



HUTCHISON CHINA MEDITECH LIMITED

Chi-Med Completes Enrollment of 416 Patients in Pivotal Phase III FRESKO Trial with Fruquintinib in Colorectal Cancer

London: Friday, May 13, 2016: Hutchison China MediTech Limited (“Chi-Med”) (AIM/Nasdaq: HCM) today announces that it has completed patient enrollment of FRESKO, its Phase III pivotal trial of fruquintinib (HMPL-013) in third-line locally advanced or metastatic colorectal cancer (“CRC”) in China, where an estimated 390,000 new cases of CRC were diagnosed in 2012.

Fruquintinib is a highly selective small molecule drug candidate that has been shown to inhibit vascular endothelial growth factor receptors (VEGFR) 24 hours a day via an oral dose, without known off-target toxicities. The FRESKO trial is evaluating the efficacy of fruquintinib versus placebo, with all patients receiving best supportive care (“BSC”). The primary endpoint is overall survival (“OS”).

“Completing enrollment of our first Phase III clinical trial is an important milestone for our company,” said Christian Hogg, Chief Executive Officer of Chi-Med. “We believe fruquintinib has the potential to significantly improve outcomes in several types of solid tumors. While we wait for the FRESKO CRC data to mature over the balance of the year, we are focused on accelerating the ongoing Phase III FALUCA pivotal trial in non-small cell lung cancer (“NSCLC”), and launching additional studies of fruquintinib, including a Phase II study in gastric cancer in combination with paclitaxel, new studies in the U.S., and certain exploratory studies in combination with other oncology agents.”

The FRESKO trial was launched following a 71-patient, randomized, double-blind Phase II trial of fruquintinib as a third-line treatment for metastatic CRC. The study met its primary endpoint of progression free survival (“PFS”) of 4.73 months for patients receiving fruquintinib versus 0.99 month for the placebo arm, with a hazard ratio of 0.30 ($p < 0.001$), and had no unexpected safety issues. The positive data resulted in a US\$18 million payment to Chi-Med from its partner, Eli Lilly and Company (“Lilly”).

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Notes to Editors

About the FRESCO CRC Trial

FRESCO is a randomized, double-blind, placebo-controlled, multicenter, Phase III pivotal trial in patients with locally advanced or metastatic CRC who have failed at least two prior systemic antineoplastic therapies (i.e. third-line), including fluoropyrimidine, oxaliplatin and irinotecan. The results of the preceding Phase II trial were presented at the 2015 European Cancer Congress (ESMO; [see poster](#)).

The first patient was dosed on December 12, 2014. A total of 416 patients were randomized 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 BSC; or placebo plus BSC.

The primary endpoint is OS, with secondary endpoints including PFS, objective response rate, disease control rate and duration of response. Once a pre-specified number of OS events (deaths) have occurred, data analysis will commence. We expect to publish top-line results at the end of 2016 or in early 2017.

Additional details of the FRESCO study may be found at clinicaltrials.gov, using identifier [NCT02314819](#).

According to the 2012 Chinese Cancer Registry annual report, CRC was 10.3% of the total China cancer incidence, or about 390,000 new cases.

Other Fruquintinib Clinical Development Overview

In addition to CRC, fruquintinib is also in clinical development for lung cancer and gastric cancer.

Lung: In June 2014, Chi-Med initiated a second proof-of-concept (“POC”) Phase II trial of fruquintinib in third-line NSCLC patients in China. 91 patients received fruquintinib plus BSC or placebo plus BSC at a 2:1 ratio. Top-line results demonstrated that the trial succeeded in meeting the primary efficacy endpoint of PFS, with no unexpected safety issues. Detailed results will be presented at an upcoming scientific conference in 2016. The positive results of this trial triggered a US\$10 million payment from Lilly and the initiation of FALUCA in December 2015, a 520-patient Phase III pivotal study of fruquintinib in third-line NSCLC patients in China. Additional details about this study may be found at clinicaltrials.gov, using identifier [NCT02691299](#).

Gastric: Chi-Med is nearing completion of a Phase Ib dose-finding study of fruquintinib, in combination with paclitaxel, in second-line gastric cancer patients and plans to initiate a Phase II POC study in 2016. Additional details about this study may be found at clinicaltrials.gov, using identifier [NCT02415023](#).

Chi-Med receives reimbursement for costs associated with clinical development in China from Lilly according to a pre-specified cost-sharing rate.

About Chi-Med

Chi-Med is a China-based, globally-focused healthcare group which researches, develops, manufactures and sells pharmaceuticals and health-related consumer products. Its Innovation Platform, Hutchison MediPharma Limited, is focused on discovering, developing and commercializing innovative therapeutics in oncology and autoimmune diseases. Its pipeline of eight novel oral compounds for cancer and inflammation is in development in North America, Europe, Australia and Greater China.

Chi-Med's 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: 0001). For more information, please visit: www.chi-med.com.

Forward-Looking Statements

This announcement 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 in solid tumor indications, 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 a drug candidate to meet the primary or secondary endpoint of a study, the ability of a drug candidate to obtain regulatory approval in different jurisdictions, the ability of a drug candidate to gain commercial acceptance after obtaining regulatory approval, the potential market of a drug candidate 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 announcement, whether as a result of new information, future events or circumstances or otherwise.