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 – First Commercial Sale of ORPATHYS® in China, Triggering a US$25 million Milestone Payment from AstraZeneca

HUTCHMED (China) Limited ("HUTCHMED") announces the first commercial sale in China of ORPATHYS® (savolitinib), HUTCHMED's oral, potent, and highly selective small molecule inhibitor of MET, a receptor tyrosine kinase, which occurred on July 12, 2021.

This follows less than three weeks after the June 22, 2021 approval of ORPATHYS® in China for the treatment of patients with locally advanced or metastatic non-small cell lung cancer ("NSCLC") with MET exon 14 skipping alterations who have progressed following prior systemic therapy or are unable to receive chemotherapy.

Under the terms of the license and collaboration agreement between HUTCHMED and AstraZeneca AB (publ) ("AstraZeneca"), a US$25 million non-creditable and non-refundable milestone payment is triggered by the first commercial sales of ORPATHYS® in China. HUTCHMED is responsible for the clinical development, marketing authorization, manufacturing and supply of ORPATHYS® in China, while AstraZeneca is responsible for its commercialization for which it will pay HUTCHMED fixed royalties of 30% based on all China sales.

More than a third of the world's lung cancer patients are in China and, among those with NSCLC, approximately 2-3% have tumors with MET exon 14 skipping alterations, a targetable mutation in the MET gene.[1,2,3] This mutation is more common (13-22%) among patients with pulmonary sarcomatoid carcinoma (PSC), a rare and aggressive subtype of NSCLC usually resistant to chemotherapy.[1,4]

About ORPATHYS®

ORPATHYS® is an oral, potent, and highly selective MET tyrosine kinase inhibitor ("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) or gene amplification.

ORPATHYS® is marketed 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. 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.

ORPATHYS® development in NSCLC

Phase II study of ORPATHYS® monotherapy in MET Exon 14 skipping alteration NSCLC (NCT02897479) – In June 2021, ORPATHYS® was granted drug registration conditional approval by the National Medical Products Administration of China (NMPA) for MET Exon 14 skipping alteration NSCLC. The approval was based on the results of a Phase II study in China; results of this study were presented during the American Society of Clinical Oncology ASCO20 Virtual Scientific Program in May 2020, and updated results were published in The Lancet Respiratory Medicine[5] in June 2021. At a median follow up of 17.6 months, ORPATHYS® demonstrated an objective response rate ("ORR") of 42.9% (95% confidence interval [CI] 31.1-55.3) and median progression-free survival ("PFS") of 6.8 months (95% CI 4.2-9.6) in the overall trial population. PFS was clinically meaningful across subgroups, and ORR results were consistent regardless of prior treatment or tumor histology, including in patients with the PSC subtype (40.0%, 95% CI 21.1-61.3) and patients with other NSCLC subtypes (44.4%,

95% CI 29.6-60.0). Disease control rate ("DCR") in the overall trial population was 82.9% (95% CI 72.0-90.8). The safety and tolerability profile of ORPATHYS® was consistent with previous trials, and no new safety signals were identified.

SAVANNAH Phase II study of ORPATHYS® in combination with TAGRISSO® in patients who have progressed following TAGRISSO® due to MET amplification or overexpression (NCT03778229) – This is a single-arm, open-label, global study in epidermal growth factor receptor ("EGFR") mutation positive NSCLC patients with MET amplified/overexpressed tumors following progression after treatment with TAGRISSO®, an EGFR TKI owned by AstraZeneca.

Phase III study of ORPATHYS® in combination with TAGRISSO® in patients who have progressed following EGFR TKI treatment due to MET amplification (in planning) – This is a randomized, open-label study in China in EGFR mutation positive NSCLC patients with MET amplified tumors following progression after treatment with any EGFR TKI.

Phase III study of ORPATHYS® in combination with TAGRISSO® in treatment naïve patients with EGFR mutant positive NSCLC with MET overexpression (in planning) – This is a randomized, blinded study in China in untreated, unresectable or metastatic patients with EGFR mutation positive NSCLC with MET positive tumors.

ORPATHYS® development in kidney cancer

SAVOIR randomized, controlled study of ORPATHYS® monotherapy in MET-driven papillary renal cell carcinoma ("RCC") (NCT03091192) – In May 2020, data from 60 patients in this global study of ORPATHYS® monotherapy compared with sunitinib monotherapy in MET-driven papillary RCC was presented at the ASCO 2020 Program and published simultaneously in JAMA Oncology[6]. ORPATHYS® demonstrated encouraging activity, including an ORR of 27% versus 7% for sunitinib, with no ORPATHYS® responding patients experiencing disease progression at data cut-off, and an encouraging overall survival ("OS") hazard ratio of 0.51 (95% CI: 0.21–1.17; *p*=0.110) with median not reached at data cut-off.

