



HUTCHISON CHINA MEDITECH LIMITED

Press Release

Chi-Med Initiates a Phase II Combination Study of Fruquintinib with Iressa[®] (gefitinib) in First-Line Non-Small Cell Lung Cancer

London: Monday, January 16, 2017: Hutchison China MediTech Limited (“Chi-Med”) (AIM/Nasdaq: HCM) today announces that it has initiated a Phase II study of a combination therapy using fruquintinib and Iressa[®] in the first-line setting for patients with advanced or metastatic non-small cell lung cancer (“NSCLC”) in China. Fruquintinib is a highly selective and potent oral inhibitor of vascular endothelial growth factor receptors (“VEGFR”). The first drug dose was administered on January 9, 2017.

This Phase II combination therapy study is a multi-center, single-arm, open-label study. The objectives are to evaluate the safety and tolerability as well as preliminary efficacy of the combination therapy in the first-line setting for advanced or metastatic non-squamous NSCLC patients with epidermal growth factor receptor (“EGFR”) activating mutations. Treatment will be continued until disease progression or intolerable toxicity occurs. Additional details about this study may be found at clinicaltrials.gov, using identifier [NCT02976116](https://clinicaltrials.gov/ct2/show/study/NCT02976116).

About NSCLC and Tyrosine Kinase Inhibitors (“TKIs”) to address EGFR-driven NSCLC

At an advanced stage, tumors secrete large amounts of vascular endothelial growth factors (“VEGF”), which are protein ligands that stimulate formation of excessive vasculature (angiogenesis) around the tumor in order to provide greater blood flow, oxygen, and nutrients to the tumor. VEGF and VEGFR play a pivotal role in tumor-related angiogenesis. Inhibition of the VEGF/VEGFR pathway represents an important therapeutic strategy in blocking the development of new blood vessels essential for tumors to grow and invade.

Every year, it is estimated that approximately 1.7 million new patients around the world are diagnosed with NSCLC, according to Frost & Sullivan. Lung cancer is the leading cause of cancer death among both men and women, accounting for about one-quarter of all cancer deaths (American Cancer Society), and more than breast, prostate and colorectal cancers combined.

NSCLC patients with EGFR activating mutations, which are an estimated 10-15% of NSCLC patients in the United States and Europe and 30-40% of NSCLC patients in Asia, are particularly sensitive to treatment with currently available EGFR-TKIs. However, tumors almost always develop resistance to treatment leading to disease progression. Combining therapies that inhibit different signaling pathways has the potential to be more effective than inhibition of a single pathway and to overcome tumor resistance.

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 without known off-target toxicities. It is currently under the joint development in China by Chi-Med and its partner Eli Lilly and Company. Two late-stage, pivotal Phase III registration studies are ongoing in colorectal cancer (FRESCO) and lung cancer (FALUCA). In addition, fruquintinib is also in clinical development for gastric cancer.

Colorectal: The FRESCO trial is a randomized, double-blind, placebo-controlled, multi-center, Phase III pivotal trial in patients with locally advanced or metastatic colorectal cancer who have failed at least two prior systemic antineoplastic therapies, including fluoropyrimidine, oxaliplatin and irinotecan. Enrollment was completed in May 2016. 416 patients were randomized at a 2:1 ratio to receive either: 5 mg of fruquintinib orally once per day, on a three-weeks-on / one-week-off cycle, plus best supportive care (“BSC”); or placebo plus BSC. The primary endpoint is overall survival (“OS”), with secondary endpoints including progression free survival (“PFS”), objective response rate, disease control rate and duration of response. Additional details of the FRESCO study may be found at clinicaltrials.gov, using identifier [NCT02314819](https://clinicaltrials.gov/ct2/show/study/NCT02314819).

Lung: The FALUCA trial is a randomized, double-blind, placebo-controlled, multi-center, Phase III registration study targeted at treating patients with advanced non-squamous NSCLC, who have failed two lines of systemic chemotherapy. Enrollment began in December 2015. Patients are randomized at a 2:1 ratio to receive either: 5 mg 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, ORR, DCR and duration of response. Chi-Med plans to enroll approximately 520 patients in about 45 centers across China. Additional details about FALUCA study may be found at clinicaltrials.gov, using identifier [NCT02691299](https://clinicaltrials.gov/ct2/show/study/NCT02691299).

Gastric: Chi-Med completed a Phase Ib dose finding study of fruquintinib in combination with paclitaxel, which established a combination regimen that was well tolerated. Additional details about this study may be found at clinicaltrials.gov, using identifier [NCT02415023](https://clinicaltrials.gov/ct2/show/study/NCT02415023).

About Iressa[®], an EGFR-TKI

Iressa[®] (gefitinib) is a targeted monotherapy developed by AstraZeneca for the treatment of patients with advanced or metastatic EGFR activating mutation positive NSCLC. Iressa[®] acts by inhibiting the tyrosine kinase enzyme in the EGFR, thus blocking the transmission of signals involved in the growth and spread of tumors. Iressa[®] is approved in 91 countries worldwide.

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: 0001). For more information, please visit: 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. In addition, as certain studies rely on the use of Iressa[®] as a combination therapeutic with fruquintinib, such risks and uncertainties include assumptions regarding the safety, efficacy, supply and continued regulatory approval of Iressa[®]. 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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