



HUTCHISON CHINA MEDITECH

Chi-Med and Lilly to Collaborate in Commercializing Elunate® in China

Hong Kong, Shanghai, & Florham Park, NJ: Tuesday, July 28, 2020: Hutchison China MediTech Limited (“[Chi-Med](#)”) (Nasdaq/AIM: HCM) and Eli Lilly and Company (“Lilly”) today announce an amendment to the 2013 License and Collaboration Agreement on Fruquintinib with Lilly Shanghai, an affiliate of Lilly. The 2020 Amendment covers the expansion of Chi-Med’s role in the commercialization of Elunate® (fruquintinib capsules) in China.

Under the terms of the 2020 Amendment, Lilly will maintain the exclusive commercialization rights, and as a consequence, will continue to consolidate the sales of Elunate® in China. Chi-Med will collaborate with Lilly in commercializing Elunate® across China.

In a joint statement, Mr. Christian Hogg, CEO of Chi-Med and Mr. Julio Gay-Ger, President & General Manager, Lilly China, said “After many years of constructive and successful collaboration, Lilly and Chi-Med believe that this agreement now establishes the optimal structure that will allow us to leverage the full resources of both companies to maximize the potential of Elunate® in China.”

Starting October 1, 2020, Chi-Med will be responsible, through its commercial team in oncology of over 320 staff, for the development and execution of all on-the-ground medical detailing, promotion and local and regional marketing activities in China for Elunate®. Lilly and Chi-Med will continue to collaborate, as before, in the formulation and execution of national marketing strategy and events in China for Elunate®.

Chi-Med and Lilly will share gross profits linked to sales target performance. Subject to meeting pre-agreed sales targets, Lilly will pay Chi-Med an estimated total of 70% to 80% of Elunate® sales in the form of royalties, manufacturing costs and service payments. There is no upfront payment by Lilly or Chi-Med relating to this amendment.

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 Lilly in China.

About fruquintinib in metastatic colorectal cancer (“mCRC”)

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 mCRC that have been previously treated with fluoropyrimidine, oxaliplatin and irinotecan, including those who have previously received anti-VEGF therapy and/or anti-epidermal growth factor receptor (“EGFR”) therapy (RAS wild type). Results of the FRESCO study, a Phase III pivotal registration trial of fruquintinib in 416 patients with mCRC in China demonstrating improvement in overall survival, 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 Phase Ib clinical study to evaluate fruquintinib in U.S. patients with advanced solid tumors. Proof-of-concept cohorts in patients with mCRC and metastatic breast cancer were added in 2019 (clinicaltrials.gov identifier: [NCT03251378](#)).

Chi-Med is initiating FRESCO-2, a randomized, double-blind, placebo-controlled, multicenter Phase III registration trial in refractory mCRC in the U.S., Europe and Japan. The primary endpoint of the study is overall

survival. Over 500 patients will be enrolled from approximately 130 sites in 10 countries. The U.S. Food and Drug Administration (FDA) granted Fast Track Designation for development for mCRC patients in June 2020. The FRESCO-2 study design was also reviewed and endorsed by the European Medicines Agency (EMA) and Japanese Pharmaceuticals and Medical Devices Agency (PMDA) (clinicaltrials.gov identifier: [NCT04322539](https://clinicaltrials.gov/ct2/show/study/NCT04322539)).

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 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. The primary efficacy endpoint is overall survival. 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 (clinicaltrials.gov identifier: [NCT03223376](https://clinicaltrials.gov/ct2/show/study/NCT03223376)).

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](https://clinicaltrials.gov/ct2/show/study/NCT03223376) (BGB-A317), [Tyvyt](https://clinicaltrials.gov/ct2/show/study/NCT03223376)[®] (sintilimab, IBI308) and [geptanolimab](https://clinicaltrials.gov/ct2/show/study/NCT03223376) (GB226, genolimzumab).

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.

About Lilly

Lilly is a global healthcare leader that unites caring with discovery to create medicines that make life better for people around the world. We were founded more than a century ago by a man committed to creating high-quality medicines that meet real needs, and today we remain true to that mission in all our work. Across the globe, Lilly employees work to discover and bring life-changing medicines to those who need them, improve the understanding and management of disease, and give back to communities through philanthropy and volunteerism. To learn more about Lilly, please visit us at www.lilly.com.

Forward-Looking Statements

This announcement 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 its collaboration with Lilly and their ability to maximize the commercial potential of Elunate[®] in China under the terms of the above mentioned amendment. Forward-looking statements involve risks and uncertainties. Such risks and uncertainties include, among other things, assumptions regarding Chi-Med’s ability to successfully assume the medical detailing, promotion and local and regional marketing activities for Elunate[®] in China, that no unidentified side effects will occur which could result in the NMPA pulling fruquintinib from the market, the sufficiency of funding to support the commercialization and further clinical development of fruquintinib in CRC and other indications, and the impact of the COVID-19 pandemic on general economic, regulatory and political conditions. 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 announcement, whether as a result of new information, future events or circumstances or otherwise.

Inside Information

This announcement contains inside information for the purposes of Article 7 of Regulation (EU) No 596/2014.

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