Press Release

HUTCHMED Completes Rolling Submission of NDA to U.S. FDA for Surufatinib for the Treatment of Advanced Neuroendocrine Tumors

– First NDA submission by HUTCHMED in the U.S.; product launch preparations underway –

Hong Kong, Shanghai & Florham Park, NJ — Monday, May 3, 2021: HUTCHMED (China) Limited ("HUTCHMED") (Nasdaq/AIM: HCM) today announces that it completed the rolling submission of a New Drug Application ("NDA") to the U.S. Food and Drug Administration ("FDA") for surufatinib for the treatment of pancreatic and extra-pancreatic (non-pancreatic) neuroendocrine tumors ("NETs").

Dr. Marek Kania, Managing Director and Chief Medical Officer of HUTCHMED International Corporation, said, "HUTCHMED is developing six novel oncology drug candidates internationally and this surufatinib NDA represents our first ever in the United States. Having successfully launched surufatinib in China early this year, we are now looking forward, subject to its approval, to being able to provide access to this important new therapeutic option for NETs patients in the U.S. and beyond. Our surufatinib NDA submission to the FDA was completed by our rapidly expanding international team of over 70 personnel based mainly in the U.S., working side by side with our discovery and development colleagues in China."

The NDA is supported by data from two positive Phase III studies of surufatinib in NET in China (SANET-p[1] and SANET-ep[2]), and by data from a surufatinib study conducted in the U.S. in patients with pancreatic and extra-pancreatic NET. HUTCHMED previously announced that it had reached an agreement with the FDA during a pre-NDA meeting, whereby these studies may serve as the basis to support an NDA submission. Fast Track Designations granted in April 2020 by the FDA have permitted HUTCHMED to submit sections of the NDA on a rolling basis. Filing acceptance of the NDA is subject to the FDA's review of the complete application. The data package will also be used to file a Marketing Authorization Application ("MAA") to the European Medicines Agency ("EMA") in 2021, based on scientific advice from the EMA's Committee for Medicinal Products for Human Use.

HUTCHMED initiated an Expanded Access Protocol (EAP) in the U.S. to ensure patients with NET and limited therapeutic options have access to this treatment. Regulatory clearance of this protocol has been granted by the FDA and this program is open for site activation (clinicaltrials.gov identifier: NCT04814732).

In addition to the two Fast Track Designations for surufatinib development in pancreatic and extra-pancreatic NET granted by the FDA in April 2020, Orphan Drug Designation for pancreatic NET was also granted in November 2019.

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 extra-pancreatic NET ("epNET").

According to Frost & Sullivan, there were 19,000 newly diagnosed cases of NET in the U.S. in 2020. Importantly, NETs are associated with a relatively long duration of survival compared to other tumors. As a result, there were approximately 143,000 estimated patients living with NET in the U.S. in 2020.[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 receptors (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.

HUTCHMED 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 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. epNET and pNET patients (clinicaltrials.gov identifier: NCT02549937).

epNETs in China: On December 30, 2020, surufatinib was granted drug registration approval by the National Medical Products Administration of China ("NMPA") for the treatment of epNET. Surufatinib is marketed in China under the brand name Sulanda®. The approval was based on results from the SANET-ep study, a Phase III trial (clinicaltrials.gov identifier: NCT02588170) in patients with advanced epNETs 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.[4] 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%).

pNETs 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 pNET in China. It was terminated early as the pre-defined primary endpoint of PFS was met (clinicaltrials.gov identifier: NCT02589821) at a preplanned interim analysis, leading to a second NDA accepted by the NMPA in September 2020. The positive results of this study were presented at the 2020 ESMO Virtual Congress and published simultaneously in *The Lancet Oncology*[5], demonstrating that surufatinib reduces the risk of disease progression or death by 51% in patients, with median PFS of 10.9 months compared to 3.7 months on placebo (HR 0.491; 95% CI: 0.391-0.755; $p=0.0011$). The safety profile of surufatinib was manageable and consistent with observations in prior studies.

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), Tuoyi® (toripalimab) and Tyvyt® (sintilimab), which are approved as monotherapies in China.

About HUTCHMED

HUTCHMED (Nasdaq/AIM: HCM) (formerly Hutchison China MediTech Limited) is an innovative, commercial-stage, biopharmaceutical company. It is committed to the discovery and global development and commercialization of targeted therapies and immunotherapies for the treatment of cancer and immunological diseases. A dedicated organization of over 1,200 personnel has advanced ten cancer drug candidates from in-house discovery into clinical studies around the world, with its first two oncology drugs now approved and launched. For more information, please visit: www.hutch-med.com or follow us on LinkedIn.

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 HUTCHMED's current expectations regarding future events, including its expectations regarding the submission of an NDA for surufatinib for the treatment of NET with the FDA and the timing of such submission, the therapeutic potential of surufatinib for the treatment of patients with NET and the further clinical development of surufatinib in this and other indications. Forward-looking statements involve risks and uncertainties. Such risks and uncertainties include, among other things, assumptions regarding the sufficiency of clinical data to support NDA approval of surufatinib for the treatment of patients with NET in the U.S., China and other jurisdictions such as the E.U., its potential to gain expeditious approvals from regulatory authorities, the safety profile of surufatinib, HUTCHMED'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 HUTCHMED's filings with the U.S. Securities and Exchange Commission and on AIM. HUTCHMED 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] Surufatinib in advanced neuroendocrine tumors – pancreatic.
[2] Surufatinib in advanced neuroendocrine tumors – extra-pancreatic (non-pancreatic).
[3] According to Frost & Sullivan, in 2020, there were 19,000 newly diagnosed cases of NETs in the U.S. and an estimated 143,000 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.