



HUTCHISON CHINA MEDITECH LIMITED

## **Chi-Med Submits New Drug Application to CFDA for Fruquintinib in Advanced Colorectal Cancer**

*– Application accepted by CFDA for technical review by the Center for Drug Evaluation –*

*– Triggers RMB30.8 million milestone payment from Eli Lilly and Company (“Lilly”) –*

**London: Monday, June 12, 2017:** Hutchison China MediTech Limited (“Chi-Med”) (AIM/Nasdaq: HCM) today announces that the China Food and Drug Administration (“CFDA”) has acknowledged acceptance of the New Drug Application (“NDA”) for fruquintinib for the treatment of patients with advanced colorectal cancer, which triggers a milestone payment of RMB30.8 million (US\$4.5 million) from Lilly to Chi-Med. The NDA is supported by data from the successful FRESCO study, a Phase III pivotal registration trial of fruquintinib in 416 patients with locally advanced or metastatic colorectal cancer (“CRC”) in China, which was highlighted in an oral presentation at the American Society of Clinical Oncology Annual Meeting on June 5, 2017.

### **About CRC**

CRC is the second most common cancer type in China, with about 380,000 new cases per year, according to National Central Cancer Registry of China. There were approximately 1.5 million new CRC cases globally in 2015 which are expected to increase to approximately 1.7 million new cases per year by 2020, according to Frost & Sullivan.

### **About Fruquintinib**

Fruquintinib is a highly selective small molecule drug candidate that has been shown to inhibit vascular endothelial growth factor receptor (“VEGFR”) 24 hours a day via an oral dose, with lower off-target toxicities compared to other targeted therapies. Its tolerability, along with its clean drug-drug interaction profile demonstrated to date, may enable rational combination with other cancer therapies such as in our ongoing clinical trials of fruquintinib in combination with chemotherapy and targeted therapy.

At an advanced stage, tumors secrete large amounts of VEGF, a protein ligand, to stimulate formation of excessive vasculature (angiogenesis) around the tumor to provide greater blood flow, oxygen, and nutrients to the tumor. VEGF and VEGFR play pivotal roles in tumor-related angiogenesis, and fruquintinib inhibits the VEGF/VEGFR pathway. This represents an important therapeutic strategy in blocking the development of new blood vessels essential for tumors to grow and invade.

Fruquintinib is currently under joint development in China by Chi-Med and its partner Lilly. Chi-Med and Lilly jointly announced top-line results from the FRESCO CRC trial on March 3, 2017. In addition, fruquintinib is being studied in China in a Phase III pivotal trial in non-small cell lung cancer (“NSCLC”), known as FALUCA; and a Phase II study using fruquintinib combined with Iressa® (gefitinib) in the first-line setting for patients with advanced or metastatic NSCLC. Other studies currently being planned, and soon to be initiated, include a Phase III study in gastric cancer in combination with paclitaxel in China, new studies in the United States, and certain exploratory studies in combination with other oncology agents.

### **About Chi-Med**

Chi-Med is an innovative biopharmaceutical company which researches, develops, manufactures and sells pharmaceuticals and healthcare products. Its Innovation Platform, Hutchison MediPharma Limited, 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](http://www.chi-med.com).

## Forward-Looking Statements

*This announcement contains forward-looking statements within the meaning of the “safe harbor” provisions of the U.S. Private Securities Litigation Reform Act of 1995. These forward-looking statements reflect Chi-Med’s current expectations regarding future events, including its expectations for the clinical development of fruquintinib, plans to initiate clinical studies for fruquintinib, its expectations as to whether such studies would meet their primary or secondary endpoints, and its expectations as to the timing of the completion and the release of results from such studies. Forward-looking statements involve risks and uncertainties. Such risks and uncertainties include, among other things, assumptions regarding enrollment rates, timing and availability of subjects meeting a study’s inclusion and exclusion criteria, changes to clinical protocols or regulatory requirements, unexpected adverse events or safety issues, the ability of drug candidate fruquintinib to meet the primary or secondary endpoint of a study, to obtain regulatory approval in different jurisdictions, to gain commercial acceptance after obtaining regulatory approval, the potential market of fruquintinib for a targeted indication and the sufficiency of funding. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. For further discussion of these and other risks, see Chi-Med’s filings with the U.S. Securities and Exchange Commission and on AIM. Chi-Med undertakes no obligation to update or revise the information contained in this announcement, whether as a result of new information, future events or circumstances or otherwise.*

## Inside Information

This announcement contains inside information for the purposes of Article 7 of Regulation (EU) No 596/2014.

## CONTACTS

### Investor Enquiries

Christian Hogg, CEO +852 2121 8200

### U.K. & International Media Enquiries

Anthony Carlisle, Citigate Dewe Rogerson +44 7973 611 888 (Mobile) [anthony.carlisle@cdrconsultancy.co.uk](mailto:anthony.carlisle@cdrconsultancy.co.uk)

### U.S. Based Media Enquiries

Brad Miles, BMC Communications +1 (917) 570 7340 (Mobile) [bmiles@bmccommunications.com](mailto:bmiles@bmccommunications.com)  
Susan Duffy, BMC Communications +1 (917) 499 8887 (Mobile) [sduffy@bmccommunications.com](mailto:sduffy@bmccommunications.com)

### Investor Relations

Matt Beck, The Trout Group +1 (917) 415 1750 (Mobile) [mbeck@troutgroup.com](mailto:mbeck@troutgroup.com)  
David Dible, Citigate Dewe Rogerson +44 7967 566 919 (Mobile) [david.dible@citigatedr.co.uk](mailto:david.dible@citigatedr.co.uk)

### Panmure Gordon (UK) Limited

Richard Gray / Andrew Potts +44 (20) 7886 2500