



HUTCHISON CHINA MEDITECH

Press Release

Chi-Med Announces First Commercial Launch of Fruquintinib Capsules (Elunate®)

London: Monday, November 26, 2018: Hutchison China MediTech Limited (“Chi-Med”) (AIM/Nasdaq: HCM) today announces the first commercial launch of fruquintinib capsules (Elunate®) with the initiation of product sales in China. Elunate® is for the treatment of patients with metastatic colorectal cancer (“CRC”) that have been previously treated with fluoropyrimidine, oxaliplatin and irinotecan, including those who have previously received or are unsuitable for anti-vascular endothelial growth factor (VEGF) therapy and/or anti-epidermal growth factor receptor (EGFR) therapy (*Ras* wild type).

CRC is the second most common cancer type in China¹, with about 380,000 new cases per year². The market launch of Elunate® in China is being conducted through collaboration with Chi-Med’s partner Eli Lilly and Company (“Lilly”).

“This launch is a major milestone for Chi-Med,” said Simon To, Chairman of Chi-Med. “We are very proud to have brought fruquintinib from its initial discovery through to its first sale, and now look forward to seeing patients in China benefit from this important new therapy.” He added, “This achievement reinforces Chi-Med’s position as a fast emerging biotech company, and illustrates China’s capability to emerge as an important global force in oncology innovation.”

Fruquintinib was first approved by the National Medical Products Administration of China (“NMPA”) in September 2018 for the treatment of advanced CRC, becoming the first China-discovered and -developed pharmaceutical for a mainstream oncology indication to be unconditionally approved in China. Chi-Med has established a manufacturing facility in Suzhou, China to produce fruquintinib.

Dr. Wang Li, Senior Vice President, Head of Lilly China Drug Development & Medical Affairs Center, said, “We look forward to working with Chi-Med to bring this novel medicine to patients, addressing the significant unmet need in colorectal cancer in China.”

Given the broad relevance of anti-angiogenesis therapies in cancer biology and the observed effects in various cancers to date, Chi-Med is developing fruquintinib in multiple further indications, including in combination with other cancer therapies.

About Other Fruquintinib Development Programs

Global Development

Phase I monotherapy in the U.S.: In December 2017, Chi-Med initiated 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 (clinicaltrials.gov identifier [NCT03251378](#)). This study is almost complete, and proof-of-concept (“POC”) studies are expected to begin in 2019.

China Development

Colorectal cancer in China: The NMPA [approved the first NDA](#) for fruquintinib for the treatment of patients with advanced CRC in September 2018. 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 and was published in The Journal of the American Medical Association, [JAMA](#), in June 2018 (clinicaltrials.gov identifier [NCT02314819](#)).

Gastric cancer in China: In October 2017, Chi-Med initiated a pivotal Phase III clinical trial of fruquintinib in combination with Taxot® (paclitaxel), known as the FRUTIGA study, in approximately 500 patients with advanced gastric or gastroesophageal junction (GEJ) adenocarcinoma who have progressed after first-line standard chemotherapy (clinicaltrials.gov identifier [NCT03223376](#)). An interim analysis on FRUTIGA, to establish POC, is anticipated during the first half of 2019 and if successful could trigger a POC milestone payment from Lilly. The FRUTIGA study followed a Phase I/II clinical trial in 34 patients with

gastric cancer that demonstrated that combination therapy of fruquintinib and Taxol® was generally well-tolerated with promising tumor response (clinicaltrials.gov identifier [NCT02415023](#)).

Lung cancer in China: The FALUCA trial is a randomized, double-blind, placebo-controlled, multi-center, Phase III registration study targeted at treating patients with advanced non-squamous non-small cell lung cancer (“NSCLC”), who have failed two lines of systemic chemotherapy. 527 patients were 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 best supportive care (“BSC”); or placebo plus BSC. On November 16, 2018, Chi-Med announced that FALUCA did not meet the primary endpoint to demonstrate a statistically significant increase in overall survival compared to placebo, however the data did show statistically significant improvement in all secondary endpoints including progression-free survival, objective response rate, disease control rate and duration of response as compared to the placebo. The safety profile of the trial was in line with that observed in prior clinical studies. Full detailed results are expected to be disclosed at an upcoming scientific meeting. Additional details about this study can be found at clinicaltrials.gov, using identifier [NCT02691299](#).

Along with FALUCA, fruquintinib is concurrently being studied in a Phase II study in combination with Iressa® (gefitinib) in patients with untreated advanced or metastatic NSCLC (clinicaltrials.gov identifier [NCT02976116](#)). Preliminary results were highlighted in an [oral presentation](#) at the 18th World Conference on Lung Cancer on October 16, 2017.

