Press Release

HUTCHMED Initiates Phase II Registration Study of HMPL-689 in Patients with Follicular Lymphoma and Marginal Zone Lymphoma in China

— Single-arm study in ~180 patients, with ORR as primary endpoint —

— Relapsed/refractory FL and MZL constitute approximately 25% of all NHL —

— HMPL-689 trials are also underway in these and other NHL subtypes in the U.S., Europe and China —

Hong Kong, Shanghai & Florham Park, NJ — Thursday, April 29, 2021: Hutchison China MediTech Limited ("HUTCHMED") (Nasdaq/AIM: HCM) has initiated a registration-intent Phase II clinical trial of HMPL-689, its highly selective and potent PI3Kδ inhibitor, in China in patients with relapsed or refractory follicular lymphoma ("FL") and marginal zone lymphoma ("MZL"), two subtypes non-Hodgkin's lymphoma ("NHL"). The first patient was dosed today.

The clinical trial is a multi-center, single-arm, open-label clinical study to evaluate the efficacy and safety of HMPL-689 once a day oral monotherapy in approximately 100 patients with relapsed/refractory FL and approximately 80 patients with relapsed/refractory MZL. Relapsed/refractory is defined when a patient has not achieved response (complete response or partial response) after the latest line of systemic treatment, or has progressive disease or relapse after achieving response. The primary endpoint is objective response rate ("ORR"), with secondary endpoints including complete response rate (CRR), progression-free survival (PFS), time to response (TTR) and duration of response (DoR). The trial is being conducted in over 35 sites in China. More information will be available at clinicaltrials.gov, using identifier NCT04849351.

The initiation of the Phase II trial is based on the highly promising preliminary results from the Phase Ib expansion study ongoing in China, which show that HMPL-689 was well tolerated, exhibiting dose-proportional pharmacokinetics ("PK"), a manageable toxicity profile, and single-agent clinical activity in relapsed/refractory B-cell lymphoma patients. Additional details may be found at clinicaltrials.gov, using identifier NCT03128164.

About PI3Kδ and NHL

PI3Kδ (phosphoinositide 3-kinase delta) is a lipid kinase that controls the activation of several important signaling proteins. Upon an antigen binding to B-cell receptors, PI3Kδ can be activated through the Lyn and Syk signaling cascade. The abnormal activation of B-cell receptor signaling is closely related to the development of B-cell type hematological cancers, which represent approximately 85% of all NHL cases. Therefore, PI3Kδ is considered to be a promising target for drugs that aim to prevent or treat hematologic cancer.

FL accounts for approximately 17% of NHL and MZL accounts for approximately 8% of NHL. In the U.S., there were estimated 13,000 and 6,000 new cases of FL and MZL in 2020, respectively. In China, there were estimated 16,000 and 7,000 new cases of FL and MZL in 2020, respectively [1,2,3].

About HMPL-689

HMPL-689 is a novel, selective and potent oral inhibitor targeting the isoform PI3Kδ. HMPL-689's PK properties are favorable with good oral absorption, moderate tissue distribution and low clearance in preclinical PK studies, suggesting a low risk of drug accumulation and drug-to-drug interaction. Because of its high target selectivity and optimal PK profile, HMPL-689 has the potential to demonstrate an optimal benefit-risk profile in this class.

HUTCHMED has initiated an extensive, globally-focused clinical development pathway for HMPL-689. In addition to the currently Phase II trial and the supportive Phase I trial in China, HMPL-689 is also being evaluated in an ongoing Phase I/Ib study in the U.S. and Europe in patients with relapsed or refractory NHL.

HUTCHMED currently retains all rights to HMPL-689 worldwide.

About HUTCHMED

HUTCHMED (Nasdaq/AIM: HCM) 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 1,200 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 therapeutic potential of HMPL-689 for patients with FL, MZL and NHL, the further clinical development for HMPL-689, its expectations as to whether such studies would meet their primary or secondary endpoints, 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 enrollment rates, timing and availability of subjects meeting a study's inclusion and exclusion criteria, changes to clinical protocols or regulatory requirements, unexpected adverse events or safety issues, the ability of HMPL-689, including as a combination therapy, to meet the primary or secondary endpoint of a study, to obtain regulatory approval in different jurisdictions, to gain commercial acceptance after obtaining regulatory approval, the potential market of HMPL-689 for a targeted indication, the sufficiency of funding and the impact of the COVID-19 pandemic on general economic, regulatory and political conditions. 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.

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

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[1] Source: NCCN® - https://www.nccn.org
[2] Source: SEER - https://seer.cancer.gov/statfacts/html/follicular.html
[3] Source: GLOBOCAN https://gco.iarc.fr/