Press Release

HUTCHMED Initiates a Phase Ib/II Trial of Surufatinib in Combination with Tislelizumab in Patients with Advanced Solid Tumors

Hong Kong, Shanghai & Florham Park, NJ — Wednesday, March 24, 2021: Hutchison China MediTech Limited ("HUTCHMED") (Nasdaq/AIM: HCM) has initiated a Phase Ib/II study of surufatinib in combination with BeiGene's tislelizumab in patients with advanced solid tumors in the U.S. and Europe. The first patient was dosed on March 23, 2021. This trial is to explore potential synergistic activity of the novel, oral angio-immuno kinase inhibitor surufatinib with the anti-PD-1 antibody tislelizumab in enhancing overall antitumor activity from inhibition of angiogenesis along with stimulation of an immune response.

This is an open-label study to evaluate the safety, tolerability, pharmacokinetics and efficacy of surufatinib in combination with tislelizumab in patients with advanced solid tumors. The study consists of two parts: dose finding (Part 1) and dose expansion (Part 2). Part 1 will be conducted to determine the recommended Phase II dose ("RP2D") and/or the maximum tolerated dose (MTD) of surufatinib in combination with tislelizumab in patients with advanced or metastatic solid tumors who have progressed on, or are intolerant to, standard therapies. Part 2 will be an open-label, multi-cohort design to evaluate the anti-tumor activity of surufatinib in combination with tislelizumab in patients with specific types of advanced or metastatic solid tumors, including neuroendocrine tumors, colorectal cancer, small cell lung cancer, gastric cancer, and soft tissue sarcoma. Patients will receive the RP2D determined in Part 1 of this study. Additional details may be found at clinicaltrials.gov, using identifier NCT04579757.

About Neuroendocrine Tumors ("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 non-pancreatic NET ("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 19,000 newly diagnosed cases of NETs in the U.S. in 2018. Importantly, NETs 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 NETs in the U.S. in 2018.

About Colorectal Cancer ("CRC")

CRC is cancer that starts in either the colon or rectum. CRC is the third most common cancer worldwide, estimated to have caused more than 935,000 deaths in 2020.[1] In the U.S., an estimated 150,000 people were diagnosed with CRC and 53,000 people died from CRC in 2020.[2] In Europe, CRC is the second most common cancer, with an estimated 507,000 new cases and 240,000 deaths in 2020.[4]

About Small Cell Lung Cancer ("SCLC")

Cancer of the lungs and bronchus were estimated to be diagnosed in over 228,000 people in the U.S. and 477,000 people in Europe during 2020.[3,4] SCLC accounts for 10-15% of newly diagnosed lung cancer cases.[5] SCLC carries a lower five-year survival rate (6.6%) relative to lung cancer in general (20.5%).[3,6]

About Gastric Cancer ("GC")

GC is cancer that starts in the stomach. In the U.S., an estimated 27,000 people were diagnosed with GC during 2020, with overall expected five-year survival rate of 32%.[7] In Europe, GC was estimated to be diagnosed in 136,000 new patients and be the cause of 97,000 deaths in 2020.[4]

About Soft Tissue Sarcoma ("STS")

STS is a heterogeneous group of tumors that start in different soft tissues, such as muscles, tendons, and blood vessels. In the U.S., an estimated 13,000 people were diagnosed with STS for during 2020, with overall five-year survival rate of 65%.[8] In Europe, annual incidence of STS is estimated to be approximately 23,000.[9]

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.

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 marketing authorization application (MAA) submission to the European Medicines Agency (EMA) in Europe. The basis to support these filings includes the completed SANET-ep[10] and SANET-p[11] 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.[12] 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*[13], 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 Tislelizumab

Tislelizumab (BGB-A317) is a humanized IgG4 anti-PD-1 monoclonal antibody specifically designed to minimize binding to FcγR on macrophages. In pre-clinical studies, binding to FcγR on macrophages has been shown to compromise the anti-tumor activity of PD-1 antibodies through activation of antibody-dependent macrophage-mediated killing of T effector cells. Tislelizumab is the first drug from BeiGene's immuno-oncology

biologics program and is being developed internationally as a monotherapy and in combination with other therapies for the treatment of a broad array of both solid tumor and hematologic cancers.

The NMPA has granted tislelizumab full approval for first-line treatment of patients with advanced squamous non-small cell lung cancer (NSCLC) in combination with chemotherapy. Tislelizumab has also received conditional approval from the NMPA for the treatment of patients with classical Hodgkin's lymphoma (cHL) who received at least two prior therapies, and for the treatment of patients with locally advanced or metastatic urothelial carcinoma (UC) with PD-L1 high expression whose disease progressed during or following platinum-containing chemotherapy or within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy. Full approval for these indications is contingent upon results from ongoing randomized, controlled confirmatory clinical trials.

In addition, three supplemental Biologics License Applications for tislelizumab have been accepted by the Center for Drug Evaluation (CDE) of the NMPA and are under review for first-line treatment of patients with advanced non-squamous NSCLC in combination with chemotherapy, for the second- or third-line treatment of patients with locally advanced or metastatic NSCLC who progressed on prior platinum-based chemotherapy, and for previously treated unresectable hepatocellular carcinoma.

Currently, 15 potentially registration-enabling clinical trials are being conducted in China and globally, including 12 Phase 3 trials and two pivotal Phase 2 trials.

In January 2021, BeiGene and Novartis entered into a collaboration and license agreement to develop, manufacture, and commercialize tislelizumab in North America, Europe, and Japan.

Tislelizumab is not approved for use outside of China.

About HUTCHMED

HUTCHMED (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 advanced ten cancer drug candidates from discovery into clinical studies around the world and has an extensive commercial infrastructure in its home market of China. For more information, please visit: www.hutch-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 and other federal securities laws, including statements regarding the clinical development of surufatinib in combination with tislelizumab, HUTCHMED's and BeiGene's roles and responsibilities in the collaboration, the opportunity and potential benefits of their product candidates both as monotherapies and in combination, and other information that is not historical information. Actual results may differ materially from those indicated in the forward-looking statements as a result of various important factors, including the ability of HUTCHMED and BeiGene to develop and receive regulatory approvals for the combination therapies in the collaboration; the risk that the potential benefits of the collaboration do not materialize or do not outweigh the costs; the ability of HUTCHMED and BeiGene to demonstrate the efficacy and safety of their respective drug candidates as monotherapies or in combination; the clinical results for such drug candidates, which may not support further development or marketing approval; actions of regulatory agencies, which may affect the initiation, timing and progress of clinical trials and marketing approval; HUTCHMED's and BeiGene's ability to achieve commercial success for their marketed products and drug candidates, if approved; HUTCHMED's and BeiGene's ability to obtain and maintain protection of intellectual property for their respective technology and drugs; BeiGene's and HUTCHMED's reliance on third parties to conduct drug development, manufacturing and other services; BeiGene's limited experience in obtaining regulatory approvals and commercializing pharmaceutical products and BeiGene's and HUTCHMED's ability to obtain additional funding for operations and to complete the development and commercialization of their drug candidates; and the impact of the COVID-19 pandemic on BeiGene's and HUTCHMED's clinical development, regulatory, commercial and other operations. 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 or BeiGene's filings with the U.S. Securities and Exchange Commission and, in the case of HUTCHMED, on AIM. All information in this press release is as of the date of this press release, and neither HUTCHMED nor BeiGene undertakes a duty to update such information unless required by law.

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