Press Release

HUTCHMED Announces Savolitinib sNDA Accepted in China for Treatment-Naïve or Previously Treated Patients with Locally Advanced or Metastatic MET Exon 14 NSCLC

— Oral presentation at the European Lung Cancer Congress 2024 of Phase IIIb data demonstrating median PFS of 13.7 months and median OS not reached in treatment-naïve patients —

— If approved, would confirm 2021 conditional approval and expand indication to more patients —

Hong Kong, Shanghai & Florham Park, NJ — Thursday, March 28, 2024: HUTCHMED (China) Limited ("HUTCHMED") (Nasdaq/AIM:HCM; HKEX:13) today announces that the supplemental New Drug Application ("sNDA") for savolitinib, in adult patients with locally advanced or metastatic non-small cell lung cancer ("NSCLC") with mesenchymal epithelial transition factor ("MET") exon 14 skipping alteration, has been accepted for review by the China National Medical Products Administration (NMPA). If approved, the new label indication for savolitinib will be expanded to include treatment-naive patients in China.

Savolitinib was previously granted conditional approval in China 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. 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. More than a third of the world's lung cancer patients are in China and, among those with NSCLC globally, approximately 2-3% have tumors with MET exon 14 skipping alterations.

Preliminary efficacy and safety data from the first-line cohort of the confirmatory Phase IIIb clinical trial (NCT04923945) 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 on March 20, 2024.

The data from this study provide confirmatory evidence for savolitinib as a targeted treatment option for treatment-naïve or previously treated patients with MET exon 14 skipping alteration NSCLC. In treatment-naïve patients, objective response rate ("ORR") was 62.1% (95% CI: 51.0% to 72.3%), disease control rate ("DCR") was 92.0% (95% CI: 84.1% to 96.7%) and median duration of response ("DoR") was 12.5 months (95% CI: 8.3 months to 15.2 months), as assessed by an independent review committee. Median progression free survival ("PFS") was 13.7 months (95% CI: 8.5 months to 16.6 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% (95% CI: 28.4% to 50.9%), DCR was 92.4% (95% CI: 84.2% to 97.2%) and median DoR was 11.1 months (95% CI: 6.6 months to not reached), as assessed by an independent review committee. Median PFS was 11.0 months (95% CI: 8.3 months to 16.6 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%).

About NSCLC and MET aberrations

Lung cancer is the leading cause of cancer death among men and women, 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 U.S. and Europe and 30-40% of patients in Asia have EGFRm NSCLC. [3,4,5,6]

MET is a tyrosine kinase receptor that has an essential role in normal cell development.[7] 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 TKIs for metastatic EGFR-mutated NSCLC.[7,8] Approximately 2-3% of NSCLC patients have tumors with MET exon 14 skipping alterations, a targetable mutation in the MET gene.[9] Among patients who experience disease progression post-osimertinib treatment, approximately 15-50%

present with MET aberration.[10,11,12,13,14] The prevalence of MET depends on the sample type, detection method and assay cut-off used.[15]

About Savolitinib (ORPATHYS® in China)

Savolitinib is an oral, potent and highly selective MET tyrosine kinase inhibitor 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.

Savolitinib is marketed in China under the brand name ORPATHYS® for the treatment of patients with non-small cell lung cancer with MET exon 14 skipping alterations who have progressed following prior systemic therapy or are unable to receive chemotherapy. 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. Starting on March 1, 2023, ORPATHYS® was included in the National Reimbursement Drug List (NRDL) for the treatment of locally advanced or metastatic NSCLC adult patients with MET exon 14-skipping alterations who have progressed after or unable to tolerate platinum-based chemotherapy.

In 2011, AstraZeneca and HUTCHMED entered a global licensing and collaboration agreement to jointly develop and commercialize savolitinib. Joint development of savolitinib in China is led by HUTCHMED, while AstraZeneca leads development outside of China. HUTCHMED is responsible for the marketing authorization, manufacturing and supply of savolitinib in China. AstraZeneca is responsible for the commercialization of savolitinib in China and worldwide. Sales of savolitinib 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. It has approximately 5,000 personnel across all its companies, at the center of which is a team of about 1,800 in oncology/immunology. Since inception, HUTCHMED has focused on bringing cancer 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 marketed in the U.S. 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 U.S. 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 different jurisdictions and to gain commercial acceptance after obtaining regulatory approval; the potential market of savolitinib for a targeted indication; and the sufficiency of funding. 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 U.S. 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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REFERENCES

1 World Health Organization. International Agency for Research on Cancer. All cancers fact sheet. Available at: https://gco.iarc.fr/today/-data/factsheets/cancers/39-All-cancers-fact-sheet.pdf. Accessed November 2022.

2 American Cancer Society. What is Lung Cancer? Available at: https://www.cancer.org/cancer/lung-cancer/about/what-is.html. Accessed November 2022.

3 Knight SB, *et al.* Progress and prospects of early detection in lung cancer. *Open Biol.* 2017;7(9): 170070.

4 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;2121-27.

5 Zhang Y, *et al*. The prevalence of EGFR mutation in patients with non-small cell lung cancer: a systematic review and meta-analysis. *Oncotarget*. 2016;7(48).

6 Szumera-Ciećkiewicz A, *et al*. EGFR Mutation Testing on Cytological and Histological Samples in 11. Non-Small Cell Lung Cancer: a Polish, Single Institution Study and Systematic Review of European Incidence. *Int J Clin Exp Pathol*. 2013:6;2800-12.

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. *Journal of Hematology & Oncology.* 2019;63.

9 Vuong HG, *et al*. Clinicopathological implications of MET exon 14 mutations in non-small cell lung cancer – A systematic review and meta-analysis. *Lung Cancer* 2018; 123: 76-82.

10 Soria JC, *et al*. Osimertinib in Untreated EGFR-Mutated Advanced Non-Small-Cell Lung Cancer. *N Engl J Med*. 2018;378(2):113-125.

11 Mok TS, *et al*. Osimertinib or Platinum-Pemetrexed in EGFR T790M-Positive Lung Cancer. *N Engl J Med.* 2017;376(7):629-640.

12 Hartmaier R, *et al*. Tumor genomics in patients (pts) with advanced epidermal growth factor receptor mutant (EGFRm) non-small cell lung cancer (NSCLC) whose disease has progressed on first-line (1L) osimertinib therapy in the Phase II ORCHARD study. *Cancer Res* 15 June 2022; 82 (12_Supplement): LB078.

13 Piotrowska, *et al*. MET amplification (amp) as a resistance mechanism to osimertinib. *Journal of Clinical Oncology* 2017 35:15_suppl, 9020-9020.

14 Hartmaier, *et al*. Detection of MET-mediated EGFR tyrosine kinase inhibitor (TKI) resistance in advanced non-small cell lung cancer (NSCLC): biomarker analysis of the TATTON study. *Cancer Res* (2019) 79 (13_Supplement): 4897.

15 Coleman N, *et al*. Beyond epidermal growth factor receptor: MET amplification as a general resistance driver to targeted therapy in oncogene-driven non-small-cell lung cancer. *ESMO Open*. 2019;6(6).