



HUTCHISON CHINA MEDITECH

## Press Release

# Chi-Med Announces Surufatinib Granted FDA Orphan Drug Designation for Pancreatic Neuroendocrine Tumors

**London: Monday, November 25, 2019:** Hutchison China MediTech Limited (“[Chi-Med](#)”) (AIM/Nasdaq: HCM) today announces that the U.S. Food and Drug Administration (“FDA”) has granted Orphan Drug designation to surufatinib for the treatment of pancreatic neuroendocrine tumors (“NET”).

“NET is an area of significant unmet medical need. The current treatment options are very limited,” said Christian Hogg, CEO of Chi-Med. “The FDA granting Orphan designation is a positive step and continues to reinforce the importance of our research and development in bringing surufatinib to more patients in need.”

If approved by the FDA as an orphan treatment, surufatinib will be entitled to seven years of market exclusivity for the approved indication. Orphan Drug designation also affords certain development cost benefits in the U.S.

Surufatinib is under investigation in multiple solid tumors in China and the U.S., both as a monotherapy and in combination with immunotherapies.

Surufatinib is the second novel oncology drug discovered by Chi-Med to successfully complete a Phase III trial in China. A New Drug Application (“NDA”) for surufatinib for the treatment of patients with advanced non-pancreatic NET was accepted for review by the China National Medical Products Administration (NMPA) on November 11, 2019.

### About FDA Orphan Drug Designation

The FDA Orphan Drug Designation Program provides orphan status to drugs and biologics which are defined as those intended for the safe and effective treatment, diagnosis or prevention of rarer diseases/disorders that affect fewer than 200,000 people in the U.S., or that affect more than 200,000 persons but are not expected to recover the costs of developing and marketing a treatment drug.

### 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 neuroendocrine tumors 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.

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

*Neuroendocrine tumors in the U.S. and Europe:* We are planning a U.S. registration study in neuroendocrine tumors patients based on the encouraging data from the Phase II and Phase III studies of surufatinib in neuroendocrine tumors in China (clinicaltrials.gov identifier: [NCT02267967](https://clinicaltrials.gov/ct2/show/study/NCT02267967)), and the ongoing Phase Ib study in the U.S. (clinicaltrials.gov identifier: [NCT02549937](https://clinicaltrials.gov/ct2/show/study/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](https://clinicaltrials.gov/ct2/show/study/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-programmed cell death protein 1 (PD-1) monoclonal antibodies. This included global collaborations to evaluate the combination of surufatinib with Tuoyi<sup>®</sup>, approved in China by Shanghai Junshi Biosciences Co. Ltd, and with Tyvyt<sup>®</sup>, approved in China by Innovent Biologics, Inc.

## **About Neuroendocrine Tumors (NET)**

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 non-pancreatic neuroendocrine tumors. Approved targeted therapies include Sutent<sup>®</sup> and Afinitor<sup>®</sup> 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 tumor patients in 2018 and, considering the current incidence to prevalence ratio in China, potentially as many as 300,000 patients living with the disease in the country<sup>1</sup>. It is estimated that approximately 80% of the patients living with neuroendocrine tumors in China are non-pancreatic neuroendocrine tumor patients.

## **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 470 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.

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](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 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 this 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 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*

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<sup>1</sup> According to Frost & Sullivan, in 2018, there were 19,000 newly diagnosed cases of NETs in the U.S and an estimated 141,000 patients living with NETs. The current incidence to prevalence ratio in China is estimated at 4.4, lower than the 7.4 ratio in the U.S. due to lower access to treatment options.

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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