HUTCHISON CHINA MEDITECH

Press Release

Chi-Med Highlights Surufatinib Phase III Results in Neuroendocrine Tumors at ESMO 2020 and Publications in *The Lancet Oncology*

— Phase III SANET-p demonstrated surufatinib reduces the risk of disease progression or death by 51% in patients with pancreatic neuroendocrine tumors ("NET") —

— SANET-p results complement previously presented positive Phase III SANET-ep results in patients with non-pancreatic NET, including across multiple subgroups —

— Results of both SANET-p and SANET-ep studies published in The Lancet Oncology –

Hong Kong, Shanghai, & Florham Park, NJ: Sunday, September 20, 2020: Hutchison China MediTech Limited ("Chi-Med") (Nasdaq/AIM: HCM) today announces that positive results of the Phase III study of **s**urufatinib in **a**dvanced **ne**uroendocrine **t**umors – **p**ancreatic ("SANET-p") were presented as a proffered paper session at the European Society for Medical Oncology ("ESMO") Virtual Congress 2020 (Abstract Number 1156O). Results from SANET-p, in addition to previously presented results from Phase III study of **s**urufatinib in **a**dvanced **ne**uroendocrine **t**umors – **e**xtra-**p**ancreatic ("SANET-ep"), are published today in *The Lancet Oncology*.

"Surufatinib demonstrated statistically significant and clinically meaningful benefits in patients with advanced pancreatic NET. These results, combined with positive results from the parallel study of surufatinib in patients with non-pancreatic NET, support surufatinib as a promising treatment option for well-differentiated NET patients regardless of tumor origin," commented Dr. Jianming Xu, lead investigator for the SANET-p study, Head of the Department of Gastrointestinal Oncology, The Fifth Medical Center, General Hospital of the PLA in Beijing.

As announced in January 2020, the Independent Data Monitoring Committee ("IDMC") for the SANET-p trial recommended that the study stop early because it had met the pre-defined primary endpoint of progression free survival ("PFS") during a planned interim analysis. At data cut-off as of November 11, 2019, 172 patients were randomized 2:1 to treatment with either 300 mg of surufatinib orally daily (N=113) or placebo control (N=59), on a 28-day cycle. Median PFS was 10.9 months for patients treated with surufatinib, as compared to 3.7 months for patients in the placebo group (hazard ratio ["HR"] 0.491; 95% confidence interval ["CI"] 0.391-0.755; *p*=0.0011). Benefit was observed across most major subgroups of pNET patients. Objective response rates (ORR) were 19.2%[1] for the 104 efficacy evaluable patients in the surufatinib group versus 1.9%[2] for the 53 efficacy evaluable patients in the placebo group, with a disease control rate (DCR) of 80.8% versus 66.0%, respectively. Most patients in the trial had Grade 2 disease with heavy tumor burden, including liver metastasis and multiple organ involvement. Efficacy was also supported by Blinded Independent Image Review Committee (BIIRC) assessment, with a median PFS of 13.9 months for surufatinib as compared to 4.6 months for placebo (HR 0.339; 95% CI 0.209-0.549; *p*<0.0001).

The safety profile of surufatinib was manageable and consistent with observations in prior studies. Treatment was well tolerated for most patients, with discontinuation rates as a result of treatment emergent adverse events of 10.6% in the surufatinib group as compared to 6.8% in the placebo group.

In the U.S., the Food and Drug Administration ("FDA") granted surufatinib two Fast Track Designations, for both the non-pancreatic NET and pancreatic NET development programs, and Orphan Drug Designation for pancreatic NET development. A rolling new drug application ("NDA") submission is being prepared, to be followed by a marketing authorization application ("MAA") submission to the European Medicines Agency ("EMA") in Europe, based on the robust data from the two studies and the ongoing multi-cohort Phase Ib study in the U.S. In December 2019, an NDA for surufatinib for the treatment of patients with advanced non-pancreatic NET was granted Priority Review status by the China National Medical Products Administration ("NMPA"). A second NDA for surufatinib for the treatment of patients with advanced pancreatic NET has also been accepted by the NMPA.

About NET

NET 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, NET 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.[3]

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).

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 IDMC to determine that the study met the pre-defined primary endpoint of PFS and should be stopped early. The positive results of this trial were highlighted in an oral presentation at the 2019 ESMO Congress (clinicaltrials.gov identifier: NCT02588170) and published in *The Lancet Oncology* in September 2020.[4] Median PFS was 9.2 months for patients treated with surufatinib, as compared to 3.8 months for patients in the placebo group (HR 0.334; 95% CI: 0.223-0.499; p<0.0001).

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), leading to a second NDA accepted by the China NMPA. The results of this study were presented at the ESMO Virtual Congress 2020 and published simultaneously in *The Lancet Oncology*.[5]

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: 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® (toripalimab, developed by Shanghai Junshi Biosciences Co. Ltd.) and Tyvyt® (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.

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 submission of an NDA for surufatinib for the treatment of NET in the U.S., China and other jurisdictions, the therapeutic potential of surufatinib for the treatment of patients with NET, the further clinical development for surufatinib in this and other indications, 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 the clinical data to support NDA approval of surufatinib for the treatment of patients with NET in the U.S. and China or other jurisdictions, its potential to gain expeditious approvals from regulatory authorities, the safety profile of surufatinib, 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 surufatinib, including as a combination therapy, to meet the primary or secondary endpoint of a study, its ability to fund, implement and complete its further clinical development and commercialization plans for surufatinib, the timing of these events, and the impact of the COVID-19 pandemic on general economic, regulatory and political conditions. In addition, as certain studies rely on the use of capecitabine, tislelizumab, Tuoyi®, and Tyvyt® as combination therapeutics with surufatinib, such risks and uncertainties include assumptions regarding the safety, efficacy, supply and continued regulatory approval of these therapeutics. 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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[1] Responses in the surufatinib group included 13 confirmed partial responses and 7 unconfirmed partial responses.
[2] There was 1 confirmed partial response in the placebo group.
[3] 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.
[4] Xu J, Shen L, Zhou Z, et al. Surufatinib in advanced extrapancreatic neuroendocrine tumours (SANET-ep): a randomised, double-blind, placebo-controlled, phase 3 study [published online ahead of print, 2020 Sep 20]. *Lancet Oncol.* 2020;S1470-2045(20)30496-4. DOI: 10.1016/S1470-2045(20)30496-4.
[5] Xu J, Shen L, Bai C, et al. Surufatinib in advanced pancreatic neuroendocrine tumours (SANET-p): a randomised, double-blind, placebo-controlled, phase 3 study [published online ahead of print, 2020 Sep 20]. *Lancet Oncol.* 2020; S1470-2045(20)30493-9. DOI: 10.1016/S1470-2045(20)30493-9.