HUTCHMED Announces NMPA Approval of Surufatinib (Sulanda® in China) for Advanced Pancreatic Neuroendocrine Tumors

– Second New Drug Application ("NDA") approved for Sulanda in China –

– The pivotal Phase III SANET-p trial demonstrated surufatinib reduced risk of progression or death by 51% in patients with advanced pancreatic NET –

Hong Kong, Shanghai, & Florham Park, NJ: Friday, June 18, 2021: HUTCHMED (China) Limited ("HUTCHMED") (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 advanced pancreatic neuroendocrine tumors ("pNETs"). This follows the approval of surufatinib in China in December 2020 for the treatment of advanced extra-pancreatic (non-pancreatic) neuroendocrine tumors ("epNETs").

The Company was made aware through the website of the NMPA that surufatinib's approval for drug registration by the NMPA for the treatment of pNETs was completed and is now pending certification.

Christian Hogg, Chief Executive Officer of HUTCHMED, commented, "Since its launch in January this year, patients with epNETs have benefited from treatment with surufatinib through its unique mode of action by both inhibiting angiogenesis and promoting the body's immune response against tumor cells. With today's approval, we are now able to provide this unique therapy to NET patients with pancreatic tumor origin as well."

Surufatinib is marketed in China under the brand name Sulanda®.

HUTCHMED's oncology commercial team today covers more than 2,500 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.

This NMPA approval was supported by the SANET-p study, a Phase III pivotal study (clinicaltrials.gov identifier: NCT02589821) in patients with advanced pancreatic NETs conducted in China. The study met the pre-defined primary endpoint of progression-free survival ("PFS") at a preplanned interim analysis and was stopped early. The positive results of this trial were highlighted in an oral presentation at the 2020 ESMO Congress and published in The Lancet Oncology[1] in September 2020. Median PFS was 10.9 months for patients treated with surufatinib, as compared to 3.7 months for patients in the placebo group (hazard ratio ["HR"] 0.491; 95% confidence interval ["CI"] 0.391-0.755; *p*=0.0011). Benefit was observed across most major subgroups of pNET patients. The safety profile of surufatinib was manageable and consistent with observations in prior studies. Treatment was well tolerated for most patients, with discontinuation rates as a result of treatment emergent adverse events of 10.6% in the surufatinib group as compared to 6.8% in the placebo group.

In China, there were an estimated 71,300 newly diagnosed NET patients in 2020. Considering the current incidence to prevalence ratio, there may be as many as 300,000 patients living with the disease.[2]

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 pNET or 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 19,700 newly diagnosed cases of NETs in the U.S. in 2020. Importantly, NETs are associated with a relatively long duration of survival compared to other tumors.

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.

HUTCHMED currently retains all rights to surufatinib worldwide.

About Other 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 was submitted on April 30, 2021, and a MAA submission to the European Medicines Agency (EMA) is planned. 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 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 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.[3] 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%).

Biliary tract cancer in China: In March 2019, HUTCHMED 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: HUTCHMED 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) 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 1,300 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 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 HUTCHMED'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 NET patients in China, 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 HUTCHMED'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, 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 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.

CONTACTS

Investor Enquiries

Mark Lee, Senior Vice President	+852 2121 8200
Annie Cheng, Vice President	+1 (973) 567 3786

Media Enquiries

Americas – Brad Miles, Solebury Trout	+1 (917) 570 7340 (Mobile) bmiles@troutgroup.com
Europe – Ben Atwell / Alex Shaw, FTI Consulting	+44 20 3727 1030 / +44 7771 913 902 (Mobile) / +44 7779 545 055 (Mobile) HUTCHMED@fticonsulting.com
Asia – Joseph Chi Lo / Zhou Yi, Brunswick	+852 9850 5033 (Mobile) / +852 9783 6894 (Mobile) HUTCHMED@brunswickgroup.com

Nominated Advisor

Freddy Crossley / Atholl Tweedie, Panmure Gordon (UK) Limited	+44 (20) 7886 2500

---

[1] 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.

[2] According to Frost & Sullivan. 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.

[3] 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.