



HUTCHISON CHINA MEDITECH LIMITED

Initiation of fruquintinib Phase III registration trial in non-small cell lung cancer

London: Tuesday, 8 December 2015: Hutchison China MediTech Limited (“Chi-Med”) (AIM: HCM) today announces that Hutchison MediPharma Limited (“HMP”), its drug R&D subsidiary, has initiated FALUCA, a Phase III registration study for fruquintinib (HMPL-013) in third-line non-squamous non-small cell lung cancer (“NSCLC”) patients in China. Fruquintinib is an investigational small molecule which selectively inhibits vascular endothelial growth factor receptors (“VEGFR”). Preparations and site selection began in August this year, with the first patient dosed on 8 December 2015.

FALUCA is a randomised, double-blind, placebo-controlled, multi-centre, Phase III registration study targeted at treating patients with advanced non-squamous NSCLC, who have failed two lines of systemic chemotherapy. Patients will be 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. The primary endpoint is overall survival, with secondary endpoints including progression free survival, objective response rate, disease control rate and duration of response. HMP plans to enrol approximately 520 patients in about 45 centres across China, with top-line results expected in 2017.

In September this year, Chi-Med announced that the Phase II proof-of-concept (“POC”) trial of fruquintinib in patients with third-line non-squamous NSCLC in China had successfully achieved the primary endpoint of progression free survival (“PFS”) with no unexpected safety issues. The detailed results of this Phase II study will be presented in a global scientific conference in 2016.

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Notes to Editors

About fruquintinib

Fruquintinib is designed as a highly selective and potent oral inhibitor of VEGFR, namely VEGFR1, VEGFR2, and VEGFR3. Angiogenesis is an important mechanism in tumour pathogenesis, and inhibition of VEGF-mediated angiogenesis has been important in the treatment of a variety of cancers.

In addition to the FALUCA Phase III registration study in third-line non-squamous NSCLC detailed above, fruquintinib is being developed in metastatic colorectal cancer (“mCRC”) and gastric cancer:

Metastatic colorectal cancer fruquintinib monotherapy – HMP reported full results of the first POC Phase II study of fruquintinib in a randomised, double-blind, placebo-controlled, multi-centre Phase II clinical trial targeted at patients with third-line mCRC. This Phase II study showed fruquintinib had clearly met the primary endpoint of PFS with no unexpected safety issues. 71 patients were enrolled in the trial, and median PFS was 4.73 months in the fruquintinib arm compared with 0.99 month in the placebo arm, with a hazard ratio of 0.30 ($p < 0.001$).

As a result, HMP initiated FRESCO, a Phase III registration study in patients with mCRC who have failed at least two prior systemic cancer therapies, including flouropyrimidine, oxaliplatin and irinotecan. HMP plans to enrol more than 400 patients in about 25 centres across China for this study, with top-line results expected in 2016.

Gastric cancer fruquintinib combination with paclitaxel – HMP 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 early 2016.

Pursuant to the fruquintinib licensing, co-development, and commercialisation agreement entered into by HMP and Eli Lilly and Company in October 2013, HMP will receive reimbursements for costs associated with both FRESCO and FALUCA according to a pre-specified cost-sharing rate.

About VEGF and NSCLC in China

At an advanced stage, tumours secrete large amounts of VEGF, a protein ligand, to stimulate formation of excessive vasculature (angiogenesis) around the tumour in order to provide greater blood flow, oxygen, and nutrients to the tumour. VEGF and VEGF receptors play a pivotal role in tumour-related angiogenesis, and inhibition of the VEGF/VEGFR pathway. This represents an important therapeutic strategy in blocking the development of new blood vessels essential for tumours to grow and invade.

Lung cancer is one of the leading malignant causes of death in the world, and there were an estimated 1.9 million new cases of lung cancer diagnosed worldwide in 2014, of which approximately 36% were from China. The very high prevalence of lung cancer in China as compared to the rest of the world is thought to be linked in part to the high incidence of cigarette smoking in the country. The number of new cases annually is expected to grow and reach an estimated 2.3 million globally by 2020. There are two major types of lung cancer: small cell lung cancer and NSCLC. NSCLC is a disease in which malignant cancer cells form in the tissues of the lung, and can be further classified based on cancer cell types with the most common ones including squamous cell carcinoma, large cell carcinoma and adenocarcinoma.

To date, several anti-VEGF/VEGFR agents have shown clinical efficacy against a number of tumour types. Given the scale and growth in the China oncology market, the market for VEGF/VEGFR inhibitors in China is expected to develop quickly in the next few years.

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 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 announcement contains forward-looking statements that reflect Chi-Med's current expectations regarding future events, including its plans to initiate clinical studies for its drug candidates in the targeted 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 enrolment 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 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. 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.