



HUTCHISON CHINA MEDITECH LIMITED

## Chi-Med initiates sulfatinib U.S. clinical trials

**London: Friday, 6 November 2015:** Hutchison China MediTech Limited (“Chi-Med”) (AIM: HCM) today announces that Hutchison MediPharma Limited (“HMP”), its drug R&D subsidiary, has initiated the Phase I clinical trial of sulfatinib (HMPL-012) in the United States. Its U.S. Investigational New Drug application was submitted and cleared earlier this year and the first patient was dosed on 4 November 2015. HMP is also planning to initiate two Phase III registration studies for the treatment of neuroendocrine tumours (“NET”) and a Phase Ib study for the treatment of thyroid cancer with sulfatinib in China by the end of 2015.

This Phase I dose escalation study is to assess the safety and tolerability of sulfatinib in U.S. patients with advanced solid tumours. A U.S. Phase II study in NET is expected to be initiated based on the conclusion of this Phase I dose escalation study.

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”), a receptor for a protein which also plays a role in tumour growth. In a Phase I clinical trial in China focusing on NET patients, sulfatinib’s objective response rate among the 18 efficacy-evaluable NET patients was 44.4%. By comparison, sunitinib and everolimus, the two approved single agent therapies for pancreatic NET, achieved objective response rates of less than 10% in their pivotal clinical trials. Furthermore, NET responses to sulfatinib have been observed to improve gradually with time. Results of the Phase I trial in China will be reported at the AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics in November 2015 and will be made available at [www.chi-med.com/news/](http://www.chi-med.com/news/).

Sulfatinib is the first oncology candidate that HMP has taken through proof-of-concept in China and expanded to a U.S. clinical study without a partner.

**Ends**

### Enquiries

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## **Notes to Editors**

### **Overview of sulfatinib clinical development**

In addition to the U.S. Phase I clinical trial, HMP is conducting or in the process of initiating four clinical trials in China.

#### NET

In October 2014, HMP initiated a multi-centre, 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, projected to enrol approximately 80 patients, is near to completion of patient enrolment. Results to date of this open-label Phase Ib study appear generally in line with the positive results from the Phase I study.

Encouraged by these results, HMP now plans to start two Phase III registration studies in China by the end of 2015, one in pancreatic NET patients and a second in advanced carcinoid (non-pancreatic) NET patients.

#### Thyroid cancer

HMP 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. Sulfatinib's VEGFR/FGFR1 inhibition profile is believed to have strong potential in second-line thyroid cancer patients, particularly in China where there are few safe and effective treatment options for this patient population. HMP plans to enrol approximately 50 patients with locally advanced or metastatic radioactive iodine-refractory differentiated thyroid cancer or medullary thyroid cancer into this study, with approximately 25 patients in each tumour type.

### **About NET**

NET arises from neuroendocrine cells and develop predominantly in the digestive or respiratory tracts but can also occur in many areas of the body. Diagnosing NET is difficult due to the small tumour size and diverse occurrence with patients showing varied or no symptoms. As a result, it has been difficult to accurately estimate the number of NET incidences per year. There were approximately 19,000 new cases of NET and a cumulative prevalence of approximately 141,000 cases in the United States in 2014.

### **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 around 250 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.hmpglobal.com](http://www.hmpglobal.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](http://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.