

# Second proof-of-concept trial of fruquintinib achieves its primary endpoint

London: Wednesday, 2 September 2015: Hutchison China MediTech Limited ("Chi-Med") (AIM: HCM) today announces that Hutchison MediPharma Limited ("HMP"), its drug R&D subsidiary, successfully achieved the primary endpoint in the second proof-of-concept ("POC") trial of fruquintinib in patients with advanced non-squamous non-small cell lung cancer ("NSCLC") in China. The top-line results demonstrated that the trial clearly succeeded in meeting the primary efficacy endpoint of progression free survival ("PFS").

Assessment of secondary efficacy endpoints, including objective response rate, disease control rate, and overall survival is ongoing, with all appearing in-line with expectations at the August 2015 five-month data cut-off. The adverse events demonstrated in this POC study are consistent with the known safety profile for fruquintinib without major unexpected safety issues. Full detailed results from this trial will be disclosed in due course.

This is the second POC Phase II study for fruquintinib aimed at comparing the efficacy and safety of fruquintinib plus best supportive care ("BSC") versus placebo plus BSC in patients with NSCLC as a third-line therapy. It is a randomised, double-blind, placebo-controlled, multi-centre, POC Phase II study to treat NSCLC patients who have failed second-line chemotherapy. A total of 91 patients were randomised to receive fruquintinib plus BSC or placebo plus BSC at a 2:1 ratio. The trial was initiated in June 2014 and completed patient enrolment in March 2015.

The first POC Phase II study for fruquintinib, targeted at patients with metastatic third-line colorectal cancer, clearly met its primary endpoint of superior median PFS versus placebo in March 2015 and detailed results will be presented at the upcoming 2015 European Cancer Congress later this month.

### **Ends**

## **Enquiries**

**Chi-Med** Telephone: +852 2121 8200

Christian Hogg, CEO

Panmure Gordon (UK) Limited Telephone: +44 20 7886 2500

Richard Gray Andrew Potts

 Citigate Dewe Rogerson
 Telephone:
 +44 20 7638 9571

 Anthony Carlisle
 Mobile:
 +44 7973 611 888

 David Dible
 Mobile:
 +44 7967 566 919

#### **Notes to Editors**

### **About fruquintinib**

Fruquintinib is designed to selectively inhibit vascular endothelial growth factor ("VEGF") receptors, 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 October 2013, HMP entered into a licensing, co-development and commercialisation agreement with Eli Lilly for fruquintinib. Other on-going clinical studies, beyond NSCLC, include:

First POC Phase II Study in Metastatic Colorectal Cancer - In April 2014, HMP initiated the first POC Phase II study of fruquintinib, which was a randomised, double-blind, placebo-controlled, multi-centre Phase II clinical trial targeted at patients with third-line metastatic colorectal cancer ("mCRC") who had failed at least two prior lines of treatment. This first POC study clearly met the primary endpoint of superior median PFS versus placebo without major unexpected safety issues in March 2015. Detailed results from this trial will be presented at the upcoming 2015 European Cancer Congress meeting in late September in Vienna, Austria.

**Phase III Study in mCRC** - In December 2014, 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. Top-line results are expected in 2016.

**Phase Ib Study in Combination with Paclitaxel** - In early 2015, HMP initiated a Phase Ib dose-finding study of fruquintinib, in combination with paclitaxel, in second-line gastric cancer patients.

### **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 ("VEGFRs") play a pivotal role in tumour-related angiogenesis, and inhibition of the VEGF/VEGFR pathway. This represents an exciting 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 HMP**

HMP is a novel drug R&D company focusing on discovering, developing and commercialising innovative therapeutics in oncology and autoimmune diseases. With a team of around 250 scientists and staff, its pipeline is comprised of novel oral compounds for cancer and inflammation in development in North America, Europe, Australia and Greater China.

HMP is a subsidiary of Chi-Med. For more information, please visit: www.hmplglobal.com.

#### **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.