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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 Receives Approval to Commercialize ELUNATE® in Macau

— First homegrown innovative medicine approved in Macau based on China clinical data —

HUTCHMED (China) Limited ("HUTCHMED") today announces that it has received approval to market fruquintinib (ELUNATE® in China), a selective and potent oral inhibitor of vascular endothelial growth factor receptors ("VEGFR") 1, 2 and 3, in the Macau Special Administrative Region.

The approval follows the latest update to the provisions on new drug importation which allows drugs that have been approved in one or more specified jurisdictions to be authorized for use in Macau. Prior to the update, regulations required approval from at least two other jurisdictions. Fruquintinib was approved in Mainland China by the National Medical Products Administration ("NMPA") in September 2018 for the treatment of metastatic colorectal cancer ("CRC"). ELUNATE® will become the first homegrown innovative oncology drug to be marketed in Macau based on its approval by the NMPA.

Dr. Karen Atkin, Chief Operating Officer of HUTCHMED, said, "With the rapid pace of innovation in China's biotech sector in recent years, more homegrown innovative drugs are being developed and launched in China. We are encouraged by the Macau government's policy for registration of novel therapies, such as ELUNATE®, based on China clinical trial data. We now look forward to patients in Macau having full access to ELUNATE® in the coming months."

About Fruquintinib

Fruquintinib is a highly selective and potent oral inhibitor of VEGFR-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 favorable tolerability in patients treated to date, along with fruquintinib's low potential for drug-drug interactions based on preclinical assessment, suggests that it may also be highly suitable for combinations with other anti-cancer therapies.

About Fruquintinib Approval in China

Metastatic CRC in China: Fruquintinib was approved for marketing by the China NMPA in September 2018 and commercially launched in China in late November 2018 under the brand name ELUNATE®. It was included in the China National Reimbursement Drug List (NRDL) in January 2020. ELUNATE® is indicated for the treatment of patients with metastatic CRC who have been previously treated with fluoropyrimidine, oxaliplatin and irinotecan, including those who have previously received anti-VEGF therapy and/or anti-EGFR therapy (RAS wild type). Results of the FRESCO study[1], a Phase III pivotal registration trial of fruquintinib in 416 patients with metastatic CRC in China, were published in *The Journal of the American Medical Association*, JAMA, in June 2018 (clinicaltrials.gov identifier: NCT02314819).

About Fruquintinib Development

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:

Metastatic CRC in the U.S., Europe, and Japan: The U.S. Food and Drug Administration ("FDA") granted Fast Track Designation for the development of fruquintinib for the treatment of patients with metastatic CRC in June 2020. A Phase III registration study of fruquintinib for the treatment of patients with metastatic CRC, FRESCO-2, is currently underway in the U.S., Europe, Japan and Australia. Additional details of the study may be found at clinicaltrials.gov, using identifier NCT04322539. The U.S. FDA has acknowledged that the totality of the fruquintinib clinical data, including the FRESCO-2 study (if positive), the prior positive Phase III FRESCO study demonstrating improvement in overall survival that led to fruquintinib approval for metastatic CRC in China in 2018, and additional completed and ongoing supporting studies in metastatic CRC, could potentially support a New Drug Application (NDA) for the treatment of patients with advanced metastatic CRC (third-line and above). The FRESCO-2 study design was also reviewed and endorsed by The European Medicines Agency (EMA) and Japanese Pharmaceuticals and Medical Devices Agency (PMDA).

Gastric Cancer ("GC") in China: In October 2017, HUTCHMED initiated the FRUTIGA study, a randomized, double-blind, Phase III trial evaluating the efficacy and safety of fruquintinib combined with paclitaxel for second-line treatment of advanced gastric or esophagogastric junction ("GEJ") adenocarcinoma. The trial is designed to enroll patients who did not respond to first-line standard chemotherapy. Subjects receive either fruquintinib combined with paclitaxel or placebo combined with paclitaxel. Patients are randomized at a 1:1 ratio and stratified according to factors such as stomach vs. GEJ tumor type and performance status. The primary efficacy endpoint is overall survival (OS). Secondary efficacy endpoints include progression-free survival (as defined by RECIST 1.1), objective response rate, disease control rate, duration of response, and quality-of-life score (EORTC QLQ-C30, version 3.0). Biomarkers related to the antitumor activity of fruquintinib will also be explored (clinicaltrials.gov identifier: NCT03223376). In June 2020, HUTCHMED completed a planned interim data review. Based on the preset criteria, the Independent Data Monitoring Committee (IDMC) recommended that the trial continue.

Immunotherapy combinations: HUTCHMED has entered into collaboration agreements to evaluate the safety, tolerability and efficacy of fruquintinib in combination with PD-1 monoclonal antibodies, including with tislelizumab (BGB-A317, developed by BeiGene, Ltd) and sintilimab (IBI308, developed by Innovent Biologics, Inc. and marketed as TYVYT® in China).

- *Metastatic breast and endometrial cancers in the U.S.:* HUTCHMED initiated this open-label, multi-center, non-randomized, Phase Ib/II study in the U.S. to assess the safety and efficacy of fruquintinib in combination with tislelizumab in patients with advanced, refractory triple negative breast cancer ("TNBC") and endometrial cancer ("EMC"). This study is being conducted to investigate if the addition of fruquintinib can potentially induce activity to immune checkpoint inhibitor therapy in TNBC and EMC. Additional details of the study may be found at clinicaltrials.gov, using identifier NCT04577963. Safety and preliminary efficacy of fruquintinib were demonstrated in advanced solid tumors, including TNBC, in a Phase I study conducted in China (NCT01645215) and a Phase I/Ib study is ongoing in the United States (NCT03251378).

- *Gastric, colorectal and non-small cell lung cancers in China & Korea:* BeiGene, Ltd. initiated this open-label, multi-center, Phase II study to assess the safety and efficacy of fruquintinib in combination with tislelizumab in patients with advanced or metastatic, unresectable GC, CRC or non-small cell lung cancer ("NSCLC"). Additional details of the study may be found at clinicaltrials.gov, using identifier NCT04716634.

- *Solid tumors in China:* HUTCHMED initiated this open-label, multi-center, non-randomized, Phase II study to assess the safety and efficacy of fruquintinib in combination with sintilimab in patients with advanced EMC, cervical cancer, CRC, GC, hepatocellular carcinoma (HCC), NSCLC or renal cell carcinoma (RCC). Additional details of the study may be found at clinicaltrials.gov, using identifier NCT03903705. Preliminary results of certain cohorts were presented at the 2021 American Society of Clinical Oncology Annual Meeting (ASCO) and the Chinese Society of Clinical Oncology Annual Meeting (CSCO).

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 4,600 personnel across all its companies, at the center of which is a team of over 1,500 in oncology/immunology. Since inception it has advanced 12 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 regarding the therapeutic potential of fruquintinib for the treatment of patients with advanced CRC 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 New Drug Application approval of fruquintinib for the treatment of patients with advanced CRC in 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] Li J, Qin S, Xu RH, et al. Effect of Fruquintinib vs Placebo on Overall Survival in Patients With Previously Treated Metastatic Colorectal Cancer: The FRESCO Randomized Clinical Trial. *JAMA*. 2018;319(24):2486-2496. doi:10.1001/jama.2018.7855.

By Order of the Board

Edith Shih
Non-executive Director and Company Secretary

Hong Kong, March 1, 2022

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

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

Non-executive Directors:
Dr Dan ELDAR
Ms Edith SHIH

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