



HUTCHISON CHINA MEDITECH LIMITED

Press Release

Chi-Med Highlights Phase III Fruquintinib Data in Oral Presentation at ASCO

Chicago: Monday, June 5, 2017: Hutchison China MediTech Limited (“Chi-Med”) (AIM/Nasdaq: HCM) announced that results from its pivotal Phase III trial with fruquintinib, its novel vascular endothelial growth factor receptor (“VEGFR”) kinase inhibitor, were highlighted in an oral presentation today during the American Society of Clinical Oncology Annual Meeting (“ASCO”), held in Chicago. Results showed that FRESCO, a randomized, double-blind, placebo-controlled, multi-centered Phase III trial assessing fruquintinib in patients with locally advanced or metastatic colorectal cancer (“CRC”) in China, met all primary and secondary endpoints including significant improvements in overall and progression-free survival with a manageable safety profile and lower off-target toxicities compared to other targeted therapies.

“Data from this 416-patient trial showed that treatment with fruquintinib resulted in statistically significant and clinically meaningful survival benefits in colorectal cancer patients who failed two previous lines of systemic therapy,” said Dr. Jin Li, Director of the Department of Oncology, Tongji University affiliated Shanghai East Hospital. “Importantly, adverse events associated with fruquintinib therapy were manageable and controllable. Particularly encouraging was that fruquintinib showed relatively low frequency and less severe liver function abnormalities as compared with other targeted therapies used in this disease setting.”

“The totality of safety and efficacy data suggest fruquintinib can be an important new treatment option for patients whose colorectal cancer continues to progress,” he concluded.

Efficacy Results

The FRESCO trial is a randomized, double-blind, placebo-controlled, multicenter, Phase III pivotal trial in patients with locally advanced or metastatic CRC who have failed at least two prior systemic antineoplastic therapies, including fluoropyrimidine, oxaliplatin and irinotecan. No drugs have been approved in third-line CRC in China, with best supportive care (“BSC”) being the general standard of care. Enrollment was completed in May 2016. 519 patients were screened. The intention-to-treat (ITT) population of 416 patients was randomized at a 2:1 ratio to receive either: 5mg of fruquintinib orally once per day, on a three-weeks-on / one-week-off cycle, plus BSC (278 patients); or placebo plus BSC (138 patients). Randomization was stratified for prior anti-VEGF therapy and K-Ras gene status. The trial was concluded on January 17, 2017.

The primary endpoint of median overall survival (OS) was 9.30 months [95% CI 8.18–10.45] in the fruquintinib group vs. 6.57 months [95% CI 5.88–8.11] in the placebo group, with a hazard ratio of 0.65 [95% CI: 0.51–0.83; two-sided $p < 0.001$].

The secondary endpoint of median progression-free survival (PFS) was 3.71 months [95% CI 3.65–4.63] in the fruquintinib group vs. 1.84 months [95% CI 1.81–1.84] in the placebo group, with a hazard ratio of 0.26 [95% CI: 0.21–0.34; two-sided $p < 0.001$].

Significant benefits were also seen in other secondary endpoints. The fruquintinib group disease control rate (DCR) was 62.2% vs. 12.3% for placebo ($p < 0.001$), while the overall response rate (ORR) was 4.7% vs. 0% for placebo ($p = 0.012$).

Safety and Tolerability Results

Results showed that fruquintinib had a manageable safety profile with lower off-target toxicities compared to other targeted therapies, and did not demonstrate the sometimes severe and fatal hepatotoxicity (liver toxicity) observed with other therapies in this disease setting. The most frequently reported fruquintinib-related grade ≥ 3 adverse events included hypertension (21.2%), hand-foot skin reaction (10.8%), proteinuria (3.2%) and diarrhea (2.9%), all associated with VEGFR inhibition. No other grade ≥ 3 adverse events exceeded 1.4% in the fruquintinib population, including hepatic function adverse events such as

elevations in bilirubin (1.4%), alanine aminotransferase (ALT) (0.7%) or aspartate aminotransferase (AST) (0.4%).

Dose interruptions or reductions occurred in only 35.3% and 24.1% of patients in the fruquintinib arm, respectively, and only 15.1% of patients discontinued treatment vs. 5.8% for placebo.

The FRESCO study may be found at clinicaltrials.gov using identifier [NCT02314819](https://clinicaltrials.gov/ct2/show/study/NCT02314819). The presentation will be available at chi-med.com/wp-content/uploads/2017/06/pre170605-013asco.pdf.

Chi-Med expects to complete the New Drug Application (NDA) submission for fruquintinib to the China Food and Drug Administration imminently. The Company also expects to initiate U.S. clinical studies in 2017.

About Fruquintinib

Fruquintinib 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 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 Eli Lilly and Company ("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.

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[®] (gefitinib) and Taxol[®] (paclitaxel) as a combination

therapeutic with fruquintinib, such risks and uncertainties include assumptions regarding the safety, efficacy, supply and continued regulatory approval of Iressa® and Taxot®. 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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