

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

## The first proof-of-concept trial of fruquintinib achieves primary efficacy endpoint

**London: Monday, 30 March 2015**: Chi-Med, today announces that Hutchison MediPharma Limited ("HMP"), its majority owned drug R&D company, successfully achieved the primary endpoint in the first proof-of-concept ("POC") trial of fruquintinib in patients with metastatic colorectal cancer ("mCRC") in China. The 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.

This is 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 trial was initiated in April 2014 and completed patient enrolment in August 2014.

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| <b>Chi-Med</b><br>Christian Hogg, CEO                              | Telephone:                       | +852 2121 8200   |
| <b>Panmure Gordon (UK) Limited</b><br>Richard Gray<br>Andrew Potts | Telephone:                       | +44 20 7886 2500   |
| <b>Citigate Dewe Rogerson</b><br>Anthony Carlisle<br>David Dible   | Telephone:<br>Mobile:<br>Mobile: | +44 20 7638 9571<br>+44 7973 611 888<br>+44 7967 566 919 |

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### Notes to Editors

### About fruquintinib

Fruquintinib is designed to selectively inhibit vascular endothelial growth factor ("VEGF") receptors, namely VEGFR1, VEGFR2, and VEGFR3. In the first-in-human Phase I clinical trial 40 patients were treated with fruquintinib. Detailed results of the Phase I clinical trial are available at <a href="http://chi-med.com/eng/irinfo/presentations.htm">http://chi-med.com/eng/irinfo/presentations.htm</a>, and were presented at the annual meeting of the American Association for Cancer Research in April 2013. Based on the Phase I data in mCRC, a Phase Ib study was initiated which treated a further 62 mCRC patients. Detailed results of the Phase Ib clinical trial were presented at the annual meeting of the American Society of Clinical Oncology in May 2014, and also can be found at <a href="http://chi-med.com/eng/irinfo/presentations.htm">http://chi-med.com/eng/irinfo/presentations.htm</a>.

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 mid 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.

In October 2013, HMP entered into a licensing, co-development and commercialisation agreement with Eli Lilly and Company for fruquintinib.

## 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.