



HUTCHISON CHINA MEDITECH

## Press Release

# Chi-Med Announces Second NDA Acceptance in China for Surufatinib in Pancreatic Neuroendocrine Tumors

**Hong Kong, Shanghai, & Florham Park, NJ: Thursday, September 17, 2020:** Hutchison China MediTech Limited (“[Chi-Med](#)”) (Nasdaq/AIM: HCM) today announces that its New Drug Application (“NDA”) for surufatinib for the treatment of patients with advanced pancreatic neuroendocrine tumors (“NET”) has been accepted for review by the China National Medical Products Administration (“NMPA”).

The NDA is supported by data from the successful SANET-p study, a Phase III pivotal study of surufatinib in advanced neuroendocrine tumors – pancreatic patients in China for whom there is no effective therapy. The study was terminated early following positive interim analysis completed in January 2020. The positive results of the study demonstrating improvement in progression free survival (“PFS”) will be presented at the 2020 European Society for Medical Oncology Congress (“ESMO”) (Abstract Number [1156O](#)). This is the second NDA acceptance for surufatinib. The first NDA for non-pancreatic NET was accepted by the NMPA in November 2019 and was granted priority review status in December 2019.

Chi-Med currently retains all worldwide rights to surufatinib. This drug candidate is under investigation in multiple solid tumors in China and the U.S., both as a monotherapy and in combination with immunotherapies.

In the U.S., the Food and Drug Administration (“FDA”) granted Fast Track Designation status to surufatinib for both the non-pancreatic NET and pancreatic NET development programs in April 2020. Chi-Med has initiated preparatory work for the U.S. NDA and intends to utilize a rolling submission, which is expected to start in late 2020. In addition, the Marketing Authorization Application (“MAA”) submission in Europe is planned for 2021.

### About NET

NETs 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. NET are typically classified as pancreatic NET or non-pancreatic NET. Approved targeted therapies include Sutent® and Afinitor® for pancreatic NET, or well-differentiated, non-functional gastrointestinal or lung NET.

According to Frost and Sullivan, there were 19,000 newly diagnosed cases of NET in the U.S. in 2018. Importantly, NETs 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 NET in the U.S. in 2018.

In China, there were approximately 67,600 newly diagnosed NET 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.

### 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, where there may be synergistic anti-tumor effects.

Chi-Med currently retains all rights to surufatinib worldwide.

### About Surufatinib Development

*NET in the U.S. and Europe:* In the U.S., surufatinib was granted [Fast Track Designations](#) for development in pancreatic and non-pancreatic (extra-pancreatic) NET in April 2020, and [Orphan Drug Designation](#) for

pancreatic NET in November 2019. A U.S. FDA NDA submission is being prepared, to be followed by a MAA submission to the EMA in Europe. The basis to support these filings includes the completed SANET-ep and SANET-p studies, along with existing data from surufatinib in U.S. non-pancreatic and pancreatic NET patients (clinicaltrials.gov identifier: [NCT02549937](https://clinicaltrials.gov/ct2/show/study/NCT02549937)).

*Non-pancreatic NET in China:* In November 2019, a NDA for surufatinib for the treatment of patients with advanced non-pancreatic NET was [accepted for review](#) by the NMPA and [granted Priority Review](#) status in December 2019. The NDA is supported by data from the successful SANET-ep study, a Phase III study of surufatinib in patients with advanced non-pancreatic NET in China for whom there is no effective therapy. A 198-patient interim analysis was conducted in June 2019, leading the Independent Data Monitoring Committee (“IDMC”) to determine that the study met the pre-defined primary endpoint of progression-free survival (“PFS”) and should be stopped early. The [positive results](#) of this trial were highlighted in an oral presentation at ESMO 2019 (clinicaltrials.gov identifier: [NCT02588170](https://clinicaltrials.gov/ct2/show/study/NCT02588170)).

*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. Following an interim analysis review conducted in January 2020 by the IDMC that recommended the registrational study be terminated early as the pre-defined primary endpoint of [PFS had already been met](#) (clinicaltrials.gov identifier: [NCT02589821](https://clinicaltrials.gov/ct2/show/study/NCT02589821)), leading to a second NDA accepted by the China NMPA. The results of this study will be presented at ESMO 2020.

*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:* We have entered into collaboration agreements to evaluate the safety, tolerability and efficacy of surufatinib in combination with anti-PD-1 monoclonal antibodies, including with [tislelizumab](#) (BGB-A317, developed by BeiGene, Ltd.), [Tuoyi](#)<sup>®</sup> (toripalimab, developed by Shanghai Junshi Biosciences Co., Ltd.) and [Tyvyt](#)<sup>®</sup> (sintilimab, developed by Innovent Biologics, Inc.), which are approved in China.

## **About Chi-Med**

Chi-Med (Nasdaq/AIM: HCM) is an innovative, commercial-stage, biopharmaceutical company committed, over the past twenty years, to the discovery and global development of targeted therapies and immunotherapies for the treatment of cancer and immunological diseases. It has a portfolio of nine cancer drug candidates currently in clinical studies around the world and extensive commercial infrastructure in its home market of China. 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 therapeutic potential of surufatinib for the treatment of patients with pancreatic NET, 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 pancreatic NET in China, its potential to gain expeditious approvals for surufatinib in other jurisdictions such as the U.S., E.U. or Japan, the safety profile of surufatinib, the potential for surufatinib to become a new standard of care for 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, the timing of these events, and the impact of the COVID-19 pandemic on general economic, regulatory and political conditions. 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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