



HUTCHISON CHINA MEDITECH

Press Release

Chi-Med's New Drug Application for Surufatinib in Non-Pancreatic Neuroendocrine Tumors Granted Priority Review in China

London: Friday, December 20, 2019: Hutchison China MediTech Limited ("[Chi-Med](#)") (AIM/Nasdaq: HCM) today announces that the Center for Drug Evaluation (CDE) of China's National Medical Products Administration ("NMPA") has granted Priority Review status to the New Drug Application ("NDA") for surufatinib for the treatment of patients with advanced non-pancreatic neuroendocrine tumors ("NET").

"Surufatinib is our second drug to be granted priority review by the NMPA," says Christian Hogg, Chief Executive Officer of Chi-Med. "We are working closely with the NMPA as they review our NDA for the treatment of non-pancreatic NET. Surufatinib being granted priority review is a positive step forward in potentially bringing this innovative drug to patients, who currently have very limited treatment options."

In November 2019, the NDA for surufatinib for the treatment of non-pancreatic NET was accepted for review by the NMPA, and the U.S. Food and Drug Administration granted Orphan Drug designation to surufatinib for the treatment of pancreatic NET.

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. In November 2019, the NDA was accepted for review by the NMPA.

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](#)), and the ongoing Phase Ib study in the U.S. (clinicaltrials.gov identifier: [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](#)).

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[®], approved in China by Shanghai Junshi Biosciences Co. Ltd, and with Tyvyt[®], 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[®] 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 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 country¹. 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 490 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 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 non-pancreatic NET, pancreatic NET 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 under priority review in China and 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 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.

¹ 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.

CONTACTS

Investor Enquiries

Mark Lee, Senior Vice President
Annie Cheng, Vice President
David Dible, Citigate Dewe Rogerson

Xuan Yang, Solebury Trout

+852 2121 8200
+1 (973) 567 3786
+44 7967 566 919 (Mobile)
david.dible@citigatedewerogerson.com
+1 (415) 971 9412 (Mobile)
xyang@troutgroup.com

Media Enquiries

UK & Europe – Anthony Carlisle, Citigate Dewe Rogerson

Americas – Brad Miles, Solebury Trout

Hong Kong & Asia ex-China – Joseph Chi Lo, Brunswick
– Zhou Yi, Brunswick

Mainland China – Sam Shen, Edelman

+44 7973 611 888 (Mobile)
anthony.carlisle@cdrconsultancy.co.uk
+1 (917) 570 7340 (Mobile)
bmiles@troutgroup.com
+852 9850 5033 (Mobile)
jlo@brunswickgroup.com
+852 9783 6894 (Mobile)
yzhou@brunswickgroup.com
+86 136 7179 1029 (Mobile)
sam.shen@edelman.com

Nominated Advisor

Atholl Tweedie, Panmure Gordon (UK) Limited

+44 (20) 7886 2500