



HUTCHISON CHINA MEDITECH LIMITED

Fruquintinib Phase II clinical results in colorectal cancer to be presented at the 2015 European Cancer Congress

London: Monday, 14 September 2015: Hutchison China MediTech Limited (“Chi-Med”) (AIM: HCM) today announces that Hutchison MediPharma Limited (“HMP”), its drug R&D subsidiary, will present the detailed clinical results of its Phase II proof-of-concept (“POC”) clinical trial of fruquintinib in metastatic colorectal cancer (“mCRC”) at the European Cancer Congress, which will be held in Vienna, Austria from 25 to 29 September 2015.

Fruquintinib is a highly selective vascular endothelial growth factor (“VEGF”) receptor inhibitor that is being evaluated across several solid tumour types in clinical trials, including colorectal cancer, non-small cell lung cancer and gastric cancer. In March 2015, Chi-Med announced that the first POC study of fruquintinib in patients with mCRC clearly met its primary endpoint of progression free survival (“PFS”) by demonstrating superiority compared with placebo. Fruquintinib was well tolerated in this study, showing no major unexpected safety issues and a safety profile consistent with that of its class.

The POC study was a randomised, double-blind, placebo-controlled, multi-centre Phase II clinical trial to compare the efficacy and safety of fruquintinib plus best supportive care against placebo plus best supportive care in mCRC patients who had failed at least 2 prior lines of chemotherapy, including fluoropyrimidine, oxaliplatin and irinotecan. Patients were randomised at a 2:1 ratio to receive either 5 mg of fruquintinib orally once per day on a three-weeks-on, one-week-off schedule or placebo. Treatment was given in 28-day cycles until disease progressed or non-tolerable toxicity occurred. Tumour assessments were conducted using RECIST 1.1 criteria. The primary efficacy endpoint for the trial was PFS. Secondary efficacy endpoints included objective response rate, disease control rate and overall survival. Safety endpoints included adverse events, laboratory tests, vital signs and electrocardiogram measurements. Data was analysed up to 11 February 2015, approximately six months after the last patient had been enrolled.

71 patients were enrolled in the trial, of which 47 were enrolled into the fruquintinib arm and 24 into the placebo arm. Patient baseline characteristics were similar between the two treatment arms. The median fruquintinib exposure was 84 days whereas the median was 21 days in the placebo arm. 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 ($p < 0.001$). The disease control rate in the fruquintinib arm was 68.1%, compared with 20.8% in the placebo arm ($p < 0.001$). 46.8% (22/47) and 62.5% (15/24) of patients died in the fruquintinib and placebo arms, respectively, by the date of data cut-off, with median overall survival of 7.6 months and 5.5 months in the fruquintinib and placebo arms, respectively. The five most common fruquintinib treatment-related adverse events were hand-foot syndrome, hypertension, dysphonia, proteinuria and AST elevation, which is similar to those reported in this class.

The detailed study results will be presented on 27 September 2015 at the European Cancer Congress and will then be made available at <http://chi-med.com/eng/irininfo/presentations.htm>:

Title: A randomised, double-blind, placebo-controlled, multi-centre Phase II clinical trial of fruquintinib in patients with metastatic colorectal cancer.

Authors: Jin Li, et al.

Abstract: #2111

Session: Gastrointestinal Malignancies - Colorectal Cancer

Date & Time: Sunday 27 September 2015, 09:15 AM–11:15 AM

The European Cancer Congress, organised by the European Society for Medical Oncology and the European Cancer Organisation this year, is the largest European multidisciplinary oncology platform for presenting data to a global audience.

Ends

Enquiries

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

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 for fruquintinib.

First POC Phase II Study in Metastatic Colorectal Cancer - In April 2014, HMP initiated the first POC Phase II study of fruquintinib in 71 patients, which was a randomised, double-blind, placebo-controlled, multi-centre Phase II clinical trial targeted at patients with mCRC. The detailed results of this study were described above in this announcement.

Second POC Phase II Study in Non-small Cell Lung Cancer - In June 2014, HMP initiated the second POC Phase II study of fruquintinib in 91 patients, which was a randomised, double-blind, placebo-controlled, multi-centre Phase II clinical trial targeted at patients with advanced non-squamous non-small cell lung cancer. Chi-Med reported the top line results of this study on 2 September 2015, which showed that fruquintinib had clearly met the primary endpoint of PFS with no unexpected safety issues.

Phase III Study in Metastatic Colorectal Cancer - 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 flouropyrindine, 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.

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.

Detailed results of these clinical trials were presented or will be presented at the annual meetings of the American Association for Cancer Research, the American Society of Clinical Oncology and the European Society of Medical Oncology and can be found at <http://chi-med.com/eng/irinfo/presentations.htm>.

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 a subsidiary of Chi-Med. For more information, please visit: www.hmpglobal.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.