

# Hutchison China MediTech Limited ("Chi-Med") (AIM: HCM)

# Chi-Med announces positive fruquintinib proof-of-concept study results trigger payments from Lilly

**London: Wednesday, 13 May 2015**: Chi-Med today announces that Hutchison MediPharma Limited ("HMP"), its majority owned drug R&D company, is set to receive a total of US\$18 million in payments, in the second quarter of 2015, from Eli Lilly and Company ("Lilly"). The payments have been triggered by the positive result of the first proof-of-concept ("POC") study of fruquintinib in the treatment of patients with metastatic colorectal cancer ("mCRC") in China. Fruquintinib, a novel selective inhibitor of the Vascular Endothelial Growth Factor ("VEGF") receptor tyrosine kinases, was discovered by HMP. Full details of the mCRC POC results will be published at a major medical meeting later this year.

Pursuant to the licensing, co-development, and commercialisation agreement entered into by HMP and Lilly in October 2013, HMP will receive a US\$10 million mCRC POC milestone. In addition, HMP will receive a total of US\$8 million in reimbursements for costs associated with the planning and launch of the FRESCO Phase III mCRC registration study in China, as well as for the establishment of related clinical supply production facilities in Suzhou, Jiangsu province in China.

Christian Hogg, Chief Executive Officer of Chi-Med said: "We are very glad to have formally reached POC on mCRC, the first potential indication for fruquintinib. Our collaboration with Lilly is of great importance to HMP, and we look forward to continuing to work together to make fruquintinib a great success in the coming years."

#### **Ends**

## **Enquiries**

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#### **Notes to Editors**

## **About fruquintinib**

Fruquintinib is designed to selectively inhibit 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 and Company for fruquintinib.

In April 2014, HMP initiated the first 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 mCRC as a third-line or above therapy. It is a randomised, double-blind, placebo-controlled, multi-centre, POC Phase II study to treat mCRC patients who have failed at least two prior chemotherapies, including fluoropyrimidine, oxaliplatin and irinotecan. A total of 71 patients were randomised to receive fruquintinib plus BSC or placebo plus BSC at a 2:1 ratio.

The POC Phase II study in mCRC completed patient enrolment in August 2014 and in March 2015. HMP announced that top-line results demonstrated that the trial clearly succeeded in meeting the primary efficacy endpoint of progression free survival. 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 February 2015 six-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.

In June 2014, HMP initiated the second POC Phase II study, which was a randomised, double-blind, placebo-controlled, multi-centre Phase II clinical trial targeted at patients with non-squamous non-small cell lung cancer ("NSCLC"). A total of 91 patients were randomised to receive fruquintinib plus BSC or placebo plus BSC at a 2:1 ratio. The NSCLC POC Phase II study completed enrolment in March 2015, with top-line results expected in the middle of 2015.

In October 2014, HMP initiated a Phase Ib dose-finding study of fruquintinib, in combination with paclitaxel, in second line gastric cancer patients.

In December 2014, HMP initiated FRESCO, a Phase III registration study in patients with mCRC, who have failed at least two prior systemic antineoplastic therapies, including flouropyrimidine, oxaliplatin and irinotecan. FRESCO will enrol more than 400 patients in 25 centres in China, with top-line results expected in 2016.

### About VEGF and colorectal cancer 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.

In 2012, there were an estimated 390,000 cases of colorectal cancer diagnosed in China, 10.2% of the total China cancer incidence, making colorectal cancer the third most commonly diagnosed cancer in China. It was the fifth most common cause of cancer death in China after lung, liver, stomach and oesophagus cancer.

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 majority owned by Chi-Med. For more information, please visit: www.hmplglobal.com.

### **About Chi-Med**

Chi-Med is a China-based healthcare group focused on researching, developing, manufacturing and selling pharmaceuticals and health-related consumer products. Its Drug R&D Division focuses on discovering and developing innovative therapeutics in oncology and autoimmune diseases. Its China Healthcare Division manufactures, markets and distributes prescription and over-the-counter pharmaceuticals in China. Its emerging Consumer Products Division focuses on organic and natural consumer products in Asia.

Chi-Med is majority owned by the multinational conglomerate Hutchison Whampoa Limited (SEHK:13). For more information, please visit: www.chi-med.com.