HUTCHISON CHINA MEDITECH

Press Release

Chi-Med Plans to Submit Marketing Authorization Application for Surufatinib Following Scientific Advice from EMA's CHMP

Hong Kong, Shanghai, & Florham Park, NJ: Monday, August 10, 2020: Hutchison China MediTech Limited ("Chi-Med") (Nasdaq/AIM: HCM) today announces that it received scientific advice from the European Medicines Agency's ("EMA") Committee for Medicinal Products for Human Use ("CHMP") for surufatinib for the treatment of patients with advanced neuroendocrine tumors ("NET"). Based on the CHMP advice, we have concluded that the completed SANET-ep (non-pancreatic NET) and SANET-p (pancreatic NET) studies, along with existing data from surufatinib in U.S. non-pancreatic and pancreatic NET patients, could form the basis to support a marketing authorization application ("MAA"). Given that no filing issues were identified, the MAA submission is planned for 2021, following submission for the U.S. Food and Drug Administration ("FDA") new drug application ("NDA").

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., Europe and Japan: 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. All such interactions are based on the robust data from the two positive Phase III studies of surufatinib in NET in China, and the ongoing multi-cohort Phase Ib study in the U.S. that began in November 2015 (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 China National Medical Products Administration ("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 the 2019 European Society for Medical Oncology Congress ("ESMO") (clinicaltrials.gov identifier: 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), we submitted our second NDA to the China NMPA and are now waiting for formal acceptance. 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).

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 EU MAA and U.S. NDA for surufatinib for the treatment of NET with the EMA and FDA respectively, the timing of such submissions, the therapeutic potential of surufatinib for the treatment of patients with NET, the further clinical development of 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 its data to support NDA approval of surufatinib for the treatment of patients with NET in the E.U., U.S. and China or other jurisdictions such as the E.U. or Japan, its potential to gain expeditious approvals from regulatory authorities, the safety profile of surufatinib, 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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