

Press Release

Chi-Med to Discuss Surufatinib Phase III and U.S. Phase I/Ib Efficacy and Safety Data Presented at the 2019 ESMO Annual Meeting

- *Surufatinib achieved primary endpoint, reducing the risk of progression or death by 67% in patients with non-pancreatic neuroendocrine tumors (“NET”) in the Phase III SANET-ep study –*
- *Preparations underway for the potential submission of surufatinib New Drug Application (“NDA”) by year end 2019 for non-pancreatic NET tumors in China –*
- *Treatment options are limited for the 90% of all global NET patients whose tumors originate outside of the pancreas. Surufatinib represents an important potential advancement for these patients –*
- *Conference call and webcast to be held on Monday, September 30, 2 p.m. Barcelona time to review surufatinib data –*

London: Sunday, September 29, 2019: Hutchison China MediTech Limited (“Chi-Med”) (AIM/Nasdaq: HCM) today presented the results of the Phase III study of surufatinib in advanced neuroendocrine tumors – extra-pancreatic (SANET-ep) at the 2019 European Society for Medical Oncology Congress (“ESMO”). The study has met the pre-defined primary endpoint of progression free survival (“PFS”) early. Patients treated with surufatinib were 67% less likely to see their disease progress or die as compared to patients on placebo control, assessed by local investigators.

Chi-Med is holding an investor conference call and webcast on Monday, September 30, to review the SANET-ep data. In addition, safety and tolerability data presented from an ongoing U.S. Phase Ib study of surufatinib in pancreatic NET patients who are refractory to Sutent® and Afinitor® will also be discussed.

SANET-ep – Phase III study in patients with extra-pancreatic (non-pancreatic) NET in China:

As announced in June 2019, the independent Data Monitoring Committee (“IDMC”) for the trial recommended that the study stop early because it had met the pre-defined primary endpoint of PFS during a planned interim analysis. Preparations are now underway for the potential NDA submission by year end 2019 for this indication in China.

At data cut-off as of March 31, 2019, 198 patients were randomized 2:1 to treatment with either 300 mg of surufatinib orally daily (N=129) or placebo control (N=69), on a 28-day cycle. Median PFS per investigator assessment was 9.2 months for patients treated with surufatinib, as compared to 3.8 months for patients in the placebo group (hazard ratio [“HR”] 0.334; 95% confidence interval [“CI”] 0.223-0.499; p<0.0001).

The efficacy of surufatinib was seen across all subgroups, and supported by statistically significant improvement as measured by secondary efficacy endpoints including objective response rate (“ORR”), disease control rate (“DCR”), time to response (“TTR”), duration of response (“DoR”), safety, and tolerability. Efficacy was also supported by Blinded Independent Image Review Committee (“BIIRC”) assessment. Overall survival (“OS”) data was not mature, with only 18.7% OS events at data cut-off. Surufatinib was generally well-tolerated in this study and the safety profile is consistent with observations in prior clinical studies.

Dr. Jianming Xu, co-lead investigator for the SANET-ep study, Head of the Department of Gastrointestinal Oncology, The Fifth Medical Center, General Hospital of the People’s Liberation Army in Beijing, said: “The SANET-ep results showed that surufatinib meaningfully benefited Chinese patients with progressive, advanced extra-pancreatic NET, across multiple measures of efficacy and was generally well tolerated. Importantly, these positive results were achieved in patients regardless of tumor origin and in patients who received prior systematic treatment for their disease.”

Dr. Lin Shen, co-lead investigator for the SANET-ep study, Vice President of the Beijing Cancer Hospital and Head of its Department of Gastroenterological Oncology, said: “NET is a disease that many oncologists encounter in their practices. Both in China and globally, options are limited for NET patients whose tumors originate outside of the pancreas. These patients account for over 90% of all NET cases. The SANET-ep results represent an important potential advancement in clinical practice for these patients.”

Summary of key efficacy results:

	Surufatinib (n=129)	Placebo (n=69)	Hazard Ratio (95% CI), p-value
Primary endpoint: PFS (investigator assessment)	9.2 months	3.8 months	0.334 (0.223-0.499), p<0.0001
Secondary endpoints:			
ORR	10.3%	0%	(5.6%-17.0%), p=0.0051
DCR	86.5%	65.6%	Odds Ratio 3.3 (1.5-7.3), p=0.0022
TTR	3.7 months		(1.8, 5.5)
DoR	5.6 months		(2.0, 17.5)

Investor Audio Webcast and Conference Call Scheduled on Monday at 2 p.m. Barcelona Time (1 p.m. London time, 8 a.m. New York time, 8 p.m. Hong Kong time):

Participating on the webcast will be members of the Chi-Med management team as well as Dr. James Yao, Chair of Gastrointestinal Oncology at MD Anderson Cancer Center and one of the lead investigators for Chi-Med's ongoing Phase I/Ib surufatinib study in NET. Toll-free dial-in numbers are as follows: U.K. 0808 109 0700; U.S. 1 866 966 5335; Mainland China 4001 200558; and Hong Kong 800 900 476.

