



HUTCHISON CHINA MEDITECH LIMITED

Chi-Med initiates sulfatinib Phase III registration study in pancreatic neuroendocrine tumor patients

London: Monday, March 21, 2016: Hutchison China MediTech Limited (“Chi-Med”) (AIM/Nasdaq: HCM) today announces that Hutchison MediPharma Limited (“HMP”), its drug R&D subsidiary, has initiated SANET-p, a Phase III registration trial of sulfatinib (HMPL-012) in China in patients with pancreatic neuroendocrine tumors (“NETs”). The first patient was dosed on March 18, 2016.

The protocol for SANET-p is similar to SANET-ep, a Phase III registration trial in patients with extra-pancreatic NETs. SANET-p is a randomized, double-blind, placebo-controlled, multi-center Phase III sulfatinib registration study to treat patients with low or intermediate grade advanced NET whose disease has progressed, locally advanced or distant metastasized and for whom there is no effective therapy. Patients are randomized at a 2:1 ratio to receive either 300 milligrams of sulfatinib orally once per day, or placebo, on an every 28-day treatment cycle. The primary objective of this study is to evaluate the progression-free survival of sulfatinib as compared to that of placebo, with secondary endpoints including objective response rate (“ORR”), disease control rate, time to response, duration of response, overall survival, safety and tolerability. Approximately 195 patients are expected to be enrolled in the SANET-p study from more than 20 centers across China, with top-line results expected in 2018. Additional details about this study may be found at clinicaltrials.gov, using identifier [NCT02589821](https://clinicaltrials.gov/ct2/show/study/NCT02589821).

Sulfatinib is an oral drug candidate that selectively inhibits the tyrosine kinase activity associated with the vascular endothelial growth factor receptor (“VEGFR”) and fibroblast growth receptor (“FGFR”), two tyrosine kinase receptors associated with angiogenesis and tumor growth. HMP believes that sulfatinib’s VEGFR/FGFR1 inhibition profile has strong potential in second-line thyroid cancer patients, particularly in China where there are few safe and effective treatment options for this patient population.

Including this trial, HMP is conducting five Phase II and Phase III clinical trials of sulfatinib in China and the U.S.

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Notes to Editors

Overview of sulfatinib clinical development

NETs arise from neuroendocrine cells and develop predominantly in the digestive or respiratory tracts but can also occur in many areas of the body. Diagnosing NETs is difficult due to the small tumor size and diverse occurrence with patients showing varied or no symptoms. As a result, it has been difficult to accurately estimate the number of NETs incidences per year. There were approximately 19,000 new cases of NETs and a cumulative prevalence of approximately 144,000 cases in the U.S. in 2015, according to Frost and Sullivan.

In 2014, HMP completed the first-in-human Phase I clinical trial of sulfatinib in China; the detailed results were presented at the American Association for Cancer Research-National Cancer Institute-European Organisation for Research and Treatment of Cancer International Conference on Molecular Targets and Cancer Therapeutics in early November 2015 (www.chi-med.com/sulfatinib-ph1-eortc-2015/). The Phase I clinical data indicates that sulfatinib has a superior ORR in NET patients. An ORR of 44% was observed for sulfatinib in 18 evaluable patients, compared to less than 10% for sunitinib and everolimus, the two approved targeted therapies for pancreatic NET patients. Additional details about this study may be found at clinicaltrials.gov, using identifier [NCT02133157](https://clinicaltrials.gov/ct2/show/study/NCT02133157).

In October 2014, HMP initiated a multi-center, single-arm, open-label Phase Ib/II study in broad spectrum NET patients (pancreatic, gastrointestinal, liver, lymph and lung, among others) in China to further evaluate the efficacy, safety, tolerability, and pharmacokinetic characteristics of sulfatinib. This study completed enrolment of 81 patients in December 2015. HMP expects to report top line results of this study during the course of 2016. Additional details about this study may be found using identifier [NCT02267967](https://clinicaltrials.gov/ct2/show/study/NCT02267967).

