

Hong Kong Press Release

HUTCHMED's ELUNATE® (fruquintinib) Listed with Full Subsidy in the Hong Kong Hospital Authority Drug Formulary

- *First innovative oncology medicine ever to get enlisted in HA Drug Formulary directly under the Special Drug category —*
- *First new drug approved by 1+ Mechanism listed in the Hospital Authority Drug Formulary —*
- *Rapid enlistment and 1+ approval accelerate patient access to an important treatment option —*
- *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 —*

Hong Kong — Thursday, October 3, 2024: HUTCHMED (China) Limited ("HUTCHMED") today announced that ELUNATE® (fruquintinib) was enlisted in the Drug Formulary of the Hong Kong Hospital Authority ("HA"), categorized as a Special Drug. Patients prescribed these new medicines under specific conditions in public hospitals and clinics are only required to pay for the standard fees and charges. ELUNATE® was approved by the Pharmacy and Poisons Board of Hong Kong in January 2024 for the treatment of adult patients with metastatic colorectal cancer ("CRC") who have been previously treated with available standard therapies.

"The fully subsidized enlistment in the HA's Drug Formulary has come less than six months following ELUNATE's approval under the new 1+ Mechanism. We can clearly see and truly appreciate the government's efforts to accelerate the pathway for novel therapies to reach local patients and remove financial barriers in accessing this treatment option," said **Dr Tony SK MOK, medical oncologist and Independent Non-executive Director of HUTCHMED**. "The HUTCHMED story began in Hong Kong. Since the approval of ELUNATE, the HUTCHMED team has been laser-focused on bringing this innovative treatment option as quickly as possible to patients in need. We are committed to continuing our mission to bring novel therapies to more patients in Hong Kong and beyond."

"Colorectal cancer is the second most prevalent cancer indication in Hong Kong," said **Mr Wai Kit CHAN, Chairman of the Cancer Patient Alliance**. "It is very encouraging to see the first cancer drug approved under the 1+ mechanism to be enlisted and categorized as a Special Drug. Not only does it mean patients have access to a meaningful treatment option, but the enlistment will also alleviate the burden that devastating diseases like cancer impose on these patients and their family. This has become possible through the hard work and collaboration of the local government and drug developers."

According to the HA, the enlistment is expected to take effect in mid-October, 2024. Fruquintinib was discovered and developed in-house by HUTCHMED and is marketed in Hong Kong under the brand name ELUNATE®.

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 the 1+ Mechanism and Fruquintinib Approval in Hong Kong

The Government of the Hong Kong Special Administrative Region announced a new mechanism for registration of new drugs (“1+” mechanism) in October 2023. 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).

ELUNATE® was granted marketing approval by the Pharmacy and Poisons Board of Hong Kong in January 2024, for the treatment of adult patients with previously treated metastatic CRC. This marked the first medicine to be approved under the 1+ mechanism, based on its approval in mainland China, supported with local clinical data.

About Fruquintinib

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

Fruquintinib is co-marketed in China in partnership with Eli Lilly & Company under the brand name ELUNATE®. ELUNATE® was included in the mainland China National Reimbursement Drug List (NRDL) in January 2020. Since its launch in China, over 100,000 patients with colorectal cancer have been treated with fruquintinib. Takeda has the exclusive worldwide license to fruquintinib outside of mainland China, Hong Kong and Macau, and markets fruquintinib under the brand name FRUZAQLA®. FRUZAQLA® is approved in Canada, the European Union, Japan, Switzerland, the United Kingdom and the United States, with additional regulatory applications in several other jurisdictions worldwide.

About HUTCHMED

HUTCHMED is an innovative, commercial-stage, biopharmaceutical company. It is committed to the discovery, 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, HUTCHMED has focused on bringing cancer drug candidates from in-house discovery to patients around the world, with its first three oncology medicines marketed in China, the first of which is also marketed in the US and Europe. For more information, please visit: www.hutch-med.com or follow us on [LinkedIn](#).

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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.

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; and HUTCHMED and its licensees' ability to successfully develop, manufacture and commercialize fruquintinib. 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.

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