



HUTCHISON CHINA MEDITECH

## Press Release

# Chi-Med Announces the Continuation of Phase III FRUTIGA Study of Fruquintinib in Second-Line Gastric Cancer in China Following a Planned Interim Data Review

**London: Thursday, June 4, 2020:** Hutchison China MediTech Limited (“[Chi-Med](#)”) (Nasdaq/AIM: HCM) today announces that the Independent Data Monitoring Committee (IDMC) of the FRUTIGA study of fruquintinib has completed a planned interim data review. Based on the preset criteria, the IDMC recommended that the trial continue.

FRUTIGA is a Phase III trial in China of **fru**quintinib in combination with paclitaxel (**Taxol**®) in the treatment of patients with advanced **g**astric **a**denocarcinoma or gastroesophageal junction (“**GEJ**”) adenocarcinoma who have progressed after first-line standard chemotherapy.

### About Fruquintinib

Fruquintinib is a highly selective and potent oral inhibitor of vascular endothelial 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 be highly suitable for combinations with other anti-cancer therapies.

### About FRUTIGA in Gastric Cancer

FRUTIGA is 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 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.

Additional details about this study can be found at [clinicaltrials.gov](https://clinicaltrials.gov), using identifier [NCT03223376](https://clinicaltrials.gov/ct2/show/study/NCT03223376).

FRUTIGA was initiated following the results of an open label, multi-center Phase Ib dose finding/expansion study of fruquintinib in combination with paclitaxel (Taxol®) as a second-line treatment in patients with advanced gastric cancer ([clinicaltrials.gov](https://clinicaltrials.gov) identifier [NCT02415023](https://clinicaltrials.gov/ct2/show/study/NCT02415023)).

### Other Fruquintinib Development

Fruquintinib was approved for marketing in China by the NMPA in September 2018 and commercially launched by Eli Lilly and Company (“Lilly”) in late November 2018 under the brand name Elunate®. Elunate® is for the treatment of patients with metastatic colorectal cancer 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 colorectal cancer (“CRC”) in China, were [published](#) in The Journal of the American Medical Association, JAMA, in June 2018 ([clinicaltrials.gov](https://clinicaltrials.gov) identifier: [NCT02314819](https://clinicaltrials.gov/ct2/show/study/NCT02314819)).

Chi-Med retains all rights to fruquintinib outside of China and is partnered with Lilly in China.

*Global development of fruquintinib in CRC:* We are initiating a Phase III registration study, known as the FRESCO-2 study, in the U.S., Europe and Japan in CRC. FRESCO-2 is expected to start enrolling patients in

mid-2020. Based on our agreement with the U.S. Food and Drug Administration (FDA), the FRESCO and FRESCO-2 studies, if positive, could support our New Drug Application (NDA).

*Immunotherapy combinations:* We have 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), [Tyvyt®](#) (sintilimab, IBI308) and [geptanolimab](#) (GB226, genolimzumab).

## About Chi-Med

Chi-Med (Nasdaq/AIM: HCM) is an innovative 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 eight 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](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 in gastric cancer and other indications, the ability of fruquintinib to gain commercial acceptance in China and the potential market of fruquintinib for patients with metastatic CRC who have failed two prior treatments in China. 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, Chi-Med’s ability to obtain or maintain regulatory approval in different jurisdictions and that no unidentified side effects will occur which could result in the NMPA pulling fruquintinib from the market, fruquintinib’s ability to gain commercial acceptance in China, including the sufficiency of funding to support commercialization of fruquintinib in metastatic CRC and that the benefits obtained from fruquintinib during clinical trials will be the same for all patients who are prescribed fruquintinib. In addition, as certain studies rely on the use of Taxol®, tislelizumab, Tyvyt® or geptanolimab as combination therapeutics with fruquintinib, such risks and uncertainties include assumptions regarding the safety, efficacy, supply and continued regulatory approval of Taxol®, tislelizumab, Tyvyt® and geptanolimab. 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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