



HUTCHISON CHINA MEDITECH

## Press Release

### Chi-Med Initiates a Phase IIb/III Trial of Surufatinib in Patients with Unresectable or Metastatic Biliary Tract Cancer in China

**London: Friday, March 29, 2019:** Hutchison China MediTech Limited (“Chi-Med”) (AIM/Nasdaq: HCM) has initiated a registration-enabling Phase IIb/III study comparing surufatinib (HMPL-012 or sulfatinib) with capecitabine in patients with advanced biliary tract cancer (“BTC”) whose disease progressed on first-line chemotherapy. This major unmet medical need is a heterogeneous group of rare malignancies arising from the biliary tract epithelia and the gallbladder. The first patient was dosed on March 22, 2019 in China.

The study is a randomized, open-label, active-control, multi-center, study investigating the effects of surufatinib, an oral small molecule angio-immuno kinase inhibitor that can simultaneously block tumor angiogenesis and immune evasion, versus the chemotherapy agent capecitabine, as a second-line therapy in patients with unresectable or metastatic BTC. The primary endpoint is overall survival (OS). Secondary outcomes include measures of tumor control such as progression free survival (“PFS”), objective response rate (ORR), disease control rate (DCR), and duration of response (DOR), quality of life, tumor biomarkers, and safety. The lead investigator of the study is Professor Jianming Xu of the Department of Gastrointestinal Oncology, the Fifth Medical Center, General Hospital of the People's Liberation Army. Additional details may be found at [clinicaltrials.gov](http://clinicaltrials.gov), using identifier [NCT03873532](https://clinicaltrials.gov/ct2/show/study/NCT03873532).

This study complements a Phase Ib/II proof-of-concept study of surufatinib in China ([clinicaltrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT02966821) identifier: [NCT02966821](https://clinicaltrials.gov/ct2/show/study/NCT02966821)) in BTC as well as a Phase Ib study in the US enrolling patients with BTC and pancreatic neuroendocrine tumors (“NET”) ([clinicaltrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT02549937) identifier: [NCT02549937](https://clinicaltrials.gov/ct2/show/study/NCT02549937)). Results of the Phase Ib/II proof-of-concept BTC study is expected to be submitted for publication in 2019.

#### About Surufatinib

Surufatinib is a novel, oral angio-immuno kinase inhibitor that selectively inhibits the tyrosine kinase activity associated with vascular endothelial growth factor receptor (VEGFR) and fibroblast growth factor receptor (FGFR), which both inhibit angiogenesis, and colony stimulating factor-1 receptor (CSF-1R), which regulates tumor-associated macrophages, promoting the body’s immune response against tumor cells. Its unique dual mechanism of action may be very suitable for possible combinations with other immunotherapies. In addition to the BTC studies, surufatinib is in proof-of-concept clinical trials in the U.S. and several proof-of-concept and late-stage clinical trials in China.

*Pancreatic NET in China:* In 2016, we initiated the SANET-p study, which is a pivotal Phase III study in patients with low- or intermediate-grade, advanced pancreatic NET in China. The primary endpoint is PFS. We expect to deliver an interim analysis in late 2019 and complete enrollment in 2020 ([clinicaltrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT02589821) identifier: [NCT02589821](https://clinicaltrials.gov/ct2/show/study/NCT02589821)).

*Non-pancreatic NET in China:* In December 2015, we initiated the SANET-ep study, which is a pivotal Phase III study in patients with low or intermediate grade advanced non-pancreatic NET in China. The primary endpoint is PFS. We expect to deliver an interim analysis in mid-2019 and complete enrollment in 2020. ([clinicaltrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT02588170) identifier: [NCT02588170](https://clinicaltrials.gov/ct2/show/study/NCT02588170)).

*Pancreatic NET in the U.S. and Europe:* The encouraging data from the Phase II study of surufatinib in pancreatic NET in China ([clinicaltrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT02267967) identifier: [NCT02267967](https://clinicaltrials.gov/ct2/show/study/NCT02267967)), and the ongoing Phase Ib study in the U.S., have led us to decide to proceed with planning a registration study in pancreatic NET patients.

*Immunotherapy combinations:* In November 2018, we entered into two collaboration agreements to evaluate the safety, tolerability and efficacy of surufatinib in combination with checkpoint inhibitors. These include a global collaboration to evaluate the combination of surufatinib with Tuoyi® (toripalimab, JS001), a PD-1 monoclonal antibody approved in China in late 2018 by Shanghai Junshi Biosciences Co. Ltd. and a collaboration in China to evaluate the combination of surufatinib with HX008, a PD-1 monoclonal antibody being developed by Taizhou Hanzhong Pharmaceuticals, Inc.. Safety run-in studies are currently being planned/underway to establish the safe and effective dose regimens for the surufatinib combinations with both Tuoyi® and HX008.

## About Chi-Med

Chi-Med (AIM/Nasdaq: HCM) is an innovative biopharmaceutical company which researches, develops, manufactures and markets pharmaceutical products. Its Innovation Platform, Hutchison MediPharma, has about 420 scientists and staff focusing on discovering, developing and commercializing targeted therapeutics and immunotherapies in oncology and autoimmune diseases. It has a portfolio of eight cancer drug candidates currently in clinical studies around the world. Chi-Med's Commercial Platform manufactures, markets, and distributes prescription drugs and consumer health products, covering an extensive network of hospitals across China.

Dual-listed on the AIM market of the London Stock Exchange and the Nasdaq Global Select Market, Chi-Med is headquartered in Hong Kong and 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 surufatinib, plans to initiate clinical studies for surufatinib, 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 surufatinib, including as a combination therapy, 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 surufatinib for a targeted indication and the sufficiency of funding. In addition, as certain studies rely on the use of Tuoyi® and HX008 as combination therapeutics with surufatinib, such risks and uncertainties include assumptions regarding the safety, efficacy, supply and continued regulatory approval for Tuoyi® and HX008. 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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