



HUTCHISON CHINA MEDITECH

## Press Release

# Chi-Med Announces Fruquintinib Granted U.S. FDA Fast Track Designation for Metastatic Colorectal Cancer

**London: Thursday, June 18, 2020:** Hutchison China MediTech Limited (“[Chi-Med](#)”) (Nasdaq/AIM: HCM) today announces that the U.S. Food and Drug Administration (“FDA”) has granted Fast Track Designation for the development of fruquintinib, for the treatment of patients with metastatic colorectal cancer (“mCRC”) who have been previously treated with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, an anti-vascular endothelial growth factor (VEGF) biological therapy, and, if RAS wild-type, an anti-epidermal growth factor receptor (EGFR) therapy.

Chi-Med is initiating a Phase III registration study, known as the FRESCO-2 study, in refractory mCRC in the U.S., Europe and Japan (clinicaltrials.gov identifier: [NCT04322539](#)). FRESCO-2 is expected to start enrolling patients in mid-2020. The U.S. FDA 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 mCRC in China in 2018; and additional completed and ongoing supporting studies in mCRC; could support a New Drug Application (“NDA”) for the treatment of patients with mCRC in the third-line setting. The adequacy of the data to support a specific indication will be assessed during the review of a New Drug Application.

### About Fast Track Designation

The FDA [Fast Track Designation](#) is one of several approaches utilized by the U.S. FDA to expedite development and review of potential medicines for serious conditions and that fulfill unmet medical needs. A potential new medicine may fill an unmet medical need by being the first therapy to address a specific serious condition, offer clinically significant advantages over available therapies, act via a different mechanism of action than available therapies, or have a benefit in patients who are unresponsive to or intolerant of available therapies. Programs that receive Fast Track Designation are entitled to more frequent interactions with the U.S. FDA on drug development plan, as well as eligibility for accelerated approval, priority review, and rolling review.<sup>1</sup>

### About Colorectal Cancer (“CRC”) in the U.S.

CRC is the third most common cancer worldwide, causing more than 880,000 deaths in 2018.<sup>2</sup> In the U.S., CRC is the fourth most common cause of new cancer cases, but the second leading cause of cancer deaths.<sup>3</sup> It is estimated that in 2020, 147,950 people will be diagnosed with CRC and 53,200 people will die from CRC in the U.S.<sup>4</sup>

### About Fruquintinib

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 also be highly suitable for combinations with other anti-cancer therapies.

Chi-Med retains all rights to fruquintinib outside of China and is partnered with Eli Lilly and Company (“Lilly”) in China.

### About Fruquintinib in mCRC

Fruquintinib was approved for marketing by the China National Medical Products Administration (“NMPA”) in September 2018 and commercially launched by Lilly in late November 2018 under the brand name Elunate®. Elunate® is for the treatment of patients with mCRC 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 mCRC in China, were [published](#) in The Journal of the American Medical Association, JAMA, in June 2018 (clinicaltrials.gov identifier: [NCT02314819](#)).

In December 2017, Chi-Med initiated a multi-center, open-label, Phase Ib clinical study to evaluate the safety, tolerability and pharmacokinetics of fruquintinib in U.S. patients with advanced solid tumors (clinicaltrials.gov identifier: [NCT03251378](#)). The study progressed into proof-of-concept trials in 2019, including patients with mCRC and metastatic breast cancer. In February 2020, an End of Phase II (EOP2) meeting was held with the U.S. FDA, and regulatory interactions with the European Medicines Agency (EMA) and Japanese Pharmaceuticals and Medical Devices Agency (PMDA) are also underway.

## Other Fruquintinib Development

**Gastric Cancer in China:** In October 2017, Chi-Med 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 GEJ adenocarcinoma. The trial is designed to enroll patients who did not respond to first-line standard chemotherapy. Subjects will receive either fruquintinib combined with paclitaxel or placebo combined with paclitaxel. Patients will be 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. 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. Additional details about this study can be found at clinicaltrials.gov, using identifier [NCT03223376](#). In June 2020, Chi-Med completed a planned interim data review. Based on the preset criteria, the Independent Data Monitoring Committee (IDMC) recommended that the trial continue.

**Immunotherapy combinations:** Chi-Med has entered into three collaboration agreements to evaluate the safety, tolerability and efficacy of fruquintinib in combination with programmed death-1 (PD-1) monoclonal antibodies, including with [tislelizumab](#) (BGB-A317), [Tyvyt®](#) (sintilimab, IBI308) and [geptanolimab](#) (GB226, genolimzumab).

## About Chi-Med

Chi-Med (Nasdaq/AIM: HCM) is an innovative biopharmaceutical company committed, over the past twenty years, to the discovery and global development of targeted therapies and immunotherapies for the treatment of cancer and immunological diseases. It has a portfolio of eight cancer drug candidates currently in clinical studies around the world and extensive commercial infrastructure in its home market of China. For more information, please visit: [www.chi-med.com](http://www.chi-med.com).

## 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 regarding the potential future benefits of Fast Track Designation and the anticipated clinical development of fruquintinib in CRC in the United States as well as Chi-Med’s clinical development plans for fruquintinib in other jurisdictions and indications. Forward-looking statements involve risks and uncertainties. Such risks and uncertainties include, among other things, assumptions regarding 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 fruquintinib, including as a combination therapy, to meet the primary or secondary endpoint of a study, its 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 combination therapeutics with fruquintinib, such risks and uncertainties include assumptions regarding the safety, efficacy, supply and continued regulatory approval of such combination 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 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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<sup>1</sup> Source: Food and Drug Administration, “Expedited Programs for Serious Conditions – Drugs and Biologics”:  
<https://www.fda.gov/files/drugs/published/Expedited-Programs-for-Serious-Conditions-Drugs-and-Biologics.pdf>

<sup>2</sup> The Global Cancer Observatory, colorectal cancer fact sheet. [https://gco.iarc.fr/today/data/factsheets/cancers/10\\_8\\_9-Colorectum-fact-sheet.pdf](https://gco.iarc.fr/today/data/factsheets/cancers/10_8_9-Colorectum-fact-sheet.pdf)

<sup>3</sup> SEER, Cancer Stat Facts: Common Cancer Sites. <https://seer.cancer.gov/statfacts/html/common.html>

<sup>4</sup> SEER, Cancer Stat Facts: Colorectal Cancer. <https://seer.cancer.gov/statfacts/html/colorect.html>