HUTCHISON CHINA MEDITECH

Press Release

Chi-Med Initiates FRESCO-2, a Global Phase III Trial of Fruquintinib in Metastatic Colorectal Cancer

Hong Kong, Shanghai, & Florham Park, NJ: Friday, September 4, 2020: Hutchison China MediTech Limited ("Chi-Med") (Nasdaq/AIM: HCM) has initiated FRESCO-2, a Phase III registration study of fruquintinib for the treatment of patients with metastatic colorectal cancer ("CRC") in the U.S., Europe and Japan. The first patient was dosed on September 3, 2020, in the U.S.

FRESCO-2 is a randomized, double-blind, placebo-controlled, multicenter trial being conducted in patients with metastatic CRC. The primary endpoint of the study is overall survival. This large phase III trial will be enrolled in approximately 130 sites in 10 countries. Additional details of the study may be found at clinicaltrials.gov, using identifier NCT04322539.

The U.S. Food and Drug Administration ("FDA") granted Fast Track Designation for the development of fruquintinib for the treatment of patients with metastatic CRC in June 2020. Clinical data including the completed Phase III FRESCO study in Chinese patients and this FRESCO-2 global study, if positive, would support a future New Drug Application (NDA) for the treatment of patients with advanced metastatic CRC (third-line and above), based on our agreement with the FDA. The FRESCO-2 study design was also reviewed and endorsed by the European Medicines Agency (EMA) and the Japanese Pharmaceuticals and Medical Devices Agency (PMDA).

About CRC

CRC is cancer that starts in either the colon or rectum. CRC is the third most common cancer worldwide, causing more than 860,000 deaths in 2018.[1] In the U.S., it is estimated that 150,000 people will be diagnosed with CRC and 53,000 people will die from CRC in 2020.[2] In Europe, CRC is the second most common cancer, with an estimated 490,000 new cases and 240,000 deaths in 2018.[3] In Japan, CRC is the most common cancer, with an estimated 150,000 new cases and 57,000 deaths in 2018.[4]

About Fruquintinib

Fruquintinib is a highly selective and potent oral inhibitor of vascular endothelial growth factor receptor ("VEGFR") 1/2/3. VEGFR inhibitors play a pivotal role in blocking tumor angiogenesis. Fruquintinib was designed to improve kinase selectivity to minimize off-target toxicities, improve tolerability and provide more consistent target coverage. The generally good tolerability in patients to date, along with fruquintinib's low potential for drug-drug interaction based on preclinical assessment, suggests that it may also be highly suitable for combinations with other anti-cancer therapies.

Chi-Med retains all rights to fruquintinib outside of China and is partnered with Eli Lilly and Company ("Lilly") in China.

About Fruquintinib in metastatic CRC

Fruquintinib was approved for marketing by the China National Medical Products Administration (NMPA) in September 2018 and commercially launched by Lilly in late November 2018 under the brand name Elunate®. Elunate® is for the treatment of patients with metastatic CRC that have been previously treated with fluoropyrimidine, oxaliplatin and irinotecan, including those who have previously received anti-VEGF therapy and/or anti-EGFR therapy (RAS wild type). Results of the FRESCO study, a Phase III pivotal registration trial of fruquintinib in 416 patients with metastatic CRC in China, were published in The Journal of the American Medical Association, JAMA, in June 2018 (clinicaltrials.gov identifier: NCT02314819).

In December 2017, Chi-Med initiated a multi-center, open-label, Phase I/Ib clinical study to evaluate the safety, tolerability and pharmacokinetics of fruquintinib in U.S. patients with advanced solid tumors (clinicaltrials.gov identifier: NCT03251378). Proof-of-concept cohorts in patients with metastatic CRC and metastatic breast cancer were added in 2019.

Other Fruquintinib Development

Gastric Cancer in China: In October 2017, Chi-Med initiated the FRUTIGA study, a randomized, double-blind, Phase III trial evaluating the efficacy and safety of fruquintinib combined with paclitaxel for second-line treatment of advanced gastric or esophagogastric junction ("GEJ") adenocarcinoma. The trial is designed to enroll patients who did not respond to first-line standard chemotherapy. Subjects will receive either fruquintinib combined with paclitaxel or placebo combined with paclitaxel. Patients will be randomized at a 1:1 ratio and stratified according to factors such as stomach vs. GEJ tumor type and performance status. The primary efficacy endpoint is overall survival. Secondary efficacy endpoints include progression-free survival (as defined by RECIST 1.1), objective response rate, disease control rate, duration of response, and quality-of-life score (EORTC QLQ-C30, version 3.0). Biomarkers related to the antitumor activity of fruquintinib will also be explored (clinicaltrials.gov identifier NCT03223376). In June 2020, Chi-Med completed a planned interim data review. Based on the preset criteria, the Independent Data Monitoring Committee (IDMC) recommended that the trial continue.

Immunotherapy combinations: Chi-Med has entered into three collaboration agreements to evaluate the safety, tolerability and efficacy of fruquintinib in combination with programmed death-1 (PD-1) monoclonal antibodies, including with tislelizumab (BGB-A317, developed by BeiGene, Ltd.), Tyvyt® (sintilimab, IBI308, developed by Innovent Biologics, Inc.) and geptanolimab (GB226, developed by Genor Biopharma Co. Ltd.).

About Chi-Med

Chi-Med (Nasdaq/AIM: HCM) is an innovative, commercial-stage, biopharmaceutical company committed, over the past twenty years, to the discovery and global development of targeted therapies and immunotherapies for the treatment of cancer and immunological diseases. It has a portfolio of nine cancer drug candidates currently in clinical studies around the world and extensive commercial infrastructure in its home market of China. 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 regarding the clinical development of fruquintinib in CRC in the United States, Europe and Japan, the potential therapeutic benefits of fruquintinib in CRC, Chi-Med's clinical development plans for fruquintinib in other jurisdictions and indications as well as the growth of Chi-Med. 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 fruquintinib, including as a combination therapy, to meet the primary or secondary endpoint of a study, its ability to fund, implement and complete its further clinical development and commercialization plans for fruquintinib, the timing of these events, and the impact of the COVID-19 pandemic on general economic, regulatory and political conditions. In addition, as certain studies rely on the use of combination therapeutics with fruquintinib, such risks and uncertainties include assumptions regarding the safety, efficacy, supply and continued regulatory approval of such combination therapeutics. 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] Ferlay J, Ervik M, Lam F, Colombet M, Mery L, Piñeros M, Znaor A, Soerjomataram I, Bray F (2018). Global Cancer Observatory: Cancer Today. Lyon, France: International Agency for Research on Cancer. Available from: https://gco.iarc.fr/today

[2] SEER, Cancer Stat Facts: Colorectal Cancer. seer.cancer.gov/statfacts/html/colorect.html

[3] The Global Cancer Observatory, Europe fact sheet. gco.iarc.fr/today/data/factsheets/populations/908-europe-fact-sheets.pdf

[4] The Global Cancer Observatory, Japan fact sheet. gco.iarc.fr/today/data/factsheets/populations/392-japan-fact-sheets.pdf