

#### **Press Release**

# Chi-Med's Elunate® (Fruquintinib Capsules) Included in the National Reimbursement Drug List in China

London: Thursday, November 28, 2019: Hutchison China MediTech Limited ("Chi-Med") (AIM/Nasdaq: HCM) today announces that Elunate® (fruquintinib capsules), its national class 1 targeted anticancer drug for the treatment of patients with advanced colorectal cancer ("CRC"), has been included in the updated National Reimbursement Drug List ("NRDL") released by China's National Healthcare Security Administration ("NHSA").

"Elunate® is Chi-Med's first novel oncology drug commercially launched in China," commented Mr. Christian Hogg, Chief Executive Officer of Chi-Med. "The inclusion in the NRDL is a very important step forward to broaden availability and patient access to Elunate® across China. We now look forward to our partner, Eli Lilly and Company ("Lilly"), to capitalize on the opportunity provided by this important government policy to accelerate the accessibility of Elunate® to patients across China."

Dr. Yizhe Wang, Senior VP of Lilly China and Head of Oncology and Bio-medicines, said "We are very glad to see Elunate® included in the NRDL, and we want to thank the medical experts involved in the selection process for their support. Elunate® is a new treatment option for patients with advanced colorectal cancer, and has helped several thousand patients since its launch. We believe that this will further improve its affordability, help patients reduce their economic burden and improve their lives."

# About the National Reimbursement Drug List (NRDL)

In recent years, the government in China has placed great importance on improving the public affordability of drug use. The National Healthcare Security Administration ("NHSA") regularly convenes a broad network of experts in medicine, pharmacology and pharmacoeconomics to identify innovative drugs to be considered for inclusion in the NRDL. This has led to rapid 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.

In this 2019 update, the NHSA has added and renewed over 20 Category B oncology drugs to the NRDL, including Elunate<sup>®</sup>. Effective January 1, 2020, these newly included NRDL drugs will be made available in all state-run hospital pharmacies in China and reimbursement will commence for patients included in NHSA insurance schemes.

#### **About Colorectal Cancer**

Globally, colorectal cancer is the third most commonly diagnosed cancer and the second leading cause of cancer-related deaths, according to Frost & Sullivan. Nearly 1.8 million new cases of colorectal cancer occurred in 2018. There were about 140,300 new colorectal cancer cases in the United States and 426,700 in China during 2018. The five-year survival rate of colorectal cancer is currently estimated to be approximately 64.5% in the US and 56.9% in China. Metastatic colorectal cancer represents approximately 20% of newly diagnosed cases in the US and 25% in China.

# About Elunate® (fruquintinib capsules)

Elunate® (fruquintinib capsules) was approved for marketing in China by the National Medical Products Administration ("NMPA") in September 2018 and commercially launched by Lilly in late November 2018. Elunate® is for the treatment of patients with metastatic CRC that 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, a Phase III pivotal registration trial of fruquintinib in 416 patients with CRC in China, were published in The Journal of the American Medical Association, JAMA, in June 2018 (clinicaltrials.gov identifier: NCT02314819).



Fruquintinib is a highly selective and potent oral inhibitor of vascular endothelial growth factor receptor ("VEGFR") 1/2/3. 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 be highly suitable for combinations with other anti-cancer therapies.

Chi-Med retains all rights to fruguintinib outside of China and is partnered with Lilly in China.

#### **Ongoing Clinical Development of Fruguintinib**

Global development of fruquintinib in CRC: We are currently enrolling a Phase Ib study in the United States and have initiated planning for a Phase II/III registration study in the United States and Europe in third or fourth-line metastatic CRC patients who are resistant to or intolerant of prior treatment with Stivarga® or Lonsurf® (a cytotoxic chemotherapy agent approved in third-line CRC in various countries excluding China). We expect to begin this study in 2020.

Gastric Cancer in China: In October 2017, we initiated the FRUTIGA study, a randomized, double-blind, Phase III study in China to evaluate the efficacy and safety of <u>fru</u>quintinib combined with paclitaxel (<u>Taxol</u>®) compared with paclitaxel monotherapy <u>in</u> the treatment of patients with advanced <u>gastric adenocarcinoma</u> or gastroesophageal junction (GEJ) adenocarcinoma who have progressed after first-line standard chemotherapy (clinicaltrials.gov identifier: <u>NCT03223376</u>). Over 500 patients are expected to be enrolled into the FRUTIGA study at a 1:1 ratio with the primary endpoint of this study being overall survival ("OS"). Enrollment is expected to be completed in mid-2020 with top line results in early 2021. In April 2019, we conducted an interim analysis of the FRUTIGA study for futility. The analysis evaluated PFS and OS trends after six months of therapy for the first 100 patients recruited into the study. The Independent Data Monitoring Committee (IDMC) recommended to continue the study without changes.

Lung cancer in China: Fruquintinib is being studied in a Phase II study in combination with Iressa® (gefitinib) in patients with untreated advanced or metastatic non-small cell lung cancer (clinicaltrials.gov identifier NCT02976116). Preliminary results were highlighted at the 18<sup>th</sup> World Conference on Lung Cancer in October 2017. The study is now complete and results were presented in an oral presentation at the European Society of Medical Oncology (ESMO) Asia Congress on November 23, 2019.

Immunotherapy combinations: In November 2018, we entered into two <u>collaboration agreements</u> to evaluate the safety, tolerability and efficacy of fruquintinib in combination with checkpoint inhibitors. These include a global collaboration with Innovent to evaluate the combination of fruquintinib with Innovent's Tyvyt® (sintilimab, IBI308), a PD-1 monoclonal antibody approved in China in late 2018 and a China collaboration with Genor to evaluate the fruquintinib combination with genolimzumab (GB226), a PD-1 monoclonal antibody being developed by Genor. Phase I studies have been initiated to establish the safe and effective dose regimens for the fruquintinib combinations with either Tyvyt® or genolimzumab, respectively.

### **About Chi-Med**

Chi-Med (AIM/Nasdaq: HCM) is an innovative biopharmaceutical company which researches, develops, manufactures and markets pharmaceutical products. Its Innovation Platform, Hutchison MediPharma, has about 490 scientists and staff focusing on discovering, developing and commercializing targeted therapeutics and immunotherapies in oncology and autoimmune diseases. It has a portfolio of eight cancer drug candidates currently in clinical studies around the world. Chi-Med's Commercial Platform manufactures, markets, and distributes prescription drugs and consumer health products, covering an extensive network of hospitals across China.

Chi-Med is headquartered in Hong Kong and is dual-listed on the AIM market of the London Stock Exchange and the Nasdaq Global Select Market. For more information, please visit: <a href="https://www.chi-med.com">www.chi-med.com</a>.

#### 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 Chi-Med's current expectations regarding future events, including its expectations for the commercialization of Elunate® in China, the potential benefits of Elunate®, the further clinical development of fruquintinib, plans to initiate further



clinical studies for fruquintinib, 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 Elunate®, the ability of NRDL inclusion to broaden availability and patient access to Elunate®, 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 candidate fruguintinib, including as a combination therapy, to meet the primary or secondary endpoint 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 Tyvyt® and genolimzumab as combination therapeutics with fruguintinib. such risks and uncertainties include assumptions regarding the safety, efficacy, supply and continued regulatory approval for Tyvyt® and genolimzumab. 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 Chi-Med's filings with the U.S. Securities and Exchange Commission and on AIM. Chi-Med 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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