HUTCHISON CHINA MEDITECH

Chi-Med Announces the NMPA Approval of Surufatinib (Sulanda® in China) for Non-Pancreatic Neuroendocrine Tumors

– Sulanda® is Chi-Med's first oncology drug brought to market without a partnership and the company's second oncology drug approved in China –

– The pivotal Phase III SANET-ep trial demonstrated surufatinib reduced risk of progression or death by 67%, extending PFS in all subgroups of non-pancreatic NET patients with an acceptable risk/benefit ratio –

– ~400-strong oncology commercial team in place to bring Sulanda® to patients in China –

Hong Kong, Shanghai, & Florham Park, NJ: Wednesday, December 30, 2020: Hutchison China MediTech Limited ("Chi-Med") (Nasdaq/AIM: HCM) today announces that surufatinib has been granted approval for drug registration by the National Medical Products Administration of China ("NMPA") for the treatment of non-pancreatic neuroendocrine tumors ("NETs"). Surufatinib will be marketed in China under the brand name Sulanda®. Surufatinib is Chi-Med's first self-discovered oncology drug to be approved in China without the support of a development partner, and follows the approval of Chi-Med's first oncology drug, Elunate® (fruquintinib capsules), in 2018.

Christian Hogg, Chief Executive Officer of Chi-Med commented, "We are very pleased to have achieved this major milestone for Chi-Med. The approval of surufatinib, our first un-partnered oncology drug, is a strong testament to our in-house research and development capability."

"Today's approval also marks an important development for NET patients, for whom there are currently limited treatment options. Compared with other NET therapies available in the market, surufatinib has a unique mode of action by both inhibiting angiogenesis and promoting the body's immune response against tumor cells. If our second new drug application ("NDA") in pancreatic NET is successful, this therapy would be approved in China to address all NET patients regardless of the tumor origin."

"We look forward to making this unique therapy available to patients as quickly and broadly as possible through our own expanded oncology commercial team."

Chi-Med has established an oncology commercial team that today covers more than 2,000 hospitals across China. The team is led by a leadership team highly experienced in oncology products commercialization in China with deep knowhow in the field of NETs.

The NMPA approval of Sulanda® was based on results from the SANET-ep[1] study, a Phase III trial (clinicaltrials.gov identifier: NCT02588170) in patients with advanced non-pancreatic NETs conducted in China. The study met the pre-defined primary endpoint of progression-free survival ("PFS") at a preplanned interim analysis. The positive results of this trial were highlighted in an oral presentation at the 2019 ESMO Congress and published in *The Lancet Oncology* in September 2020.[2] Median PFS was significantly longer for patients treated with surufatinib at 9.2 months, compared to 3.8 months for patients in the placebo group (HR 0.334; 95% CI: 0.223-0.499; p<0.0001). Surufatinib had an acceptable safety profile, with the most common treatment-related adverse events of grade 3 or worse being hypertension (36% of surufatinib patients vs. 13% of placebo patients), proteinuria (19% vs. 0%) and anemia (5% vs. 3%).

In China, there were an estimated 67,600 newly diagnosed NET patients in 2018. Considering the current incidence to prevalence ratio, there may be as many as 300,000 patients living with the disease.[3]

About NETs

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

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

About Surufatinib (Sulanda® in China)

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

NETs in the U.S. and Europe: In the U.S., surufatinib was granted Fast Track Designations for development in pNET and epNET in April 2020, and Orphan Drug Designation for pNET in November 2019. A U.S. FDA NDA rolling submission was initiated in December 2020, to be followed by a marketing authorization application (MAA) submission to the European Medicines Agency (EMA) in Europe. The basis to support these filings includes the completed SANET-ep and SANET-p[4] studies, along with existing data from surufatinib in U.S. non-pancreatic and pancreatic NET patients (clinicaltrials.gov identifier: NCT02549937).

Pancreatic NETs in China: The SANET-p study is a pivotal Phase III study in patients with low- or intermediate-grade, advanced pNET in China. It was terminated early as the pre-defined primary endpoint of PFS was met (clinicaltrials.gov identifier: NCT02589821) at an preplanned interim analysis, leading to a second NDA accepted by the China NMPA in September 2020. 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: A Phase IIb/III study was initiated in March 2019, 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: Chi-Med has 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 as monotherapies 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 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 regarding the commercial launch of surufatinib in China, the ability of its in-house oncology sales team to distribute surufatinib quickly and broadly, the potential market for surufatinib in non-pancreatic NET patients China, the potential approval of surufatinib in pancreatic NET, and the further clinical development for surufatinib in these and other indications in China, the United States and other jurisdictions. Forward-looking statements involve risks and uncertainties. Such risks and uncertainties include, among other things, assumptions regarding Chi-Med's ability to commercialize surufatinib, the benefits obtained from surufatinib during clinical trials being the same for all patients who are prescribed surufatinib, no unidentified side effects occurring which could result in the NMPA pulling surufatinib from the market, Chi-Med's 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 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.

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[1] Surufatinib in advanced neuroendocrine tumors – extra-pancreatic (non-pancreatic).

[2] 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.

[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] Surufatinib in advanced neuroendocrine tumors – pancreatic.

[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.