



HUTCHISON CHINA MEDITECH LIMITED

## Press Release

### Chi-Med Reports Preliminary Phase II data on Fruquintinib Combination in First-Line Lung Cancer

*– Fruquintinib in combination with Iressa® (gefitinib) shows promising efficacy and an acceptable safety profile –*

*– Further validation of strong potential for use of fruquintinib in combination with other cancer therapies due to its high kinase selectivity and attractive safety profile –*

**London: Monday, October 16, 2017:** Hutchison China MediTech Limited (“Chi-Med”) (AIM/Nasdaq: HCM) today reported preliminary clinical activity, safety, and tolerability data of fruquintinib, an investigational selective inhibitor of vascular endothelial growth factor (“VEGF”) receptor given in combination with Iressa®. These data were from an ongoing Phase II proof-of-concept trial conducted in patients with epidermal growth factor receptor (“EGFR”) mutation-positive (“EGFRm”) non-small cell lung cancer (“NSCLC”). Preliminary data from this Phase II proof-of-concept trial, the first study assessing combining fruquintinib with another tyrosine kinase inhibitor, demonstrated promising efficacy and an acceptable safety profile. The data were presented at the International Association for the Study of Lung Cancer 18<sup>th</sup> World Conference on Lung Cancer (WCLC) in Yokohama, Japan, October 15 to 18, 2017<sup>[1]</sup>.

“Having proven efficacy as a monotherapy in colorectal cancer, fruquintinib is now demonstrating its tolerability and efficacy in innovative combinations which are made possible because of its high kinase selectivity, negligible off-target toxicity, and clean drug-drug interaction profile,” said Mr. Christian Hogg, Chief Executive Officer of Chi-Med. “In January 2017, preliminary tolerability and efficacy of fruquintinib in combination with chemotherapy, Taxol® (paclitaxel), was reported in a Phase I/II trial in gastric cancer. Now, this early Iressa® combination data further validates our long-held research approach to create highly selective and optimized drug candidates.”

The study assessed fruquintinib (4 to 5mg, once daily 3-weeks-on/1-week-off) in combination with Iressa® (250mg, once daily) in China as a first-line treatment for patients with EGFRm advanced NSCLC. The most common treatment-emergent adverse events (“AEs”) in 26 patients were increased aspartate aminotransferase (“AST”) (54%), increased alanine aminotransferase (“ALT”) (46%), increased total bilirubin (DBiL) (39%), increased thyroid stimulating hormone (TSH) (39%), and rash (35%). The eight (31%) grade 3 AEs were increased ALT (19%), increased AST (4%), proteinuria (4%), and hypertension (4%). There were no serious AEs or those that lead to death.

Preliminary results in 17 efficacy evaluable patients showed an overall response rate (ORR) of 76% (13/17) and a disease control rate (DCR) of 100% (17/17). Four partial responses were not yet confirmed at the time of data cut-off.

The presentation is available at [www.chi-med.com/wclc-fruq-iressa-combo-nsclc/](http://www.chi-med.com/wclc-fruq-iressa-combo-nsclc/).

#### About Fruquintinib

Fruquintinib (HMPL-013) is a highly selective small molecule drug candidate that has been shown to inhibit VEGF receptors 24 hours a day via an oral dose, without known off-target toxicities. Its tolerability, along with its clean drug-drug interaction profile, enables rational combination with other cancer therapies such as in our ongoing clinical trials of fruquintinib in combination with chemotherapy and targeted therapy. VEGF and VEGF receptors play a pivotal role in tumor-related angiogenesis.

Fruquintinib is currently under joint development in China by Chi-Med and its partner Eli Lilly and Company (“Lilly”). Chi-Med and Lilly jointly announced top-line results from the FRESCO colorectal cancer trial on March 3, 2017. In addition, fruquintinib is being studied in China in a Phase III pivotal trial in NSCLC, known as FALUCA; and a Phase II study using fruquintinib combined with Iressa® 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).

*Iressa® is a trademark of the AstraZeneca PLC group of companies. Taxot® is a trademark of the Bristol-Myers Squibb Company.*

## 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 the 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. In addition, as certain studies rely on the use of Iressa® as a combination therapeutic with fruquintinib, such risks and uncertainties include assumptions regarding the safety, efficacy, supply and continued regulatory approval of Iressa®. 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.*

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## References

<sup>1</sup> Lu S, *et al.* A Phase II Study of Fruquintinib in Combination with Gefitinib in Stage IIIb/IV NSCLC Patients Harboring EGFR Activating Mutations. Abstract #10907. Presented at the World Lung Cancer Congress 2017, Yokohama, Japan, 15-18 October 2017.