

# Proof-of-concept study of fruquintinib in non-small cell lung cancer triggers milestone payment

**London: Friday, 23 October 2015**: Hutchison China MediTech Limited ("Chi-Med") (AIM: HCM) today announces that Hutchison MediPharma Limited ("HMP"), its drug R&D subsidiary, is set to receive a US\$10 million milestone payment, in the fourth quarter of 2015, from its partner Eli Lilly and Company ("Lilly").

The milestone payment was triggered by the positive proof-of-concept ("POC") Phase II study of fruquintinib in the treatment of patients with advanced non-squamous non-small cell lung cancer ("NSCLC") in China. Last month, top line results of this POC Phase II study were reported showing fruquintinib met the primary endpoint of progression free survival ("PFS"). The adverse events demonstrated in the POC study are consistent with the known safety profile for fruquintinib. Full details of the NSCLC Phase II POC results will be presented at a global medical conference in 2016.

Pursuant to the fruquintinib licensing, co-development, and commercialisation agreement entered into by HMP and Lilly in October 2013, HMP will receive reimbursements for costs associated with further clinical development in China for NSCLC according to a pre-specified cost-sharing rate. We now intend to initiate a pivotal Phase III study of fruquintinib in nonsquamous NSCLC in China.

Including this US\$10 million NSCLC POC milestone payment, HMP will have received a total of US\$31.7 million from Lilly so far this year.

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### Notes to Editors

### About fruquintinib

Fruquintinib is designed as a highly selective and potent oral inhibitor of vascular endothelial growth factor ("VEGF") receptors ("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 planned pivotal Phase III study in NSCLC, fruquintinib is being developed in metastatic colorectal cancer 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 in patients with third-line metastatic colorectal cancer. This Phase II study showed fruquintinib had met the primary endpoint of PFS. The adverse events demonstrated in this POC study are consistent with the known safety profile for fruquintinib. 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 metastatic colorectal cancer, 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.

## 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.