

Press Release

HUTCHMED Receives ELUNATE® (fruquintinib) Marketing Approval in Hong Kong for Treatment of Metastatic Colorectal Cancer

— First medicine approved under new “1+” mechanism by HKSAR Government, providing an important treatment option to patients in Hong Kong —

— ELUNATE® is the first oral targeted therapy approved in Hong Kong for metastatic colorectal cancer regardless of biomarker status or prior types of therapies in almost a decade —

— Fruquintinib already approved in mainland China, Macau SAR and the United States —

Hong Kong, Shanghai & Florham Park, NJ — Tuesday, January 30, 2024: HUTCHMED (China) Limited (Nasdaq/AIM:HCM, HKEX:13) (“[HUTCHMED](#)”) today announces that the marketing approval of ELUNATE® (fruquintinib) by the Pharmacy and Poisons Board of Hong Kong for the treatment of adult patients with previously treated metastatic colorectal cancer (“CRC”). ELUNATE® is a selective oral inhibitor of vascular endothelial growth factor (“VEGF”) receptors -1, -2 and -3, which play a pivotal role in blocking tumor angiogenesis.

This marks the first medicine to be approved under the new mechanism for registration of new drugs (“1+” mechanism) announced by the Government of the Hong Kong Special Administrative Region (“SAR”) in October last year. The mechanism officially commenced on November 1, 2023. It allows drugs which are beneficial for treatment of life-threatening or severely debilitating diseases to apply for registration for use in Hong Kong, if they have supporting local clinical data and recognition from relevant experts, when they have been approved by only one reference drug regulatory authority (instead of two otherwise). HUTCHMED submitted the application based on the approval of ELUNATE® from the China National Medical Products Administration (“NMPA”) supported with local clinical data. Fruquintinib was also [approved](#) by the U.S. Food and Drug Administration (“FDA”) in November 2023.

“We have made it a priority to do everything we can to bring the benefits of our innovative medicines to Hong Kong, our Company’s birthplace, and are excited to have our first medicine now approved here,” said **Dr Karen Atkin, Executive Vice President and Chief Operating Officer** of HUTCHMED. “We appreciate the streamlined drug registration process, showing the efficiency and commitment of the Hong Kong government to accelerate patient access to novel therapies. As we advance our pipeline of drug candidates in other cancer types and immunological diseases, we look forward to bringing additional therapies to benefit patients in Hong Kong.”

This approval indication is for patients with metastatic CRC who have previously received fluoropyrimidine, oxaliplatin and irinotecan-based chemotherapy, and those who have previously received or are not suitable for receiving anti-VEGF therapy or anti-epidermal growth factor receptor (EGFR) therapy (RAS wild-type).

“CRC is the second most common cancer type in Hong Kong with limited effective treatment options available, especially for previously treated metastatic CRC patients,” said **Dr Caron Li, Vice President, Oncology and Immunology, Hong Kong and Regional Markets** of HUTCHMED. “Fruquintinib, as a third-line treatment administered orally, demonstrated clinically meaningful benefits and a consistent safety profile in global clinical trials. We are honored to be the first through the “1+” mechanism and look forward to bringing this important treatment option to patients in Hong Kong as quickly as possible.

Dr Stephen Chan, an academic and a specialist in Medical Oncology, said, “Cancer remains to be a major challenge for the patients, their families and us as healthcare providers, with a rising trend in incidence over the past decades. The complex nature of cancer has made it particularly arduous for researchers to bring new advancements to the treatment. It is truly encouraging to see homegrown innovations taking on an increasingly active role to address the global unmet medical needs. We are excited to bring such meaningful treatment options to the cancer patients in Hong Kong.”

Fruquintinib will be sold and marketed in Hong Kong by HUTCHMED under the brand name ELUNATE®. It has been developed and commercialized in mainland China in partnership with Eli Lilly & Company. Takeda has the

exclusive worldwide license to fruquintinib outside of mainland China, Hong Kong and Macau. Takeda markets fruquintinib in the United States under the brand name FRUZAQLA™. Fruquintinib was added to the National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology (NCCN Guidelines) shortly after FDA approval.

About CRC in Hong Kong

CRC is a cancer that starts in either the colon or rectum. It was the second most common cancer in Hong Kong in 2021, with about 5,900 new patients diagnosed with CRC, and associated with about 2,300 deaths.¹ Although early-stage CRC can be surgically resected, metastatic CRC remains an area of high unmet need with poor outcomes and limited treatment options. Some patients with metastatic CRC may benefit from personalized therapeutic strategies based on molecular characteristics; however, most patients have tumors that do not harbor actionable mutations.^{2,3,4,5,6}

About Fruquintinib

Fruquintinib is a selective oral inhibitor of VEGF receptors (“VEGFR”) -1, -2 and -3. VEGFR inhibitors play a pivotal role in blocking tumor angiogenesis. Fruquintinib was designed to have enhanced selectivity that limits off-target kinase activity, allowing for high drug exposure, sustained target inhibition, and flexibility for the potential use as part of combination therapy. Fruquintinib has demonstrated a manageable safety profile and is being investigated in combination with other anti-cancer therapies.

