



HUTCHISON CHINA MEDITECH LIMITED

## Press Release

### Chi-Med Initiates a Phase II Study of Sulfatinib in Second-line Biliary Tract Cancer in China

**London: Monday, January 16, 2017:** Hutchison China MediTech Limited (“Chi-Med”) (AIM/Nasdaq: HCM) today announces that it has initiated a Phase II study of sulfatinib in second-line biliary tract cancer (“BTC”) patients in China. Sulfatinib is an oral, novel angio-immunokinase inhibitor that selectively targets 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. The first drug dose was administered on January 9, 2017.

This Phase II study is a multi-center, single-arm, open-label study to evaluate the efficacy and safety of sulfatinib as a monotherapy in treating advanced or metastatic BTC patients who failed one prior systemic therapy. The primary endpoint is progression free survival (“PFS”) at 16 weeks, with secondary endpoints including objective response rate (“ORR”), disease control rate (“DCR”), duration of response, PFS, overall survival (“OS”) and safety. Additional details about this study may be found at [clinicaltrials.gov](http://clinicaltrials.gov), using identifier [NCT02966821](https://clinicaltrials.gov/ct2/show/study/NCT02966821).

#### About BTC

BTC, also known as cholangiocarcinoma, is a heterogeneous group of rare but fatal malignancies arising from the biliary tract epithelia, including intrahepatic cholangiocarcinoma and extrahepatic cholangiocarcinoma. BTC is the second most frequently occurring type of liver cancer in the world, after hepatocellular carcinoma (HCC), accounting for approximately 15% of all liver cancer cases<sup>1</sup>. In 2017, there will be approximately 18,000 new BTC cases in the United States, according to the National Cancer Institute. However, in China, the incidence can be up to 40 times the rate observed in the Western world<sup>2</sup>.

Gemcitabine is the current first-line therapy for BTC patients, either as a monotherapy or in combination with cisplatin, and there is no established second-line therapy for this fatal disease worldwide. The median life expectancy is less than 12 months for patients with unresectable or metastatic disease at diagnosis. Accordingly, we see a high unmet medical need for new targeted treatment options.

#### About Sulfatinib

Sulfatinib is an oral, novel angio-immunokinase inhibitor that selectively inhibits the tyrosine kinase activity associated with VEGFR, FGFR and 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.

In addition to the BTC trial, six sulfatinib clinical trials are underway in China and the United States, including two Phase III studies in neuroendocrine tumor patients (SANET-p and SANET-ep) and a Phase II study in thyroid cancer patients.

The SANET-p trial is a randomized, double-blind, placebo-controlled, multi-center, Phase III pivotal registration trial to treat about 190 pathologically low or intermediate grade pancreatic NET patients in China whose disease has progressed, locally advanced or distant metastasized and for whom there is no effective therapy. The primary endpoint is PFS, with secondary endpoints including ORR, DCR, duration of response, time to response and OS. Additional details of the SANET-p study may be found at

<sup>1</sup> A Ananthkrishnan et al; *Epidemiology of Primary and Secondary Liver Cancers*; Semin Intervent Radiol. 2006 Mar; 23(1): 47–63.

<sup>2</sup> JA Bridgewater et al; *Biliary Tract Cancer: Epidemiology, Radiotherapy, and Molecular Profiling*; Am Soc Clin Oncol Educ Book. 2016;35:e194-203.

clinicaltrials.gov, using identifier [NCT02589821](#). The SANET-ep trial is similar to the SANET-p trial and is targeted at treating about 270 non-pancreatic NET patients in China. Additional details of the SANET-ep study may be found at clinicaltrials.gov, using identifier [NCT02588170](#).

Chi-Med is conducting an open-label Phase II clinical trial to evaluate the efficacy and safety of sulfatinib in about 50 patients with locally advanced or metastatic radioactive iodine-refractory differentiated thyroid cancer or medullary thyroid cancer in China. The primary endpoint is ORR, with secondary endpoints including the safety and tolerability, DCR, time to response and PFS. Additional details of this study may be found at clinicaltrials.gov, using identifier [NCT02614495](#).

## 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: 0001). 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.*

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