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 Announces NDA Acceptance in China for Fruquintinib in Second-Line Gastric Cancer

HUTCHMED (China) Limited ("HUTCHMED") today announces that its New Drug Application ("NDA") for fruquintinib in combination with paclitaxel for the treatment of second-line advanced gastric or gastroesophageal junction adenocarcinoma in China has been accepted for review by the China National Medical Products Administration ("NMPA").

Dr. Michael Shi, Head of R&D and Chief Medical Officer of HUTCHMED said, "The NMPA acceptance of our NDA for fruquintinib is a positive step towards addressing the significant unmet medical need for gastric cancer patients. Gastric cancer is one of the most common cancers globally, with the highest incidence and mortality rates found in Asian populations. China alone accounts for over 40% of all new gastric cancer cases in the world. Despite recent advancement in the first line setting, there are few treatments available for patients whose disease progressed on initial therapy. Fruquintinib has demonstrated clinically meaningful benefit for patients in the Phase III FRUTIGA study, and we are excited by the possibility of providing a potential new oral treatment option for patients in China."

The NDA is supported by data from the FRUTIGA study, a randomized, double-blind, Phase III study in China to evaluate fruquintinib combined with paclitaxel compared with paclitaxel monotherapy, for second-line treatment of advanced gastric cancer.

In China, fruquintinib is approved under the brand name ELUNATE® and is included in the China National Reimbursement Drug List ("NRDL"). HUTCHMED markets fruquintinib in China in partnership with Eli Lilly and Company.

In March 2023, HUTCHMED and Takeda Pharmaceutical Company Limited (TSE:4502, NYSE:TAK) closed an exclusive license agreement to further the global development, commercialization and manufacture of fruquintinib outside China.

About the Phase III FRUTIGA Trial

FRUTIGA is a randomized, double-blind, Phase III study in China to evaluate fruquintinib combined with paclitaxel compared with paclitaxel monotherapy, for second-line treatment of advanced gastric cancer. The study enrolled approximately 700 patients. Its dual-primary endpoints were progression-free survival ("PFS") and overall survival ("OS"). The trial met the PFS endpoint at a statistically and clinically meaningful level. While there was an improvement in median OS, the OS endpoint was not statistically significant per the pre-specified statistical plan. Fruquintinib also demonstrated a statistically significant improvement in secondary endpoints including objective response rate (ORR), disease control rate (DCR) and duration of response (DoR). The safety profile of fruquintinib in FRUTIGA was consistent with previously reported studies. Additional details may be found at clinicaltrials.gov, using identifier NCT03223376.

About Gastric Cancer

Gastric cancer is a cancer that starts in the stomach. It is the fifth most common cancer worldwide, estimated to have caused approximately 770,000 deaths in 2020.[1] In China, an estimated 478,000 people were diagnosed with gastric cancer and 373,000 people will have died from gastric cancer in 2020.[2]

About Fruquintinib

Fruquintinib is a highly selective and potent oral inhibitor of vascular endothelial growth factor receptor ("VEGFR") -1, -2 and -3. VEGFR inhibitors play a pivotal role in blocking tumor angiogenesis. Fruquintinib was designed to improve kinase selectivity with the intention of minimizing off-target toxicities, improving tolerability and providing more consistent target coverage. Fruquintinib has been generally well tolerated in patients to date and is being investigated in combinations with other anti-cancer therapies.

Fruquintinib was approved for marketing by the NMPA in September 2018 and commercially launched in China in November 2018 under the brand name ELUNATE® for the treatment of patients with metastatic colorectal cancer ("CRC") who have been previously treated with fluoropyrimidine, oxaliplatin and irinotecan, including those who have previously received anti-VEGF therapy and/or anti-epidermal growth factor receptor (EGFR) therapy (RAS wild type). It has been included in the NRDL since January 2020.

The safety and efficacy of fruquintinib for the following investigational uses have not been established and there is no guarantee that it will receive health authority approval or become commercially available in any country for the uses being investigated.

Filing of a rolling submission of NDA to the U.S. Food and Drug Administration ("FDA") was completed in March 2023. Submissions to the European Medicines Agency (EMA) and the Japan Pharmaceuticals and Medical Devices Agency (PMDA) are expected to be completed in 2023. The submission to the FDA is supported by positive results from FRESCO-2 study, a global double-blind, placebo-controlled, Phase III study in 691 patients with refractory metastatic CRC.[3] Additional details of the study may be found at clinicaltrials.gov, using identifier NCT04322539.

HUTCHMED is also developing fruquintinib for the treatment of multiple solid tumor cancers in combination with PD-1 monoclonal antibodies for the treatment of endometrial and other solid tumors.

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 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 regarding the therapeutic potential of fruquintinib for the treatment of patients with advanced gastric cancer and the further clinical development of fruquintinib 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 fruquintinib for the treatment of patients with advanced 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 fruquintinib, HUTCHMED's ability to fund, implement and complete its further clinical development and commercialization plans for fruquintinib, the timing of these events, and the impact of the COVID-19 pandemic on general economic, regulatory and political conditions. In addition, as certain studies rely on the use of other drug products such as paclitaxel, tislelizumab and sintilimab as combination therapeutics with fruquintinib, such risks and uncertainties include assumptions regarding the safety, efficacy, supply and continued regulatory approval of these therapeutics. 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 announcement, whether as a result of new information, future events or circumstances or otherwise.

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[1] The Global Cancer Observatory, Stomach Cancer Fact Sheet. Accessed April 6, 2023.
[2] The Global Cancer Observatory, China Fact Sheet. Accessed April 6, 2023.
[3] Dasari NA, Lonardi S, et al. LBA25 – FRESCO-2: A global phase III multiregional clinical trial (MRCT) evaluating the efficacy and safety of fruquintinib in patients with refractory metastatic colorectal cancer. *Ann Oncol*. 2022 Sep;33(suppl_7): S808-S869. 10.1016/annonc/annonc1089.

By Order of the Board

Edith Shih
Non-executive Director and Company Secretary

Hong Kong, April 18, 2023

As at the date of this announcement, the Directors of the Company are:

Executive Directors:
Mr TO Chi Keung, Simon
(Chairman)
Dr Weiguo SU
(Chief Executive Officer and Chief Scientific Officer)
Mr CHENG Chig Fung, Johnny
(Chief Financial Officer)

Non-executive Directors:
Dr Dan ELDAR
Ms Edith SHIH
Mr Lefei SUN

Independent Non-executive Directors:
Mr Paul Rutherford CARTER
(Senior Independent Director)
Dr Karen Jean FERRANTE
Mr Graeme Allan JACK
Professor MOK Shu Kam, Tony