



HUTCHISON CHINA MEDITECH

Chi-Med Announces that Surufatinib Phase III SANET-p Study Has Already Achieved its Primary Endpoint in Advanced Pancreatic Neuroendocrine Tumors in China and Will Stop Early

London: Monday, January 20, 2020: Hutchison China MediTech Limited (“[Chi-Med](#)”) (AIM/Nasdaq: HCM) today announces that the independent Data Monitoring Committee (“IDMC”) of the Phase III pivotal study of surufatinib in advanced neuroendocrine tumors – pancreatic (“SANET-p”) has completed a pre-planned interim analysis. The IDMC recommended that the study stops early as the pre-defined primary endpoint of progression free survival (“PFS”) had already been met.

Following the early success of this study, Chi-Med now plans to arrange a pre-New Drug Application (“NDA”) meeting with the China National Medical Products Administration (“NMPA”) to discuss the preparation of the NDA for surufatinib for this indication. Chi-Med intends to submit the results of the SANET-p study for presentation at an upcoming scientific conference.

Christian Hogg, Chief Executive Officer of Chi-Med, said, “This positive data is a further important milestone for Chi-Med. Following surufatinib’s NDA submission for the treatment of non-pancreatic neuroendocrine tumors, these positive results for pancreatic neuroendocrine tumors reinforce that surufatinib has the unique opportunity to address all advanced neuroendocrine tumors. We believe that no targeted therapies are approved in China or globally for such a broad spectrum of neuroendocrine tumor disease.”

In November 2019, the U.S. Food and Drug Administration (“FDA”) granted Orphan Drug designation to surufatinib for the treatment of pancreatic neuroendocrine tumors. The China NDA for surufatinib for the treatment of advanced non-pancreatic neuroendocrine tumors was accepted for review by the NMPA, and was subsequently granted Priority Review status in December. Currently Chi-Med is building an oncology-focused sales and marketing team to launch surufatinib if approved in China.

About SANET-p

SANET-p is a Phase III study in China of surufatinib in patients with low-grade or intermediate-grade advanced pancreatic neuroendocrine tumor patients for whom there is no effective therapy. In this study, patients are randomized at a 2:1 ratio to receive either 300 mg of surufatinib orally daily or placebo, on a 28-day treatment cycle. The primary endpoint of the study is to evaluate the PFS, with secondary endpoints including objective response rate (ORR), disease control rate (DCR), time to response (TTR), duration of response (DoR), overall survival (OS), safety, and tolerability. Additional details may be found at clinicaltrials.gov, using identifier [NCT02589821](https://clinicaltrials.gov/ct2/show/study/NCT02589821).

About Neuroendocrine Tumors

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 country^[1]. It is estimated that approximately 80% of the patients living with neuroendocrine tumors in China are non-pancreatic neuroendocrine tumor patients.

About Surufatinib

Surufatinib (previously known as HMPL-012 or sulfatinib) 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. Surufatinib is in several late-stage and proof-of-concept clinical trials in China and proof-of-concept clinical trials in the U.S.

According to Frost & Sullivan, the market for anti-angiogenesis VEGF/VEGFR inhibitors in China has grown from US\$500 million in 2015 to over US\$1.5 billion in 2019 and is expected to reach US\$5 billion by 2026.

Chi-Med currently retains all rights to surufatinib worldwide.

Non-pancreatic neuroendocrine tumors in China: In November 2019, an NDA for surufatinib for the treatment of patients with advanced non-pancreatic neuroendocrine tumors was accepted for review by the China NMPA. 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 IDMC to determine that the study met the pre-defined primary endpoint of 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 on September 29, 2019. (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 neuroendocrine tumors in China. The primary endpoint is PFS (clinicaltrials.gov identifier: [NCT02589821](#)).

Pancreatic neuroendocrine tumors in the U.S. and Europe: We are planning a U.S. registration study in neuroendocrine tumor patients based on the encouraging data from the Phase II and Phase III studies of surufatinib in neuroendocrine tumors in China (clinicaltrials.gov identifier: [NCT02267967](#)), and the ongoing Phase Ib study in the U.S. (clinicaltrials.gov identifier: [NCT02549937](#)). This program was granted Orphan Drug designation by the U.S. FDA.

Biliary tract cancer in China: In March 2019, we initiated a Phase IIb/III study comparing surufatinib (HMPL-012 or sulfatinib) with capecitabine in patients with advanced biliary tract cancer whose disease progressed on first-line chemotherapy. The primary endpoint is OS (clinicaltrials.gov identifier [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 Tvyvt®, approved in China by Innovent Biologics, Inc.

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 500 scientists and staff focusing on discovering, developing and commercializing targeted therapeutics and immunotherapies for the treatment of cancer 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.

Chi-Med is headquartered in Hong Kong and is dual-listed on the AIM market of the London Stock Exchange and the Nasdaq Global Select Market. For more information, please visit: www.chi-med.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 the NDA approval and launch of surufatinib for the treatment of patients with pancreatic or non-pancreatic NET in China, the further clinical development of surufatinib in these 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 pancreatic or non-pancreatic NET in China, its potential to gain expeditious approvals for surufatinib in other jurisdictions such as the U.S. and EU, the safety profile of surufatinib, the potential for surufatinib to become a new standard of care for pancreatic or non-pancreatic 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 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.

[1] 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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