

## Press Release

# HUTCHMED Receives Breakthrough Therapy Designation in China for Savolitinib for Gastric Cancer

**Hong Kong, Shanghai & Florham Park, NJ — Tuesday, August 29, 2023:** HUTCHMED (China) Limited (“[HUTCHMED](#)”) (Nasdaq/AIM:HCM; HKEX:13) today announces that the Center for Drug Evaluation of China’s National Medical Products Administration (“NMPA”) has granted Breakthrough Therapy Designation (“BTD”) to savolitinib for the treatment of locally advanced or metastatic gastric cancer or gastroesophageal junction (“GEJ”) adenocarcinoma patients with mesenchymal epithelial transition factor (“MET”) amplification who have failed at least two lines of standard therapies.

The study of savolitinib 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 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. The study is expected to enroll approximately 60 patients. Further details may be found at [clinicaltrials.gov](https://clinicaltrials.gov/using-identifier/NCT04923932) using identifier [NCT04923932](https://clinicaltrials.gov/using-identifier/NCT04923932).

### About Breakthrough Therapy Designation in China

NMPA grants BTD to new drugs that treat life-threatening diseases or serious conditions for which there are no effective treatment options, and where clinical evidence demonstrates significant advantages over existing therapies. Drug candidates with BTD may be considered for conditional approval and priority review when submitting a New Drug Application (“NDA”). This indicates that the development and review of the therapy for this disease indication may be expedited, to address patients’ unmet needs more quickly.

### About Gastric Cancer with MET Amplification

MET-driven gastric cancer has a very poor prognosis.<sup>1</sup> The ongoing registration trial follows multiple Phase II studies that have been conducted in Asia to study ORPATHYS® in MET-driven gastric cancer patients, including VIKTORY.<sup>2</sup> 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. The VIKTORY study reported a [50% ORR](#).

At American Association for Cancer Research Annual Meeting 2023 (AACR 2023), it was reported that the interim results from a China Phase II study of savolitinib in patients with MET-amplified GEJ adenocarcinomas or gastric cancer showed a 45% ORR confirmed by IRC and a 50% ORR in patients with high MET gene copy number. Duration of response (DOR) rate at 4-month was 85.7% with median follow up time of 5.5 months. The most common grade  $\geq 3$  treatment-related adverse events (“TRAE”) ( $\geq 5\%$ ) were platelet count decreased, hypersensitivity, anemia, neutropenia and hepatic function abnormal. Only 1 patient discontinued treatment due to grade 4 liver function abnormal (TRAE) and no patient died due to TRAE.

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 24,000 in China.<sup>4</sup>

### About Savolitinib

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 (“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. 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 and 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 it has focused on bringing cancer drug candidates from in-house discovery to patients around the world, with its first three oncology drugs now approved and marketed in China. For more information, please visit: [www.hutch-med.com](http://www.hutch-med.com) or follow us on [LinkedIn](https://www.linkedin.com/company/hutchmed).

## 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 for the treatment of gastric cancer and the further clinical 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 sufficiency of clinical data to support NDA approval of savolitinib for the treatment of gastric cancer in China, the U.S., Europe, Japan, Australia or other jurisdictions, its potential to gain expeditious approvals from regulatory authorities, the safety profile of savolitinib, HUTCHMED’s ability to fund, implement and complete its further clinical development and commercialization plans for savolitinib, the timing of these events, and the impact of COVID-19 on general economic, regulatory and political conditions. 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 on The Stock Exchange of Hong Kong Limited. 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.*

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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. [gco.iarc.fr/today/data/factsheets/populations/160-china-fact-sheets.pdf](https://gco.iarc.fr/today/data/factsheets/populations/160-china-fact-sheets.pdf). Accessed March 20, 2023.