

Initiation of sulfatinib Phase III registration study in neuroendocrine tumour patients

London: Friday, 18 December 2015: Hutchison China MediTech Limited ("Chi-Med") (AIM: HCM) today announces that Hutchison MediPharma Limited ("HMP"), its drug R&D subsidiary, has initiated SANET-ep, a Phase III sulfatinib (HMPL-012) registration trial in China in patients with extra-pancreatic neuroendocrine tumours ("NETs"), which are all non-pancreatic NETs, including, for example, NETs originating in the lymph, lung and across the gastrointestinal tract. Preparations and site selection had begun in the middle of this year and the first patient was dosed on 17 December 2015.

SANET-ep is a randomised, double-blind, placebo-controlled, multi-centre Phase III sulfatinib registration study to treat pathologically low or intermediate grade NET patients whose disease has progressed, locally advanced or distant metastasised and for whom there is no effective therapy. Patients will be randomised at a 2:1 ratio to receive either 300 milligrams of sulfatinib orally once per day, or placebo, on 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 270 patients will be enrolled in the SANET-ep study from more than 20 centres across China, with top-line results expected in 2018.

Additionally, the second Phase III sulfatinib registration trial, SANET-p, in pancreatic NET patients, is expected to be initiated imminently in China. SANET-p employs a similar treatment regimen and has primary and secondary endpoints similar to those for SANET-ep trial. Approximately 195 patients will be enrolled in SANET-p and is expected to start by the end of 2015, with top-line results expected in 2017.

Sulfatinib is an oral drug candidate that demonstrates dual inhibition of the tyrosine kinase activity associated with vascular endothelial growth factor receptor ("VEGFR") and fibroblast growth factor receptor ("FGFR") 1, a receptor kinase which also plays a role in tumour angiogenesis. In 2014, HMP completed the first-in-human Phase I clinical trial of sulfatinib in China; the detailed results were presented at the AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics in early November 2015 (<u>www.chi-med.com/sulfatinib-ph1-eortc-2015</u>/). The Phase I clinical data indicates that sulfatinib has the highest ORR reported to date 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.

In October 2014, HMP initiated a multi-centre, single-arm, open-label Phase Ib/II study in NET patients in China to further evaluate the efficacy, safety, tolerability and pharmacokinetic characteristics of sulfatinib. This study, projected to enrol approximately 80 patients, is near to completion of patient enrolment.

Furthermore, the Phase I and Phase Ib/II studies in China provide a guide for the selection of the recommended starting dose for the Phase I study in patients with advanced solid tumours in the United States, which had the first patient enrolled in early November 2015.

In addition to these four NET studies, HMP also plans to initiate a Phase Ib study in China to evaluate the safety, pharmacokinetics and efficacy of sulfatinib in patients with both medullary and differentiated thyroid cancer by the end of 2015.

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Enquiries

Chi-Med Christian Hogg, CEO	Telephone:	+852 2121 8200
Panmure Gordon (UK) Limited Richard Gray Andrew Potts	Telephone:	+44 20 7886 2500
Citigate Dewe Rogerson Anthony Carlisle David Dible	Telephone: Mobile: Mobile:	+44 20 7638 9571 +44 7973 611 888 +44 7967 566 919

Notes to Editors

About neuroendocrine tumours

Neuroendocrine tumours arise from neuroendocrine cells and develop predominantly in the digestive or respiratory tracts but can also occur in other organs of the body. Diagnosis of neuroendocrine tumours is difficult due to the small tumour size and diverse origination with patients showing varied or no symptoms. It is estimated that there are approximately 19,000 new cases of neuroendocrine tumours per year and a cumulative prevalence of approximately 141,000 cases in the United States in 2014.

Neuroendocrine tumours can be classified according to tumour origin, as pancreatic NET representing less than 10% of the total NET patients, and extra-pancreatic NET comprising all other non-pancreatic NETs including lung, lymph and gastrointestinal tract NETs. To date, treatment options for NET patients are limited; sunitinib and everolimus are the only two approved targeted-therapies for pancreatic NET, while there is no such a choice for extra-pancreatic NET patients.

About VEGFR and FGFR in cancer

At an advanced stage, tumours secrete large amounts of vascular endothelial growth factor ("VEGF"), a protein ligand, to stimulate formation of excessive vasculature (angiogenesis) around the tumour in order to provide greater blood flow, oxygen, and nutrients to fuel the rapid growth of the tumour. Anti-angiogenesis drugs have demonstrated benefits in a wide variety of tumour 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 signalling pathway can act to stop the growth of the vasculature around the tumour and thereby starve the tumour of the nutrients and oxygen it needs to grow rapidly.

Fibroblast cell growth factor ("FGF") also plays a key role in tumour angiogenesis. Aberrant activation of the FGF/FGFR signalling pathway is shown to be associated with cancer progression by promoting growth, survival, migration and invasion of the tumour. 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 commercialising innovative therapeutics in oncology and autoimmune diseases. With a team of over 280 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.