CALYPSO Phase I/II study of ORPATHYS® in combination with IMFINZI® PD-L1 inhibitor in RCC (NCT02819596) – The CALYPSO study is an investigator initiated open-label Phase I/II study of ORPATHYS® in combination with IMFINZI®, a PD-L1 antibody owned by AstraZeneca. The study is evaluating the safety and efficacy of the ORPATHYS®/IMFINZI® combination in patients with papillary RCC and clear cell RCC. An analysis of 41 patients enrolled in the PRCC cohort of in this study was presented at the 2021 ASCO Annual Meeting[7], showing a confirmed response rate in 14 MET-driven patients of 57%, with a median duration of response ("DoR") of 9.4 months, median PFS of 10.5 months and median OS of 27.4 months. No new safety signals were seen.

Phase III in combination with IMFINZI® PD-L1 inhibitor in MET-driven, unresectable and locally advanced or metastatic PRCC (in planning) – Based on the encouraging results of the SAVOIR and CALYPSO studies, we intend to initiate a global Phase III, open-label, randomized, controlled study of ORPATHYS® plus IMFINZI® versus sunitinib monotherapy versus IMFINZI® monotherapy in patients with MET-driven, unresectable and locally advanced or metastatic PRCC.

ORPATHYS® development in other cancer indications

Phase II study of ORPATHYS® monotherapy in advanced or metastatic MET amplified gastric cancer ("GC") or adenocarcinoma of the gastroesophageal junction ("GEJ") (NCT04923932) – This Phase II trial is an open-label, two-cohort, multi-center study to evaluate the efficacy, safety and pharmacokinetics ("PK") of ORPATHYS® in locally advanced or metastatic GC or GEJ patients whose disease progressed after at least one line of standard therapy. The primary endpoint is ORR as assessed by an independent review committee. Other endpoints include 12-week and 6-month PFS rates, median PFS, DoR, DCR, median OS, safety, PK and quality of life.

This trial follows multiple Phase II studies that have been conducted in Asia to study ORPATHYS® in MET-driven gastric cancer patients, including VIKTORY.[8] VIKTORY is an investigator initiated Phase II umbrella study in gastric cancer in South Korea in which a total of 715 patients were successfully sequenced into molecular-driven patient groups, including those with MET amplified gastric cancer. Patients whose tumors harbor MET amplification were treated with ORPATHYS® monotherapy, reporting an ORR of 50% (10/20, 95% CI: 28.0, 71.9).

ORPATHYS® opportunities are also continuing to be explored in multiple other MET-driven tumor settings via investigator-initiated studies including non-small cell lung cancer, gastric cancer and colorectal cancer.

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. A dedicated organization of over 1,300 personnel has advanced ten cancer drug candidates from in-house discovery into clinical studies around the world, with its first three oncology drugs now approved and launched. 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 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 commercial launch of ORPATHYS® in China, our ability to manufacture and supply ORPATHYS®, the ability of its partner AstraZeneca to distribute ORPATHYS® quickly and broadly, the potential market for ORPATHYS® in non-small cell lung cancer patients China, and the further clinical development for ORPATHYS® in these and other indications and in combination with other medicines in China, the United States and other jurisdictions. Forward-looking statements involve risks and uncertainties. Such risks and uncertainties include, among other things, assumptions regarding AstraZeneca's ability to effectively commercialize ORPATHYS®, the benefits obtained from ORPATHYS® during clinical trials being the same for all patients who are prescribed ORPATHYS®, no unidentified side effects occurring which could result in the NMPA pulling ORPATHYS® from the market, AstraZeneca and HUTCHMED's ability to fund, implement and complete further clinical development and commercialization plans for ORPATHYS®, the timing of these events, and the impact of the COVID-19 pandemic on general economic, regulatory and political conditions. In addition, as certain studies rely on the use of TAGRISSO® and IMFINZI® 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 U.S. Securities and Exchange Commission, on AIM and The Stock Exchange of Hong Kong Limited. 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.

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[8] Lee J, Kim ST, Kim K, et al. Tumor Genomic Profiling Guides Patients with Metastatic Gastric Cancer to Targeted Treatment: The VIKTORY Umbrella Trial. Cancer Discov. 2019;9(10):1388-1405. doi:10.1158/2159-8290.CD-19-0442.

By Order of the Board

Edith Shih
Non-executive Director and Company Secretary

Hong Kong, July 13, 2021

As at the date of this announcement, the Directors of the Company are:

Executive Directors:
Mr TO Chi Keung, Simon
(Chairman)
Mr Christian Lawrence HOGG
(Chief Executive Officer)
Mr CHENG Chig Fung, Johnny
(Chief Financial Officer)
Dr Weiguo SU
(Chief Scientific Officer)

Non-executive Directors:
Dr Dan ELDAR
Ms Edith SHIH

Independent Non-executive Directors:
Mr Paul Rutherford CARTER
(Senior Independent Director)
Dr Karen Jean FERRANTE
Mr Graeme Allan JACK
Professor MOK Shu Kam, Tony