Press Release

HUTCHMED Initiates a Japan Bridging Study to Support Surufatinib Registration for Advanced Neuroendocrine Tumors

— Following surufatinib launch in China in January 2021; NDA acceptance by the U.S. FDA for review in June 2021; and MAA validation by the EMA in July 2021 all for advanced neuroendocrine tumors —

Hong Kong, Shanghai & Florham Park, NJ — Monday, September 20, 2021: HUTCHMED (China) Limited ("HUTCHMED") (Nasdaq/AIM: HCM; HKEX: 13) today announces that it has initiated a Japan registration-enabling bridging study for surufatinib to support the registration of surufatinib in the treatment of patients with advanced neuroendocrine tumors ("NETs"). The first patient was dosed on September 15, 2021.

Based on dialogue with the Japanese Pharmaceuticals and Medical Devices Agency (PMDA), it was agreed that the surufatinib Japanese new drug application ("NDA") for the treatment of advanced NETs include results from a pivotal study to be conducted in Japan, to complement the registration data package supporting the NDA to the U.S. Food and Drug Administration ("FDA") (accepted for review in June 2021) and the Marketing Authorization Application ("MAA") to the European Medicines Agency ("EMA") (validated in July 2021). The basis for the NDA and the MAA includes data from a U.S. Phase I/II study, as well as the completed Phase III SANET-ep and SANET-p studies used to support marketing authorization in China in advanced NETs, where surufatinib is currently marketed under the brand name SULANDA®.

This Japan study is a two-stage, open label study of surufatinib where approximately 34 patients are expected to be recruited. In Part 1 of the study, the safety and tolerability of surufatinib 300mg once daily after 28 days of treatment will be assessed in patients with relapsed/refractory non-hematological malignancies; pharmacokinetics ("PK") and anti-tumor activity of surufatinib are secondary endpoints. In Part 2 of the study, efficacy will be assessed in patients with locally advanced or metastatic NETs; the primary outcome measure is objective response rate (ORR). The secondary outcome measures include disease control rate (DCR), progression free survival ("PFS"), duration of response (DoR), safety, and PK.

Surufatinib is the third potential new medicine discovered by HUTCHMED to enter into clinical development in Japan. A global Phase III registration study for fruquintinib, known as the FRESCO-2 study, is ongoing in patients with refractory metastatic colorectal cancer and is expected to enroll over 680 patients from over 150 sites in 14 countries, including Japan. A global single-arm, open-label study, known as the SAVANNAH study, is ongoing for savolitinib (partnered with AstraZeneca PLC) in combination with TAGRISSO® in non-small cell lung cancer patients whose disease progressed following TAGRISSO® due to MET amplification or overexpression.

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 (non-pancreatic) NET ("epNET").

According to Frost & Sullivan, there were 19,000 newly diagnosed cases of NET in the U.S. in 2020. Rates across the European Union (E.U.) appear largely similar to the U.S. This is supported by an analysis of global epidemiologic trends, which also show growth in the incidence of NETs worldwide.[1] Importantly, NETs are associated with a relatively long duration of survival compared to other tumors. As a result, there were approximately 140,000 estimated patients living with NET in France, Germany, Italy, Spain, and the United Kingdom in 2020.[2] In Japan, approximately 6,700 people were diagnosed with gastro-entero-pancreatic neuroendocrine neoplasms in 2016.[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

epNETs in China: On December 29, 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 PFS at a preplanned interim analysis, and was published in *The Lancet Oncology*[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: On June 16, 2021, surufatinib was granted drug registration approval by the NMPA for the treatment of pNET. The approval was based on results from the SANET-p study, a Phase III trial (clinicaltrials.gov identifier: NCT02589821) in patients with advanced pNET in China. The pre-defined primary endpoint of PFS was met at a preplanned interim analysis and was published in *The Lancet Oncology*[5], demonstrating that surufatinib reduces the risk of disease progression or death by 51% in patients, with a 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.

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.

NETs in the U.S. and Europe: A FDA NDA submission was accepted in June 2021, followed by a MAA submission to the EMA validated in July 2021. 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). 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.

HUTCHMED has initiated an Expanded Access Protocol (EAP) in the U.S. to ensure patients with NET with 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).

About HUTCHMED

HUTCHMED (Nasdaq/AIM: HCM; HKEX: 13) is an innovative, commercial-stage, biopharmaceutical company. It is committed to the discovery, global development and commercialization of targeted therapies and immunotherapies for the treatment of cancer and immunological diseases. A dedicated organization of over 1,400 personnel has advanced eleven cancer drug candidates from in-house discovery into clinical studies around the world, with its first three oncology drugs now approved. 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 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, Japan 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, on AIM and on The Stock Exchange of Hong Kong Limited. 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] Fraenkel M, Kim M, Faggiano A, de Herder WW, Valk GD; Knowledge NETwork. Incidence of gastroenteropancreatic neuroendocrine tumours: a systematic review of the literature. Endocr Relat Cancer. 2014;21(3):R153-R163. Published 2014 May 6. doi: 10.1530/ERC-13-0125.

[2] 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. Report on file.

[3] Masui T, Ito T, Komoto I, Uemoto S; JNETS Project Study Group. Recent epidemiology of patients with gastro-entero-pancreatic neuroendocrine neoplasms (GEP-NEN) in Japan: a population-based study. *BMC Cancer*. 2020;20(1):1104. Published 2020 Nov 14. doi: 10.1186/s12885-020-07581-y.

[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.