

## Press Release

### **HUTCHMED Announces NDA Acceptance in China with Priority Review Status for Savolitinib for the treatment of Gastric Cancer Patients with MET Amplification**

- *NDA supported by positive Phase II registration study data in Chinese patients; follows Breakthrough Therapy Designation granted in 2023 -*

- *Savolitinib has the potential to become the first selective MET inhibitor in China for MET-amplified gastric cancer -*

**Hong Kong, Shanghai & Florham Park, NJ - Tuesday, December 30, 2025:** HUTCHMED (China) Limited ("HUTCHMED") (Nasdaq/AIM:HCM; HKEX:13) today announces that the New Drug Application ("NDA") for savolitinib for the treatment of locally advanced or metastatic gastric cancer or gastroesophageal junction (GC/GEJ) adenocarcinoma patients with MET amplification who have failed at least two prior systemic treatments has been accepted and granted priority review by the China National Medical Products Administration ("NMPA").

This NDA is supported by data from a single-arm, multi-center, open-label, Phase II registration study of savolitinib in gastric cancer patients with MET amplification in China. The study has met its primary endpoint of objective response rate (ORR) by the Independent Review Committee (IRC) (RECIST 1.1). Additional details may be found at [clinicaltrials.gov](https://clinicaltrials.gov) using identifier [NCT04923932](https://clinicaltrials.gov/ct2/show/NCT04923932).

Gastric cancer remains one of the most common cancers and leading causes of cancer death in China. 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 NMPA has granted Breakthrough Therapy Designation to savolitinib for this potential indication in 2023. The NMPA granted this designation to this new treatment that could target a serious condition where clinical evidence demonstrates substantial advantages over existing therapies.

#### **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, 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.hutchmed.com](http://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 review of a NDA for savolitinib for the treatment of gastric cancer with the NMPA and the timing of such review therapeutic potential of savolitinib for the treatment of patients with gastric cancer and the further development of savolitinib in this and other indications. Forward-looking statements involve risks and uncertainties. Such risks and uncertainties include, among other things, assumptions regarding the timing and outcome of clinical studies and the sufficiency of clinical data to support NDA approval of savolitinib for the treatment of patients with gastric cancer or other indications in China or other jurisdictions, its potential to gain approvals from regulatory authorities on an expedited basis or at all, the safety profile of savolitinib, 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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- [1] 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
  - [2] 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
  - [3] 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
  - [4] Global Cancer Observatory. China Fact Sheet. <https://gco.iarc.who.int/media/globocan/factsheets/populations/160-china-fact-sheet.pdf>. Accessed April 7, 2025.
  - [5] Uchikawa E, et al. Structural basis of the activation of c-MET receptor. *Nat Commun*. 2021;12(4074).

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