About Fruquintinib Approval in China

Fruquintinib was approved for marketing in China in September 2018, where it is co-marketed by HUTCHMED and Lilly under the brand name ELUNATE®. It was included in the China National Reimbursement Drug List (NRDL) in January 2020. The approval was based on data from the FRESCO study, a Phase III pivotal registration trial of fruquintinib in 416 patients with metastatic CRC in China, which were [published](#) in The Journal of the American Medical Association, JAMA. Since its launch in China, fruquintinib has benefited more than 80,000 colorectal cancer patients as of mid-2023.

About Fruquintinib Approval in the United States

Fruquintinib received approval in the United States in November 2023, where it is marketed by Takeda under the brand name FRUZAQLA™. The approval was based on data from two large Phase III trials: the multi-regional FRESCO-2 trial, data from which were [published](#) in *The Lancet*, along with the FRESCO trial conducted in China. The trials investigated fruquintinib plus best supportive care versus placebo plus best supportive care in patients with previously treated mCRC. Both FRESCO and FRESCO-2 met their primary and key secondary efficacy endpoints and showed consistent benefit among a total of 734 patients treated with fruquintinib. Safety profiles were consistent across trials.

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 medicines marketed in China, the first of which is also marketed in the U.S. 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 fruquintinib for the treatment of patients with 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 efficacy and safety profile of fruquintinib; HUTCHMED and/or its licensees’ ability to fund, implement and complete its further clinical development and commercialization plans for fruquintinib; the timing

of these events; HUTCHMED and its licensees' ability to satisfy their obligations; actions of regulatory agencies, which may affect the initiation, timing and progress of clinical trials or the regulatory pathway for fruquintinib; HUTCHMED and its licensees' ability to successfully develop, manufacture and commercialize fruquintinib; and the impact of COVID-19 on general economic, regulatory and political conditions. In addition, as certain studies rely on the use of other drug products as combination therapeutics with fruquintinib, such risks and uncertainties include assumptions regarding the safety, efficacy, supply and continued regulatory approval of these therapeutics. Such forward-looking statements include, without limitation, statements regarding the plan to develop, manufacture and commercialize fruquintinib; and HUTCHMED's strategy, goals and anticipated milestones, business plans and focus. 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.

Medical Information

This press release contains information about products that may not be available in all countries, or may be available under different trademarks, for different indications, in different dosages, or in different strengths. Nothing contained herein should be considered a solicitation, promotion or advertisement for any prescription drugs including the ones under development.

CONTACTS

Investor Enquiries +852 2121 8200 / ir@hutch-med.com

Media Enquiries

Ben Atwell / Alex Shaw, FTI Consulting +44 20 3727 1030 / +44 7771 913 902 (Mobile) / +44 7779 545 055 (Mobile) / HUTCHMED@fticonsulting.com

Zhou Yi, Brunswick +852 9783 6894 (Mobile) / HUTCHMED@brunswickgroup.com

Nominated Advisor

Atholl Tweedie / Freddy Crossley / Daphne Zhang, +44 (20) 7886 2500
Panmure Gordon

¹ Hong Kong Cancer Registry, Hospital Authority. Colorectal Cancer in 2021. Available at https://www3.ha.org.hk/cancereg/pdf/factsheet/2021/colorectum_2021.pdf

² Bando H, et al. Therapeutic landscape and future direction of metastatic colorectal cancer. *Nat Rev Gastroenterol Hepatol* 2023; 20(5):306-322. doi:10.1038/s41575-022-00736-1.

³ D'Haene N, et al. Clinical application of targeted next-generation sequencing for colorectal cancer patients: a multicentric Belgian experience. *Oncotarget*. 2018;9(29):20761-20768. Published 2018 Apr 17. doi:10.18632/oncotarget.25099.

⁴ Venderbosch, et al. Mismatch repair status and braf mutation status in metastatic colorectal cancer patients: A pooled analysis of the Cairo, Cairo2, coin, and Focus Studies. *Clinical Cancer Res.*,2014; 20(20):5322-5330. doi:10.1158/1078-0432.ccr-14-0332.

⁵ Koopman, M., et al. Deficient mismatch repair system in patients with sporadic advanced colorectal cancer. *Br J Cancer*. 209;100(2), 266-273. doi:10.1038/sj.bjc.6604867.

⁶ Ahcene Djaballah S, et al. HER2 in Colorectal Cancer: The Long and Winding Road From Negative Predictive Factor to Positive Actionable Target. *Am Soc Clin Oncol Educ Book*. 2022;42:1-14. doi:10.1200/EDBK_351354.