



HUTCHISON CHINA MEDITECH LIMITED

## Press Release

### Chi-Med Completes Enrollment of 527 Patients in Pivotal Phase III FALUCA Trial with Fruquintinib in Lung Cancer

**London: Tuesday, February 13, 2018:** Hutchison China MediTech Limited (“Chi-Med”) (AIM/Nasdaq: HCM) has completed patient enrollment of **FALUCA**, its Phase III pivotal trial of fruquintinib in advanced, third-line, non-small cell **lung cancer** (“NSCLC”) patients in China. Fruquintinib is a highly selective and potent oral inhibitor of vascular endothelial growth factor receptors (“VEGFR”) 1, 2 and 3, that has met its primary endpoint in several Phase II and III clinical trials in China for the treatment of lung, colorectal and gastric cancers. Top-line FALUCA data is expected to be reported in late 2018 when the overall survival (“OS”) data is mature and, subject to a positive outcome, would be followed by a second New Drug Application (“NDA”) submission thereafter. Fruquintinib’s first NDA, for the treatment of colorectal cancer, was submitted to the China Food and Drug Administration (“CFDA”) in June 2017.

#### About Fruquintinib

Fruquintinib (HMPL-013) is a highly selective small molecule drug candidate that has been shown to inhibit VEGFR 24 hours a day via an oral dose, with lower off-target toxicities compared to other targeted therapies. Its tolerability, along with its clean drug-drug interaction profile demonstrated to date, may enable rational combination with other cancer therapies such as in our ongoing clinical trials of fruquintinib in combination with chemotherapy and targeted therapy. VEGFR plays a pivotal role in tumor-related angiogenesis.

#### About FALUCA

FALUCA is a randomized, double-blind, placebo-controlled, multi-center, Phase III registration study of fruquintinib targeted at treating patients with advanced non-squamous NSCLC, who have failed two lines of systemic chemotherapy. Patients were randomised at a 2:1 ratio to receive either 5mg of fruquintinib orally once per day, on a three-weeks-on / one-week-off cycle, plus best supportive care (“BSC”); or placebo plus BSC. Randomization was stratified by EGFR gene status and history of treatment by VEGF inhibitors. The primary endpoint is OS, with secondary endpoints including progression free survival (“PFS”), objective response rate (ORR), disease control rate (DCR) and duration of response (DoR). Additional details about this study can be found at [clinicaltrials.gov](http://clinicaltrials.gov), using identifier [NCT02691299](https://clinicaltrials.gov/ct2/show/study/NCT02691299).

It was initiated following a similar Phase II clinical trial in 91 third-line NSCLC patients that succeeded in meeting its primary efficacy endpoint of PFS, with no unexpected safety issues. Results were highlighted in an oral presentation at the 17<sup>th</sup> World Conference on Lung Cancer on December 6, 2016 ([clinicaltrials.gov](http://clinicaltrials.gov) identifier [NCT02590965](https://clinicaltrials.gov/ct2/show/study/NCT02590965)).

#### Other Fruquintinib Development Programs

*Lung cancer in China:* Along with FALUCA, fruquintinib is concurrently being studied in a Phase II study in combination with Iressa<sup>®</sup> (gefitinib) in first-line setting for patients with advanced or metastatic NSCLC ([clinicaltrials.gov](http://clinicaltrials.gov) identifier [NCT02976116](https://clinicaltrials.gov/ct2/show/study/NCT02976116)). Preliminary results were highlighted in an [oral presentation](#) at the 18<sup>th</sup> World Conference on Lung Cancer on October 16, 2017.

*Colorectal cancer in China:* The CFDA acknowledged [acceptance of the NDA](#) for fruquintinib for the treatment of patients with advanced colorectal cancer (“CRC”) in June 2017. Fruquintinib was subsequently awarded priority review status in view of its significant clinical value, according to a CFDA announcement in September 2017. The NDA is supported by data from the successful FRESCO study, a Phase III pivotal registration trial of fruquintinib in 416 patients with CRC in China, which was highlighted in an [oral presentation](#) at the American Society of Clinical Oncology Annual Meeting held on June 5, 2017 ([clinicaltrials.gov](http://clinicaltrials.gov) identifier [NCT02314819](https://clinicaltrials.gov/ct2/show/study/NCT02314819)). The FRESCO study followed an initial Phase I trial in 40 solid tumor patients, a Phase Ib study in 62 CRC patients, and a Phase II clinical trial in 71 CRC patients.

*Gastric cancer in China:* In October 2017, Chi-Med initiated a pivotal Phase III clinical trial of fruquintinib in combination with Taxol<sup>®</sup> (paclitaxel), known as the FRUTIGA study, for the treatment of over 500 patients with advanced gastric or gastroesophageal junction (GEJ) adenocarcinoma who have progressed after first-line standard chemotherapy (clinicaltrials.gov identifier [NCT03223376](#)). The FRUTIGA study followed a Phase I/II clinical trial in 34 patients that demonstrated that combination therapy of fruquintinib and Taxol<sup>®</sup> in such patients was generally well-tolerated with promising tumor response (clinicaltrials.gov identifier [NCT02415023](#)).

In China, fruquintinib is jointly developed with Eli Lilly and Company.

*United States bridging trial:* In December 2017, Chi-Med initiated a multi-center, open-label, Phase I clinical study to evaluate the safety, tolerability and pharmacokinetics of fruquintinib in U.S. patients with advanced solid tumors. Additional details about this study may be found at clinicaltrials.gov, using identifier [NCT03251378](#).

## **About Chi-Med**

Chi-Med is an innovative biopharmaceutical company which researches, develops, manufactures and sells pharmaceuticals and healthcare products. Its Innovation Platform, Hutchison MediPharma Limited, focuses on discovering and developing innovative therapeutics in oncology and autoimmune diseases for the global market. Its Commercial Platform manufactures, markets, and distributes prescription drugs and consumer health products in China.

Chi-Med is majority owned by the multinational conglomerate CK Hutchison Holdings Limited (SEHK: 1). 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 for the clinical development of fruquintinib, plans to initiate 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 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 fruquintinib to meet the primary or secondary endpoint of a study, to obtain regulatory approval in different jurisdictions, to gain commercial acceptance after obtaining regulatory approval, the potential market of fruquintinib for a targeted indication and the sufficiency of funding. 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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