HUTCHMED Announces Agreement with NHSA for Continued Inclusion of ELUNATE® and Addition of SULANDA® in the National Reimbursement Drug List in China

Hong Kong, Shanghai & Florham Park, NJ — Friday, December 3, 2021: HUTCHMED (China) Limited ("HUTCHMED") (Nasdaq/AIM: HCM; HKEX:13) today announces that, following the 2021 negotiations with the China National Healthcare Security Administration ("NHSA"), on January 1, 2022 the updated National Reimbursement Drug List ("NRDL") will continue to include ELUNATE® (fruquintinib) and will now include SULANDA® (surufatinib).

Christian Hogg, Chief Executive Officer of HUTCHMED, said, "We welcome the addition of SULANDA® into the NRDL, along with the renewal of ELUNATE®. The NRDL has made it possible for novel therapies to gain wide reach across the country for diseases with large patient populations."

ELUNATE® was first included in the NRDL on January 1, 2020, for the treatment of metastatic colorectal cancer ("CRC"). CRC was the third most diagnosed form of cancer by incidence in China in 2020, with an estimated 450,000 to 550,000 new cases each year.[1]

SULANDA® was approved in China for the treatment of advanced non-pancreatic neuroendocrine tumors ("NETs") in December 2020 and for advanced pancreatic NETs in June 2021. In China, there were an estimated 71,300 newly diagnosed NET patients in 2020, with potentially up to 300,000 patients living with the disease.[2]

HUTCHMED's third oncology drug, ORPATHYS® (savolitinib), is the first and only approved MET inhibitor in China for the treatment of patients with non-small cell lung cancer ("NSCLC") with MET exon 14 skipping alterations. It was also included in the 2021 negotiations with the NHSA, however HUTCHMED and AstraZeneca, its partner on ORPATHYS®, declined inclusion in the NRDL for 2022. This position will be reassessed next year ahead of the next NRDL update. In China, there was an estimated 13,000 newly diagnosed NSCLC patients with MET exon 14 skipping alterations each year.[1]

About the NRDL

In recent years, the government in China has placed great importance on improving the public affordability of drug use. The NHSA regularly convenes a broad network of experts in medicine, pharmacology and pharmaco-economics to identify innovative drugs to be considered for inclusion in the NRDL. This has led to expansion of reimbursement of Category B drugs, which increasingly include novel oncology drugs. Reimbursement of Category B drugs requires varying degrees of copayment from patients, depending on their province of residence or type of NHSA insurance scheme enrollment. Agreements for all included drugs are generally renewed every two years.

In this latest update of the NRDL, the NHSA is adding or renewing over 30 Category B oncology drugs, including ELUNATE® and SULANDA®. Effective January 1, 2022, included NRDL drugs are expected to be made available in all state-run hospital pharmacies in China and reimbursement will commence for patients included in NHSA insurance schemes.

About fruquintinib (ELUNATE® in China)

Fruquintinib is a highly selective and potent oral inhibitor of vascular endothelial growth factor receptors ("VEGFRs") -1, -2 and -3. VEGFR inhibitors play a pivotal role in blocking tumor angiogenesis. Fruquintinib was designed to improve kinase selectivity to minimize off-target toxicities, improve tolerability and provide more consistent target coverage. The generally good tolerability in patients to date, along with fruquintinib's low potential for drug-drug interaction based on preclinical assessment, suggests that it may also be highly suitable for combinations with other anti-cancer therapies.

Fruquintinib is marketed in China under the brand name ELUNATE® for the treatment of metastatic CRC. It is currently under clinical development for the treatment of gastric cancer and metastatic breast cancer, and in combination with PD-1 monoclonal antibodies, including with tislelizumab (BGB-A317, developed by BeiGene,

Ltd.) and sintilimab (TYVYT® in China, IBI308, developed by Innovent Biologics, Inc.). The U.S. Food and Drug Administration ("FDA") granted Fast Track Designation for the development of fruquintinib for treating metastatic CRC in June 2020. A Phase III registration study of fruquintinib in metastatic CRC, FRESCO-2, is currently underway in the U.S., Europe, Japan and Australia.

HUTCHMED retains all rights to fruquintinib outside of China. In China, HUTCHMED is partnered with Eli Lilly and Company. Since October 2021, HUTCHMED has been responsible for development and execution of all on-the-ground medical detailing, promotion and local and regional marketing.

About surufatinib (SULANDA® in China)

Surufatinib is a novel, oral inhibitor that selectively inhibits the tyrosine kinase activity associated with VEGFR and fibroblast growth factor receptor (FGFR), which both inhibit angiogenesis, and colony stimulating factor-1 receptor (CSF-1R), which regulates tumor-associated macrophages, promoting the body's immune response against tumor cells. Its unique dual mechanism of action may be very suitable for possible combinations with other immunotherapies, where there may be synergistic anti-tumor effects.

Surufatinib is marketed in China under the brand name SULANDA® for the treatment of patients with advanced NETs. It is currently under clinical development in combination with anti-PD-1 monoclonal antibodies, including with tislelizumab and toripalimab (TUOYI®, developed by Shanghai Junshi Biosciences Co., Ltd.). A U.S. FDA New Drug Application (NDA) submission was accepted in June 2021, followed by a Marketing Authorisation Application (MAA) submission to the European Medicines Agency (EMA) validated in July 2021. In the U.S., surufatinib was granted Fast Track Designations for development in pancreatic and non-pancreatic NETs in April 2020, and Orphan Drug Designation for pancreatic NETs in November 2019.

HUTCHMED currently retains all rights to surufatinib worldwide.

About savolitinib (ORPATHYS® in China)

Savolitinib is an oral, potent, and highly selective MET 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) or gene amplification.

Savolitinib is marketed in China under the brand name ORPATHYS® 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.

In 2011, following its discovery and initial development by HUTCHMED, AstraZeneca and HUTCHMED entered a global licensing agreement to jointly develop and commercialize savolitinib. Joint development 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 more than 4,500 personnel across all its companies, at the center of which is a team of over 1,400 in oncology/immunology. Since inception it has advanced eleven cancer drug candidates from in-house discovery into clinical studies 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 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 for the commercialization of fruquintinib, surufatinib and savolitinib in China, their potential benefits, their further clinical development, plans to initiate further clinical studies, its expectations as to whether such studies 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 the commercial acceptance of fruquintinib, surufatinib and savolitinib, the ability of NRDL inclusion of fruquintinib and surufatinib to broaden their availability and patient access, clinical trial enrollment rates, 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 drug candidates fruquintinib, surufatinib and savolitinib, including as combination therapies, to meet the primary or secondary endpoints of a study, to obtain regulatory approval for a targeted indication in different jurisdictions and the sufficiency of funding. In addition, as certain studies rely on the use of tislelizumab, paclitaxel, sintilimab or toripalimab as combination therapeutics, such risks and uncertainties include assumptions regarding their safety, efficacy, supply and continued regulatory approval 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, on AIM and with 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.

Inside Information

This announcement contains inside information for the purposes of Article 7 of Regulation (EU) No 596/2014 (as it forms part of retained EU law as defined in the European Union (Withdrawal) Act 2018).

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[1] According to Frost & Sullivan. Report on file.
[2] According to Frost & Sullivan. The current incidence to prevalence ratio in China is estimated at 4.4, lower than the 7.4 ratio in the U.S. due to lower access to treatment options. Report on file.