Presentation slides will be posted before the call begins. Additional numbers and the slides will be available at www.chi-med.com/event-information/, and a replay will also be available shortly after the event.

Additional details from the SANET-ep study presentation include:

- **Patient Characteristics:** 83.8% of the patients in the study had disease with pathological grade 2. 41.4% of patients had disease originating outside of the gastrointestinal (GI) tract and the lung or with unknown origin. 67.2% of patients received prior systematic anti-tumor treatment for their disease, including chemotherapy (39.9%), somatostatin analogue (31.8%), and everolimus (9.1%). More patients in the surufatinib group received prior loco-regional therapy (34.1%) relative to the placebo group (23.3%). These therapies, such as chemoembolization, radiofrequency ablation of the surrounding organs may lead to challenges in evaluating lesions in those organs. A higher proportion of patients in the placebo group had Eastern Cooperation Oncology Group (ECOG) performance score of 0 (66.7%) than in the surufatinib group (55.8%).
- **Subgroup analyses:** PFS improvement was seen in multiple pre-specified subgroups, regardless of site of primary tumor (gastrointestinal or other), whether patients received prior systematic treatment for their disease, and irrespective of their baseline ECOG performance status.
- **Safety profile** is consistent with previous reports and surufatinib is generally well-tolerated. The most common Grade ≥ 3 adverse events ("AEs") among surufatinib treated patients were hypertension (36.4% vs. 13.2%) and proteinuria (19.4% vs. 0%). Any Grade ≥ 3 AEs occurred in 76.6% of patients who received surufatinib compared to 33.8% of patients who received placebo, and 17.8% of surufatinib patients had an AE leading to discontinuation of treatment compared to 5.9% in the placebo group.
- **BIIRC Assessment:** A BIIRC performed tumor assessment retrospectively in parallel, which was used for supportive sensitivity analysis of PFS. BIIRC median PFS was not a primary or secondary endpoint of the study. Median PFS per pre-specified BIIRC was 7.4 months for patients treated with surufatinib, as compared to 3.9 months for patients in the placebo group (HR 0.657; 0.442-0.977; p=0.0372). As differences between investigator and BIIRC reviews are often observed in global NET studies, post-hoc blinded image adjudication by independent reviewers, who are particularly experienced with evaluating NET patients, was conducted for the 35 patients with PFS discrepancy ≥ 4 cycles between BIIRC and investigator assessment. Per the post-hoc blinded image adjudication, median BIIRC PFS was unchanged, although the hazard ratio was 0.570 (CI 0.381-0.852), with p-value of 0.0065.

Additional details may be found at clinicaltrials.gov, using identifier [NCT02588170](https://clinicaltrials.gov/ct2/show/study/NCT02588170). A copy of the presentation will be available at www.chi-med.com.

Surufatinib Phase I/Ib study in the US

Safety and tolerability data of surufatinib in western patients were presented at ESMO 2019 as a poster on Sunday, September 29, including data on 15 patients (12 efficacy evaluable) with heavily treated pancreatic NET. The study confirmed 300mg as the recommended Phase 2 dose (RP2D), the same as that used in the China studies. Preliminary data shows promising anti-tumor activity in the pancreatic NET patients, with ORR of 13.3% and DCR of 73.3%. Additional details may be found at clinicaltrials.gov, using identifier [NCT02549937](https://clinicaltrials.gov/ct2/show/study/NCT02549937).

About Neuroendocrine Tumors

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 other neuroendocrine tumors. Approved targeted therapies include Sutent® and Afinitor® 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 patients in 2018 and, considering the U.S. incidence to prevalence ratio, potentially as many as 300,000 patients living with the disease.

About Surufatinib

Discovered and developed solely by Chi-Med, surufatinib (previously known as HMPL-012 or sulfatinib) is a novel, oral drug candidate 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, as well as colony stimulating factor-1 receptor (CSF-1R), which regulates tumor-associated macrophages, promoting the body's immune response against tumor cells. Surufatinib's unique dual mechanism of action may be very suitable for possible combinations with other immunotherapies. Surufatinib is in proof-of-concept clinical trials in the U.S. and several proof-of-concept and late-stage clinical trials in China, for indications such as neuroendocrine tumors and biliary tract cancer.

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 440 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.

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, plans to initiate clinical studies for surufatinib, its expectations as to whether such studies 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 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 in combination therapies, to meet the primary or secondary endpoint of a study, to obtain regulatory approval in different

jurisdictions, to gain commercial acceptance after obtaining regulatory approval, the potential market of surufatinib for a targeted indication and the sufficiency of funding. 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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