In addition to SANET-p, in December 2015 HMP initiated SANET-ep, a Phase III sulfatinib registration trial in China in patients with extra-pancreatic NETs (non-pancreatic). SANET-ep is a randomized, double-blind, placebo-controlled, multi-center registration study to treat pathologically low or intermediate grade NET patients whose disease has progressed, locally advanced or distant metastasized and for whom there is no effective therapy. Additional details about this study may be found using identifier [NCT02588170](https://clinicaltrials.gov/ct2/show/study/NCT02588170).

A Phase I study in Caucasian patients also began in November 2015 in the U.S. Once HMP has established the Phase II dose among Caucasian patients in this U.S. Phase I study, HMP expects to start a U.S. Phase II study in broad spectrum NET patients in the second half of 2016. Additional details about this study may be found using identifier [NCT02549937](https://clinicaltrials.gov/ct2/show/study/NCT02549937).

In addition to these NET studies, in March 2016 HMP initiated a Phase II study in China to evaluate the safety, pharmacokinetics and efficacy of sulfatinib in patients with both medullary and differentiated thyroid cancer. Additional details about this study may be found using identifier [NCT02614495](https://clinicaltrials.gov/ct2/show/study/NCT02614495).

About VEGFR and FGFR in cancer

At an advanced stage, tumors secrete large amounts of vascular endothelial growth factor ("VEGF"), a protein ligand, to stimulate formation of excessive vasculature (angiogenesis) around the tumor in order to provide greater blood flow, oxygen, and nutrients to fuel the rapid growth of the tumor. Anti-angiogenesis drugs have demonstrated benefits in a wide variety of tumor types. VEGF and other ligands can bind to VEGF receptors, which have been shown to play a role in angiogenesis. Inhibition of the VEGF/VEGFR signaling pathway can act to stop the growth of the vasculature around the tumor and thereby starve the tumor of the nutrients and oxygen it needs to grow rapidly.

Fibroblast cell growth factor (“FGF”) also plays a key role in tumor angiogenesis. Aberrant activation of the FGF/FGFR signaling pathway is shown to be associated with cancer progression by promoting growth, survival, migration and invasion of the tumor. There is evidence that anti-VEGF therapy treatment could increase FGFR pathway activation, leading to drug resistance to anti-VEGF therapies. It is believed that simultaneously targeting VEGFR and FGFR could be an attractive approach to improve clinical efficacy.

About HMP

HMP is a novel drug R&D company focusing on discovering, developing and commercializing innovative therapeutics in oncology and autoimmune diseases. With a team of around 290 scientists and staff, its pipeline is comprised of novel oral compounds for cancer and inflammation in development in North America, Europe, Australia and Greater China. HMP is a subsidiary of Chi-Med. For more information, please visit: www.hmplglobal.com.

About Chi-Med

Chi-Med is a China-based, globally-focused healthcare group which researches, develops, manufactures and sells pharmaceuticals and health-related consumer products. Its Innovation Platform focuses on discovering and developing innovative therapeutics in oncology and autoimmune diseases for the global market. Its Commercial Platform manufactures, markets and distributes prescription drugs and consumer health products in China.

Chi-Med is majority owned by the multinational conglomerate CK Hutchison Holdings Limited (SEHK: 0001). For more information, please visit: www.chi-med.com.

Forward-Looking Statements

This announcement contains forward-looking statements that reflect Chi-Med’s current expectations regarding future events, including its plans to initiate clinical studies for its drug candidates in the targeted indications, its expectations as to whether such studies 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 enrolment 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 a drug candidate to meet the primary or secondary endpoint of a study, the ability of a drug candidate to obtain regulatory approval in different jurisdictions, the ability of a drug candidate to gain commercial acceptance after obtaining regulatory approval and the sufficiency of funding. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. 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.