Programmed cell death protein-1 (“PD-1”) checkpoint inhibitor combination: It is an important part of Chi-Med's strategy to explore the potential synergies of its drug candidates in combination with other anti-cancer treatments in several solid tumor settings. In October 2018, Chi-Med entered into a further collaboration in China to evaluate the combination of fruquintinib with genolimzumab (GB226), a PD-1 inhibitor being developed by Genor Biopharma Company Limited.

About Fruquintinib

Fruquintinib (brand name: Elunate®) is a small molecule, selective and highly potent inhibitor of VEGFR 1, 2 and 3. VEGFR inhibitors play a pivotal role in tumor-related angiogenesis, cutting off the blood supply that a tumor needs to grow rapidly. The global market for anti-angiogenesis therapies was estimated at over US\$18 billion in 2017, including both monoclonal antibodies and small molecules approved in around 30 tumor settings. During the discovery research process, which began at Chi-Med in 2007, fruquintinib was successfully designed to be differentiated by improving kinase selectivity in comparison to other approved small molecule tyrosine kinase inhibitors (TKIs), to minimize off-target toxicities, improve tolerability and provide more consistent target coverage, resulting in better clinical efficacy. The superior tolerability, along with fruquintinib's low potential for drug-drug interaction based on preclinical assessment, suggests that it may be highly suitable for innovative combinations with other anti-cancer therapies.

In October 2013, Chi-Med entered into a licensing, co-development and commercialization agreement in China with Lilly for fruquintinib. Under the terms of the agreement, the costs of development of fruquintinib, carried out by Chi-Med, are shared; Chi-Med has received upfront payments and development and regulatory approval milestone payments; and upon commercialization in China, Chi-Med would receive royalties. Chi-Med and Lilly agreed to develop fruquintinib in three initial solid tumor indications, including CRC, NSCLC and gastric cancer.

The most common adverse reactions included hypertension, hand-foot syndrome and proteinuria. Clinically effective management of these adverse effects is feasible. For important safety information about fruquintinib, please see www.chi-med.com.

About Chi-Med

Chi-Med (AIM/Nasdaq: HCM) is an innovative biopharmaceutical company which researches, develops, manufactures and markets pharmaceutical products. Its Innovation Platform, Hutchison MediPharma, has about 400 scientists and staff focusing on discovering, developing and commercializing targeted therapeutics in oncology and autoimmune diseases. It has a portfolio of eight cancer drug candidates currently in clinical studies around the world. Chi-Med's Commercial Platform manufactures, markets, and distributes prescription drugs and consumer health products, covering an extensive network of hospitals across China.

Dual-listed on the AIM market of the London Stock Exchange and the Nasdaq Global Select Market, Chi-Med is headquartered in Hong Kong and majority owned by the multinational conglomerate CK Hutchison Holdings Limited (SEHK: 1). 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 ability of fruquintinib to gain commercial acceptance in China, the potential market of fruquintinib for patients with metastatic CRC who have failed two prior treatments in China, the ability for Chi-Med to quickly provide fruquintinib to patients by year end, and the clinical development of fruquintinib in other indications. Forward-looking statements involve risks and uncertainties. Such risks and uncertainties include, among other things, assumptions regarding Chi-Med’s ability to obtain regulatory approval in different jurisdictions, to commercialize fruquintinib, that the benefits obtained from fruquintinib during clinical trials will be the same for all patients who are prescribed fruquintinib, that no unidentified side effects will occur which could result in the NMPA pulling fruquintinib from the market and the sufficiency of funding to support commercialization of fruquintinib in metastatic CRC and the development of fruquintinib in other indications. In addition, as certain studies rely on the use of Iressa® (gefitinib), Taxol® (paclitaxel), or genolimzumab (GB226) as combination therapeutics with fruquintinib, such risks and uncertainties include assumptions regarding the safety, efficacy, supply and continued regulatory approval of Iressa®, Taxol®, and genolimzumab. 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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¹ R. Zheng, H. Zeng et al, Cancer Lett. 2016 Jan 1;370(1):33-8. National estimates of cancer prevalence in China, 2011. [doi:10.1016/j.canlet.2015.10.003](https://doi.org/10.1016/j.canlet.2015.10.003). Epub 2015 Oct 13.

² W. Chen, R. Zheng et al, CA Cancer J Clin. 2016 Mar-Apr;66(2):115-32. Cancer Statistics in China, 2015. [doi:10.3322/caac.21338](https://doi.org/10.3322/caac.21338). Epub 2016 Jan 25.