



HUTCHISON CHINA MEDITECH

Press Release

Chi-Med Announces Surufatinib Granted U.S. FDA Fast Track Designations for the Treatment of Both Pancreatic and Non-Pancreatic Neuroendocrine Tumors

London: Friday, April 17, 2020: Hutchison China MediTech Limited (“[Chi-Med](#)”) (Nasdaq/AIM: HCM) today announces that the U.S. Food and Drug Administration (“FDA”) has granted two Fast Track Designations for the development of surufatinib, for the treatment of both advanced and progressive pancreatic neuroendocrine tumors (“NET”) and extra-pancreatic (non-pancreatic) NET in patients who are not amenable for surgery.

The FDA [Fast Track Designation](#) is one of several approaches utilized by the U.S. FDA to expedite development and review of potential medicines for serious conditions and that fulfill unmet medical needs. A potential new medicine may fill an unmet medical need by being the first therapy to address a specific serious condition, offer clinically significant advantages over available therapies, act via a different mechanism of action than available therapies, or have a benefit in patients who are unresponsive to or intolerant of available therapies. Programs that receive Fast Track Designation are entitled to more frequent interactions with the U.S. FDA on drug development plan, as well as eligibility for accelerated approval, priority review, and rolling review.¹

About Surufatinib

Surufatinib is a novel, oral angio-immuno kinase inhibitor that selectively inhibits the tyrosine kinase activity associated with vascular endothelial growth factor receptor (“VEGFR”) and fibroblast growth factor receptor (FGFR), which both inhibit angiogenesis, and colony stimulating factor-1 receptor (CSF-1R), which regulates tumor-associated macrophages, promoting the body’s immune response against tumor cells. Its unique dual mechanism of action may be very suitable for possible combinations with other immunotherapies.

Chi-Med currently retains all rights to surufatinib worldwide.

Neuroendocrine tumors in the U.S., Europe and Japan: We are preparing for regulatory interactions in the U.S., Europe and Japan to confirm clinical development and path to registration, based on the encouraging data from the two positive Phase III studies of surufatinib in NET in China, and the ongoing multi-cohort Phase Ib study in the U.S. (clinicaltrials.gov identifier: [NCT02549937](#)). In addition to the aforementioned grants of Fast Track Designation in pancreatic and non-pancreatic NET in the U.S., surufatinib was [granted Orphan Drug Designation](#) for pancreatic NET in November 2019.

Non-pancreatic neuroendocrine tumors in China: In November 2019, an NDA for surufatinib for the treatment of patients with advanced extra-pancreatic (non-pancreatic) neuroendocrine tumors was [accepted for review](#) by the China NMPA and [granted Priority Review](#) status in December 2019. The NDA is supported by data from the successful SANET-ep study, a Phase III study of surufatinib in advanced neuroendocrine tumors – extra-pancreatic patients in China for whom there is no effective therapy. A 198-patient interim analysis was conducted in June 2019, leading the Independent Data Monitoring Committee (“IDMC”) to determine that the study met the pre-defined primary endpoint of progression-free survival (“PFS”) and should be stopped early. The [positive results](#) of this trial were highlighted in an oral presentation at the 2019 European Society for Medical Oncology Congress (clinicaltrials.gov identifier: [NCT02588170](#)).

Pancreatic neuroendocrine tumors in China: In 2016, we initiated the SANET-p study, which is a pivotal Phase III study in patients with low- or intermediate-grade, advanced pancreatic NET in China. A second NDA for surufatinib for the treatment of patients with advanced pancreatic NET is being prepared for submission, following an interim analysis review conducted in January 2020 by the IDMC that recommended that registrational study be terminated early as the pre-defined primary endpoint of [PFS had already been met](#) (clinicaltrials.gov identifier: [NCT02589821](#)). Study results will be submitted for presentation at an upcoming scientific conference.

¹ Source: Food and Drug Administration, “Expedited Programs for Serious Conditions – Drugs and Biologics”: <https://www.fda.gov/files/drugs/published/Expedited-Programs-for-Serious-Conditions-Drugs-and-Biologics.pdf>

Biliary tract cancer in China: In March 2019, we initiated a Phase IIb/III study comparing surufatinib with capecitabine in patients with advanced biliary tract cancer whose disease progressed on first-line chemotherapy. The primary endpoint is overall survival (OS) (clinicaltrials.gov identifier [NCT03873532](https://clinicaltrials.gov/ct2/show/study/NCT03873532)).

Immunotherapy combinations: In November 2018 and September 2019, we entered into [collaboration agreements](#) to evaluate the safety, tolerability and efficacy of surufatinib in combination with anti-programmed cell death protein 1 (PD-1) monoclonal antibodies. This included global collaborations to evaluate the combination of surufatinib with Tuoyi[®], approved in China by Shanghai Junshi Biosciences Co. Ltd, and with Tyvyt[®], approved in China by Innovent Biologics, Inc.

About Neuroendocrine Tumors (NET)

Neuroendocrine tumors form in cells that interact with the nervous system or in glands that produce hormones. They can originate in various parts of the body, most often in the gut or the lungs and can be benign or malignant. Neuroendocrine tumors are typically classified as pancreatic neuroendocrine tumors or non-pancreatic neuroendocrine tumors. Approved targeted therapies include Sutent[®] and Afinitor[®] for pancreatic neuroendocrine tumors, or well-differentiated, non-functional gastrointestinal or lung neuroendocrine tumors.

According to Frost and Sullivan, there were 19,000 newly diagnosed cases of neuroendocrine tumors in the U.S. in 2018. Importantly, neuroendocrine tumors are associated with a relatively long duration of survival compared to other tumors. As a result, there were approximately 141,000 estimated patients living with neuroendocrine tumors in the U.S. in 2018 of which over 90%, or approximately 132,000, were non-pancreatic neuroendocrine tumor patients.

In China, there were approximately 67,600 newly diagnosed neuroendocrine tumor patients in 2018 and, considering the current incidence to prevalence ratio in China, potentially as many as 300,000 patients living with the disease in the country². It is estimated that approximately 80% of the patients living with neuroendocrine tumors in China are non-pancreatic neuroendocrine tumor patients.

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.

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 therapeutic potential of surufatinib for the treatment of patients with NET, the further clinical development of surufatinib in this and other indications, its expectations as to whether clinical studies of surufatinib 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 the sufficiency of its data to support NDA approval of surufatinib for the treatment of patients with NET in China, its potential to gain expeditious approvals for surufatinib in other jurisdictions such as the U.S., E.U. or Japan, the safety profile of surufatinib, the potential for surufatinib to become a new standard of care for NET patients, its ability to implement and complete its further clinical development plans for surufatinib, its potential commercial launch of surufatinib in China and other jurisdictions and the timing of these events. 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.

² According to Frost & Sullivan, in 2018, there were 19,000 newly diagnosed cases of NETs in the U.S and an estimated 141,000 patients living with NETs. The current incidence to prevalence ratio in China is estimated at 4.4, lower than the 7.4 ratio in the U.S. due to lower access to treatment options.

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