



HUTCHISON CHINA MEDITECH

## Press Release

### Chi-Med Initiates a Phase Ib/II Proof-of-Concept Trial of Sulfatinib in Pancreatic Neuroendocrine Tumors and Biliary Tract Cancer in the United States

**London: Monday, July 23, 2018:** Hutchison China MediTech Limited ("[Chi-Med](#)") (AIM/Nasdaq: HCM) has initiated a Phase Ib/II proof-of-concept study of sulfatinib in pancreatic neuroendocrine tumors ("NET") patients and in biliary tract cancer ("BTC") patients in the U.S.. Sulfatinib is an oral small molecule angio-immuno kinase inhibitor that can simultaneously block tumor angiogenesis and immune evasion. This study follows several trials that are underway in China, including two Phase III studies in pancreatic and non-pancreatic NET that commenced after positive results from a Phase II study, and a Phase II study in BTC patients. In addition, a Phase I dose escalation part of this study in the U.S. was recently completed.

This proof-of-concept study is a multi-center, single-arm, open-label study to evaluate the efficacy and safety of sulfatinib as a monotherapy in (a) patients with advanced BTC that have progressed on standard first-line chemotherapy, and (b) in patients with advanced pancreatic NET. The primary and secondary endpoints include progression-free survival ("PFS") rate, objective response rate ("ORR"), disease control rate ("DCR"), duration of response ("DoR"), time to response, overall survival ("OS"), safety and tolerability. Additional details of the study may be found at [clinicaltrials.gov](https://clinicaltrials.gov), using identifier [NCT02549937](#).

#### About Sulfatinib

Sulfatinib is a novel, oral angio-immuno kinase inhibitor that selectively inhibits the tyrosine kinase activity associated with vascular endothelial growth factor receptor ("VEGFR"), fibroblast growth factor receptor ("FGFR") and colony stimulating factor-1 receptor ("CSF-1R"), three key tyrosine kinase receptors involved in tumor angiogenesis and immune evasion. Inhibition of the VEGFR signaling pathway can act to stop angiogenesis, the growth of the vasculature around the tumor, and thereby starve the tumor of the nutrients and oxygen it needs to grow rapidly. Aberrant activation of the FGFR signaling pathway, which can be increased by anti-VEGFR therapy treatment, is shown to be associated with cancer progression by promoting tumor growth, angiogenesis and formation of the myeloid derived suppressor cells. Inhibition of the CSF-1R signaling pathway blocks the activation of tumor-associated macrophages, which are involved in suppressing immune responses against tumors. Its unique angio-immuno kinase profile supports sulfatinib as a potentially attractive candidate for exploration of possible combinations with checkpoint inhibitors against various cancers.

Sulfatinib is the first oncology candidate that we have taken through proof-of-concept in China and subsequently started clinical development in the U.S. We are currently conducting studies in six target patient populations on sulfatinib and retain all rights to sulfatinib worldwide.

#### About Sulfatinib Development in China

Sulfatinib is currently in development as a single agent for patients with NET, thyroid cancer and BTC in China.

*Pancreatic NET:* In March 2016, we initiated the SANET-p study, which is a randomized, double-blind, placebo-controlled, multi-center, Phase III pivotal registration trial to treat about 190 patients with low- or intermediate-grade, advanced pancreatic NET in China. The primary endpoint is PFS, with secondary endpoints including ORR, DCR, DoR, time to response, OS, safety and tolerability. Additional details of the SANET-p study may be found at [clinicaltrials.gov](https://clinicaltrials.gov), using identifier [NCT02589821](#). We expect to complete enrollment in 2019 and present top-line results thereafter.

*Extra-pancreatic NET:* The SANET-ep study, which was initiated in December 2015, is similar to the SANET-p study and is targeted at treating about 270 patients with advanced extra-pancreatic NET in China. Additional details of the SANET-ep study may be found at [clinicaltrials.gov](https://clinicaltrials.gov), using identifier [NCT02588170](#). We expect to complete enrollment in 2019 and present top-line results thereafter.

*Thyroid cancer:* In March 2016, we initiated Phase II in two target patient populations in China to evaluate the efficacy and safety of sulfatinib in patients with advanced medullary thyroid cancer and iodine-refractory differentiated thyroid cancer. Additional details of this study may be found at [clinicaltrials.gov](http://clinicaltrials.gov), using identifier [NCT02614495](https://clinicaltrials.gov/ct2/show/study/NCT02614495).

*BTC:* In January 2017, we began a Phase II study in patients with BTC (also known as cholangiocarcinoma), a heterogeneous group of rare malignancies arising from the biliary tract epithelia. Gemzar is the currently approved first-line therapy for biliary tract cancer patients, with a total of approximately 18,000 new patients per year in the U.S. according to the National Cancer Institute, but median survival is less than 12 months for patients with unresectable or metastatic disease at diagnosis. As a result, we see a major unmet medical need for patients who have progressed when being treated with Gemzar, and sulfatinib may offer a new targeted treatment option in this tumor type. Additional details of this study may be found at [clinicaltrials.gov](http://clinicaltrials.gov), using identifier [NCT02966821](https://clinicaltrials.gov/ct2/show/study/NCT02966821).

## **About Chi-Med**

Chi-Med is an innovative biopharmaceutical company which researches, develops, manufactures and sells pharmaceuticals and healthcare products. Its Innovation Platform, Hutchison MediPharma Limited, 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: 1). For more information, please visit: [www.chi-med.com](http://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 for the clinical development of sulfatinib, plans to initiate clinical studies for sulfatinib, 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 enrollment 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 drug candidate sulfatinib to meet the primary or secondary endpoint of a study, to obtain regulatory approval in different jurisdictions, to gain commercial acceptance after obtaining regulatory approval, the potential market of sulfatinib for a targeted indication 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. 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.*

## **CONTACTS**

### **Investor Enquiries**

Mark Lee, Senior Vice President, +852 2121 8200  
Corporate Finance & Development

### **U.K. & International Media Enquiries**

Anthony Carlisle, +44 7973 611 888 (Mobile)  
Citigate Dewe Rogerson anthony.carlisle@cdrconsultancy.co.uk

### **U.S. Based Media Enquiries**

Brad Miles, Solebury Trout +1 (917) 570 7340 (Mobile)  
bmiles@troutgroup.com  
Susan Duffy, Solebury Trout +1 (917) 499 8887 (Mobile)  
sduffy@troutgroup.com

**Investor Relations**

Xuan Yang, Solebury Trout

+1 (415) 971 9412 (Mobile)

xyang@troutgroup.com

David Dible,

+44 7967 566 919 (Mobile)

Citigate Dewe Rogerson

david.dible@citigatedewerogerson.com

**Panmure Gordon (UK) Limited**

Richard Gray / Andrew Potts

+44 (20) 7886 2500