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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 Completes Patient Enrollment of a Phase II Registration Study of Savolitinib in Gastric Cancer in China

HUTCHMED (China) Limited (“[HUTCHMED](#)”) today announces that it has completed enrollment of the registration phase of its Phase II trial of savolitinib in gastric cancer patients with *MET* amplification.

This clinical trial is a single-arm, multi-center, open-label, Phase II registration study to evaluate the efficacy, safety and tolerability of savolitinib in treating gastric cancer or gastroesophageal junction (“GEJ”) adenocarcinoma patients with *MET* amplification. Primary endpoint is objective response rate (“ORR”) evaluated by the Independent Review Committee (“IRC”) (RECIST 1.1). Secondary endpoints include progression free survival (PFS) and incidence of various adverse events (AE), among others. A total of 64 patients have been enrolled in the study. Further details may be found at [clinicaltrials.gov](https://clinicaltrials.gov) using identifier [NCT04923932](https://clinicaltrials.gov/ct2/show/study/NCT04923932).

As [reported at the American Association for Cancer Research](#) Annual Meeting, interim results from the study showed a 45% ORR confirmed by IRC and a 50% ORR in patients with high *MET* gene copy number. 4-month duration of response (DOR) rate was 85.7% with median follow up time of 5.5 months. The most common grade 3 or higher treatment-related adverse events (“TRAE”) ( $\geq 5\%$ ) were platelet count decreased, hypersensitivity, anemia, neutropenia and hepatic function abnormal. Only one patient discontinued treatment due to grade 4 liver function abnormal (TRAE) and no patient died due to TRAE.

The China’s National Medical Products Administration (“NMPA”) has granted Breakthrough Therapy Designation to savolitinib for the treatment of locally advanced or metastatic gastric cancer or GEJ adenocarcinoma patients with *MET* amplification who have failed at least two lines of standard therapies. If positive, HUTCHMED may initiate plans to apply for marketing authorization of savolitinib for gastric cancer in China in late 2025.

### About Gastric Cancer with *MET* Amplification

*MET*-driven gastric cancer has a very poor prognosis.<sup>1</sup> It is estimated that *MET* amplification accounts for approximately 4-6% of gastric cancer patients.<sup>2,3</sup> The annual incidence of *MET* amplification gastric cancer is estimated to be approximately 18,000 in China.<sup>4</sup> The ongoing registration trial follows multiple Phase II studies conducted in Asia to study savolitinib in *MET*-driven gastric cancer patients, including VIKTORY.<sup>2</sup> The VIKTORY study reported a 50% ORR in patients whose tumors harbored *MET* amplification and were treated with savolitinib monotherapy.

## About Savolitinib

Savolitinib is an oral, potent, and highly selective MET tyrosine kinase inhibitor (“TKI”) being jointly developed by AstraZeneca and HUTCHMED and commercialized by AstraZeneca. MET is a tyrosine kinase receptor that has an essential role in normal cell development.<sup>5</sup> Savolitinib 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 approved in China and is marketed under the brand name ORPATHYS® by our partner, AstraZeneca, for the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with MET exon 14 skipping alteration, representing 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 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 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.hutch-med.com](http://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 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 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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<sup>1</sup> Catenacci DV, Ang A, Liao WL, et al. MET tyrosine kinase receptor expression and amplification as prognostic biomarkers of survival in gastroesophageal adenocarcinoma. *Cancer*. 2017;123(6):1061-1070. doi:10.1002/cncr.30437

<sup>2</sup> 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-19-044

<sup>3</sup> Van Cutsem E, Karaszewska B, Kang YK, et al. A Multicenter Phase II Study of AMG 337 in Patients with MET-Amplified Gastric/Gastroesophageal Junction/Esophageal Adenocarcinoma and Other MET-Amplified Solid Tumors. *Clin Cancer Res*. 2019;25(8):2414-2423. doi:10.1158/1078-0432.CCR-18-1337

<sup>4</sup> Global Cancer Observatory. China Fact Sheet. <https://gco.iarc.who.int/media/globocan/factsheets/populations/160-china-fact-sheet.pdf>. Accessed April 7, 2025.

<sup>5</sup> Uchikawa E, et al. Structural basis of the activation of c-MET receptor. *Nat Commun*. 2021;12(4074).

By Order of the Board

**Edith Shih**

*Non-executive Director and Company Secretary*

Hong Kong, April 22, 2025

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

*(Chief Financial Officer)*

**Non-executive Directors:**

Ms Edith SHIH

Ms Ling YANG

**Independent Non-executive Directors:**

Mr Paul Rutherford CARTER

*(Senior Independent Director)*

Dr Renu BHATIA

Dr Chaohong HU

Mr Graeme Allan JACK

Professor MOK Shu Kam, Tony

Mr WONG Tak Wai