumor growth and the metastatic progression of cancer cells, and is one of the mechanisms of acquired resistance to EGFR TKI for metastatic EGFR-mutated NSCLC.[8,9] Approximately 2-3% of NSCLC patients have tumors with MET exon 14 skipping alterations, a targetable mutation in the MET gene.[10] MET aberration is a major mechanism for acquired resistance to both first/second-generation EGFR TKIs as well as third-generation EGFR TKIs like osimertinib. Among patients who experience disease progression post-osimertinib treatment, approximately 15-50% present with MET aberration.[11,12,13,14,15] The prevalence of MET aberration depends on the sample type, detection method and assay thresholds used.[16]

About ORPATHYS® (savolitinib)

ORPATHYS® 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® was previously granted conditional approval in China in June 2021 for the treatment of patients with NSCLC with MET exon 14 skipping alterations who have progressed following prior systemic therapy or are unable to receive chemotherapy. ORPATHYS® is the first selective MET inhibitor approved in China. It has been included in the National Reimbursement Drug List of China (NRDL) since March 2023. It is also currently under clinical development for multiple tumor types, including lung, kidney and gastric cancers, as a single treatment and in combination with other medicines.

In 2011, AstraZeneca and HUTCHMED entered a global licensing and collaboration agreement to jointly develop and commercialize ORPATHYS®. Joint development of ORPATHYS® in China is led by HUTCHMED, while AstraZeneca leads development outside of China. HUTCHMED is responsible for the marketing authorization, manufacturing and supply of ORPATHYS® in China. AstraZeneca is responsible for the commercialization of ORPATHYS® in China and worldwide. Sales of ORPATHYS® are recognized by AstraZeneca.

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, HUTCHMED 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 in the US, Europe and Japan. For more information, please visit: www.hutch-med.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 savolitinib, the further clinical development for savolitinib, its expectations as to whether any studies on savolitinib 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 savolitinib, 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 savolitinib 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 savolitinib, and the timing of these events. 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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