Press Release

HUTCHMED Initiates Registration Phase Enrollments of HMPL-453 for IHCC and Savolitinib for Gastric Cancer following NMPA Consultations

Hong Kong, Shanghai & Florham Park, NJ — Tuesday, April 4, 2023: HUTCHMED (China) Limited ("HUTCHMED") (Nasdaq/AIM:HCM; HKEX:13) today announces that it has consulted the China National Medical Products Administration ("NMPA") and reached an agreement to initiate the registration phase of the ongoing Phase II trial of HMPL-453 for intrahepatic cholangiocarcinoma ("IHCC") patients with fibroblast growth factor receptors ("FGFR") 2 fusion. If positive, the data from the registration phase may be used to support a future New Drug Application ("NDA") filing. The first patient received their first dose in March 2023.

In addition, it also reached an agreement to initiate the registration phase of the ongoing Phase II trial of savolitinib for gastric cancer patients with mesenchymal–epithelial transition ("MET") amplification following NMPA consultation. If positive, the data from the registration phase may be used to support a future NDA filing. The first patient also received their first dose in March 2023.

The study of HMPL-453 is a single-arm, multi-center, open-label, Phase II registration study to evaluate the efficacy, safety and pharmacokinetic of HMPL-453 in treating advanced IHCC patients with FGFR2 fusion. Primary endpoint is objective response rate ("ORR"). Secondary endpoints include progression-free survival ("PFS"), disease control rate (DCR), duration of response (DoR) and overall survival (OS). The study is expected to enroll approximately 90 additional patients. Additional details may be found at clinicaltrials.gov using identifier NCT04353375.

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 and esophagogastric junction adenocarcinoma patients with MET amplification. Primary endpoint is ORR evaluated by the Independent Review Committee (IRC) (RECIST 1.1). Secondary endpoints include PFS and incidence of various adverse events (AE). The study is expected to enroll approximately 60 additional patients. Further details may be found at clinicaltrials.gov using identifier NCT04923932.

About HMPL-453

HMPL-453 is a novel, highly selective and potent inhibitor targeting FGFR 1, 2 and 3. Aberrant FGFR signaling has been found to be a driving force in tumor growth (through tissue growth and repair), promotion of angiogenesis and resistance to anti-tumor therapies. Abnormal FGFR gene alterations are believed to be the drivers of tumor cell proliferation in several solid tumor settings.

HUTCHMED currently retain all rights to HMPL-453 worldwide.

About IHCC with FGFR2 Fusion

IHCC is one of the subtypes of primary liver cancer. In China, an estimated 61,900 newly diagnosed IHCC occurred in 2015 and the overall IHCC incidence increased by 9.2% per year between 2006 and 2015.[1] FGFR2 fusion has been reported to have a prevalence of 10-15% in IHCC patients.[2] [3]

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 Gastric Cancer with MET Amplification

MET-driven gastric cancer has a very poor prognosis.[4] 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.[5] 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.

It is estimated that MET amplification accounts for approximately 4-6% of gastric cancer patients.[5,6] The annual incidence of MET amplification gastric cancer is estimated to be approximately 24,000 in China.[7]

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 more than 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 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 and HMPL-453, the further clinical development for savolitinib and HMPL-453, its expectations as to whether any studies on savolitinib and HMPL-453 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 and HMPL-453, 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 and HMPL-453 for a targeted indication; the sufficiency of funding; and the impact of the COVID-19 pandemic 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, 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.

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