



HUTCHISON CHINA MEDITECH LIMITED

## Press Release

### Chi-Med Initiates Fruquintinib U.S. Clinical Trials

**London: Friday, December 15, 2017:** Hutchison China MediTech Limited (“Chi-Med”) (AIM/Nasdaq: HCM) has initiated the United States Phase I bridging clinical trial of fruquintinib. Fruquintinib is a highly selective and potent oral inhibitor of vascular endothelial growth factor receptors (“VEGFR”) 1, 2 and 3, that has met its primary endpoint in several Phase II and III clinical trials in China for the treatment of colorectal, lung and gastric cancers. The clinical study in the U.S. is a multi-center, open-label, Phase I clinical study to evaluate the safety, tolerability and pharmacokinetics of fruquintinib in U.S. patients with advanced solid tumors. The first drug dose was administered earlier this month. Additional details about this study may be found at [clinicaltrials.gov](http://clinicaltrials.gov), using identifier [NCT03251378](https://clinicaltrials.gov/ct2/show/study/NCT03251378).

#### About Fruquintinib Development in China

**Colorectal cancer:** The China Food and Drug Administration (“CFDA”) acknowledged [acceptance of the New Drug Application \(“NDA”\)](#) for fruquintinib for the treatment of patients with advanced colorectal cancer (“CRC”) in June 2017. Fruquintinib was subsequently awarded priority review status in view of its significant clinical value, according to a CFDA announcement in September 2017. The NDA is supported by data from the successful FRESCO study, a Phase III pivotal registration trial of fruquintinib in 416 patients with CRC in China, which was highlighted in an [oral presentation](#) at the American Society of Clinical Oncology Annual Meeting held on June 5, 2017 ([clinicaltrials.gov](http://clinicaltrials.gov) identifier [NCT02314819](https://clinicaltrials.gov/ct2/show/study/NCT02314819)). The FRESCO study followed an initial Phase I trial in 40 solid tumor patients, a Phase Ib study in 62 CRC patients, and a Phase II clinical trial in 71 CRC patients.

**Lung cancer:** Fruquintinib is being studied in a Phase III pivotal trial in approximately 520 third-line non-small cell lung cancer (“NSCLC”) patients, known as the FALUCA study ([clinicaltrials.gov](http://clinicaltrials.gov) identifier [NCT02691299](https://clinicaltrials.gov/ct2/show/study/NCT02691299)), following a Phase II clinical trial in 91 third-line NSCLC patients. Fruquintinib is concurrently being studied in a Phase II study in combination with Iressa<sup>®</sup> (gefitinib) in first-line setting for patients with advanced or metastatic NSCLC ([clinicaltrials.gov](http://clinicaltrials.gov) identifier [NCT02976116](https://clinicaltrials.gov/ct2/show/study/NCT02976116)).

**Gastric cancer:** In October 2017, Chi-Med initiated a pivotal Phase III clinical trial of fruquintinib in combination with Taxol<sup>®</sup> (paclitaxel), known as the FRUTIGA study, for the treatment of over 500 patients with advanced gastric or gastroesophageal junction (GEJ) adenocarcinoma ([clinicaltrials.gov](http://clinicaltrials.gov) identifier [NCT03223376](https://clinicaltrials.gov/ct2/show/study/NCT03223376)).

In China, fruquintinib is jointly developed with Eli Lilly and Company.

#### About Fruquintinib

Fruquintinib (HMPL-013) is a highly selective small molecule drug candidate that has been shown to inhibit 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 chemotherapy and other targeted therapies, which are being studied in our ongoing clinical trials of fruquintinib.

At an advanced stage, tumors secrete large amounts of vascular endothelial growth factor (“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.

#### 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: 1). For more information, please visit: [www.chi-med.com](http://www.chi-med.com).

## Forward-Looking Statements

*This press release 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 press release, whether as a result of new information, future events or circumstances or otherwise.*

## CONTACTS

### Investor Enquiries

Mark Lee, Senior Vice President, Corporate Finance & Development +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@citigatedewerogerson.com](mailto:david.dible@citigatedewerogerson.com)

### Panmure Gordon (UK) Limited

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