



HUTCHISON CHINA MEDITECH

Chi-Med Announces that Surufatinib Phase III SANET-ep Study Has Met its Primary Endpoint at Interim Analysis in Advanced Non-Pancreatic Neuroendocrine Tumors in China and Will Stop Early

London: Friday, June 14, 2019: Hutchison China MediTech Limited (“[Chi-Med](#)”) (AIM/Nasdaq: HCM) today announces that the independent Data Monitoring Committee (“IDMC”) of the Phase III pivotal study of surufatinib in advanced neuroendocrine tumors – extra-pancreatic (“SANET-ep”) has completed a planned interim analysis. The IDMC determined that the study has already met the pre-defined primary endpoint of progression free survival (“PFS”) and as a result the study will be stopped.

Chi-Med will now arrange for a pre-New Drug Application (“NDA”) meeting with the China National Medical Products Administration (NMPA) to discuss the preparation of the NDA for surufatinib for this indication. We intend to submit the results of the SANET-ep study for presentation at an upcoming scientific conference.

About SANET-ep

SANET-ep is a Phase III study in China of surufatinib in patients with low- or intermediate-grade advanced extra-pancreatic neuroendocrine tumors patients for whom there is no effective therapy. In this study, patients are randomized at a 2:1 ratio to receive either 300 mg of surufatinib orally daily or placebo, on a 28-day treatment cycle. The primary endpoint of the study is to evaluate the PFS, with secondary endpoints including objective response rate (ORR), disease control rate (DCR), time to response (TTR), duration of response (DoR), overall survival (OS), safety, and tolerability. Additional details may be found at clinicaltrials.gov, using identifier [NCT02588170](https://clinicaltrials.gov/ct2/show/study/NCT02588170).

About Neuroendocrine Tumors

Neuroendocrine tumors form in cells that interact with the nervous system or in glands that produce hormones. They can originate in various parts of the body, most often in the gut or the lungs and can be benign or malignant. Neuroendocrine tumors are typically classified as pancreatic neuroendocrine tumors or other neuroendocrine tumors. Approved targeted therapies include Sutent® and Afinitor® for pancreatic neuroendocrine tumors, or well-differentiated, non-functional gastrointestinal or lung neuroendocrine tumors.

According to Frost and Sullivan, there were 19,000 newly diagnosed cases of neuroendocrine tumors in the U.S. in 2018. Importantly, neuroendocrine tumors are associated with a relatively long duration of survival compared to other tumors. As a result, there were approximately 141,000 estimated patients living with neuroendocrine tumors in the U.S. in 2018 of which over 90%, or approximately 132,000, were non-pancreatic neuroendocrine tumor patients.

In China there were approximately 67,600 newly diagnosed neuroendocrine patients in 2018 and, considering the U.S. incidence to prevalence ratio, potentially as many as 490,000 patients living with the disease.

About Surufatinib

Surufatinib (previously known as HMPL-012 or sulfatinib) 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. Surufatinib is in proof-of-concept clinical trials in the U.S. and several proof-of-concept and late-stage clinical trials in China.

We currently retain all rights to surufatinib worldwide.

Pancreatic neuroendocrine tumors 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 neuroendocrine tumors in China. The primary endpoint is PFS. We expect an interim analysis in late 2019 and enrollment to complete in 2020 (clinicaltrials.gov identifier: [NCT02589821](https://clinicaltrials.gov/ct2/show/study/NCT02589821)).

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

Biliary tract cancer in China: In March 2019, we initiated a Phase Ib/III study comparing surufatinib with capecitabine in patients with advanced biliary tract cancer whose disease progressed on first-line chemotherapy. The primary endpoint is overall survival (OS) (clinicaltrials.gov identifier [NCT03873532](https://clinicaltrials.gov/ct2/show/study/NCT03873532)).

Immunotherapy combinations: In November 2018, we entered into [collaboration agreements](#) to evaluate the safety, tolerability and efficacy of surufatinib in combination with checkpoint inhibitors. This included a global collaboration to evaluate the combination of surufatinib with Tuoyi[®], a PD-1 monoclonal antibody approved in China in late 2018 by Shanghai Junshi Biosciences Co. Ltd.

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 440 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.

Forward-Looking Statements

This announcement 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 announcement, whether as a result of new information, future events or circumstances or otherwise.

Inside Information

This announcement contains inside information for the purposes of Article 7 of Regulation (EU) No 596/2014.

CONTACTS

Investor Enquiries

Mark Lee, Senior Vice President, Corporate Finance & Development

+852 2121 8200

Annie Cheng, Vice President, Corporate Finance & Development

David Dible, Citigate Dewe Rogerson

Xuan Yang, Solebury Trout

+1 (973) 567 3786

+44 7967 566 919 (Mobile)
david.dible@citigatedewerogerson.com

+1 (415) 971 9412 (Mobile)
xyang@troutgroup.com

Media Enquiries

UK & Europe – Anthony Carlisle, Citigate Dewe Rogerson

+44 7973 611 888 (Mobile)
anthony.carlisle@cdrconsultancy.co.uk

Americas – Brad Miles, Solebury Trout

+1 (917) 570 7340 (Mobile)
bmiles@troutgroup.com

Hong Kong & Asia ex-China – Joseph Chi Lo, Brunswick

+852 9850 5033 (Mobile)
jlo@brunswickgroup.com

– Zhou Yi, Brunswick

+852 9783 6894 (Mobile)
yzhou@brunswickgroup.com

Mainland China – Sam Shen, Edelman

+86 136 7179 1029 (Mobile)
sam.shen@edelman.com

Nominated Advisor

Richard Gray / Atholl Tweedie, Panmure Gordon (UK) Limited

+44 (20) 7886 2500