

Press Release

Chi-Med Initiates a Phase II Trial of Surufatinib in Combination with Tuoyi in Patients with Advanced Solid Tumors

London: Monday, January 13, 2020: Hutchison China MediTech Limited (“[Chi-Med](#)”) (AIM/Nasdaq: HCM) has initiated a Phase II study in China of surufatinib in combination with Tuoyi (toripalimab) in patients with advanced solid tumors. This follows the recent completion of the Phase I dose finding study and successful establishment of the Phase II combination dosing regimen for surufatinib and Tuoyi.

This China Phase II clinical study is part of a global collaboration with Shanghai Junshi Biosciences Co. Ltd. (“Junshi”), to evaluate surufatinib, Chi-Med’s oral angio-immuno kinase inhibitor, in combination with Tuoyi, Junshi’s anti-programmed cell death protein 1 (“PD-1”) monoclonal antibody which was approved by China’s National Medical Products Administration (“NMPA”) in December 2018. The study is designed to test the potential synergistic anti-tumor effects of the combination’s ability to simultaneously target multiple cell types and signaling pathways in the tumor microenvironment.

The Phase II study plans to explore multiple solid tumor patient populations. The primary outcome measures are objective response rate (ORR) and safety. The secondary outcomes include duration of response (DoR), progression-free survival (“PFS”), disease control rate (DCR) and overall survival (“OS”). The lead principal investigator of the study is Professor Lin Shen, Vice President of Peking University Hospital and Cancer Institute. Additional details may be found at [clinicaltrials.gov](#), using identifier [NCT04169672](#).

Christian Hogg, Chief Executive Officer of Chi-Med, said, “We are excited to move into Phase II development on the surufatinib toripalimab combination and look forward to identifying patient groups that could benefit from this innovative treatment regimen.”

In December 2019, surufatinib was granted Priority Review status by the Center for Drug Evaluation (CDE) of China’s NMPA for its New Drug Application (“NDA”) for the treatment of patients with advanced non-pancreatic neuroendocrine tumors (“NET”).

In November 2019, the NDA for surufatinib for the treatment of non-pancreatic NET was accepted for review by the NMPA, and the U.S. Food and Drug Administration granted Orphan Drug designation to surufatinib for the treatment of pancreatic NET.

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 several late-stage and proof-of-concept clinical trials in China and proof-of-concept clinical trials in the U.S.

According to Frost & Sullivan, the market for anti-angiogenesis VEGF/VEGFR inhibitors in China has grown from US\$500 million in 2015 to over US\$1.5 billion in 2019 and is expected to reach US\$5 billion by 2026.

Chi-Med currently retains all rights to surufatinib worldwide.

Non-Pancreatic NET in China: In 2015, we initiated the SANET-ep study, a Phase III study of surufatinib in advanced neuroendocrine tumors – extra-pancreatic patients in China for whom there is no effective therapy. In June 2019, a 198-patient interim analysis was conducted, leading the independent data monitoring committee to determine that the study met the pre-defined primary endpoint of progression-free survival (“PFS”) and should be stopped early. The positive results were highlighted in an oral presentation at the 2019 European Society for Medical Oncology Congress in September 2019. In November 2019, the NDA was accepted for review by the NMPA ([clinicaltrials.gov](#) identifier: [NCT02588170](#)) and subsequently granted Priority Review status.

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 an interim analysis in the first half of 2020 and enrollment to complete in 2020 (clinicaltrials.gov identifier: [NCT02589821](#)).

NET in the U.S. and Europe: We are planning a U.S. registration study in NET patients based on the encouraging data from the Phase II and Phase III studies of surufatinib in NET in China (clinicaltrials.gov identifier: [NCT02267967](#)), and the ongoing Phase II study in the U.S. (clinicaltrials.gov identifier: [NCT02549937](#)).

Biliary tract cancer in China: In March 2019, we initiated a Phase IIb/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](#)).

Immunotherapy combinations: In November 2018 and September 2019, we entered into [collaboration agreements](#) to evaluate the safety, tolerability and efficacy of surufatinib in combination with anti-PD-1 monoclonal antibodies. This included global collaborations to evaluate the combination of surufatinib with Tuoyi, approved in China by Junshi, and with Tyvyt®, approved in China by Innovent Biologics, Inc.

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 490 scientists and staff focusing on discovering, developing and commercializing targeted therapeutics and immunotherapies in cancer 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.

Chi-Med is headquartered in Hong Kong and is dual-listed on the AIM market of the London Stock Exchange and the Nasdaq Global Select Market. For more information, please visit: [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 in combination therapy with toripalimab, its expectations regarding the NDA approval and launch of surufatinib for the treatment of patients with non-pancreatic NET in China, the further clinical development of surufatinib in non-pancreatic NET, pancreatic NET and other indications, its expectations as to whether clinical studies of surufatinib 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 the sufficiency of its data to support NDA approval of surufatinib for the treatment of patients with non-pancreatic NET in China, its potential to gain expeditious approvals for surufatinib under priority review in China and in other jurisdictions such as the U.S. and EU, the safety profile of surufatinib, the potential for surufatinib to become a new standard of care for non-pancreatic NET patients, its ability to implement and complete its further clinical development plans for surufatinib, its potential commercial launch of surufatinib in China and other jurisdictions and the timing of these events. 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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