Press Release

HUTCHMED Receives Breakthrough Therapy Designation in China for Amdizalisib (HMPL-689) for Treatment of Relapsed or Refractory Follicular Lymphoma

Hong Kong, Shanghai & Florham Park, NJ — Monday, September 13, 2021: HUTCHMED (China) Limited ("HUTCHMED") (Nasdaq/AIM: HCM; HKEX: 13) today announces that the Center for Drug Evaluation of China's National Medical Products Administration ("NMPA") has granted Breakthrough Therapy Designation ("BTD") to amdizalisib (HMPL-689), a highly selective and potent PI3Kδ inhibitor, for the treatment of relapsed or refractory follicular lymphoma ("FL"), a subtype of non-Hodgkin's lymphoma ("NHL").

NMPA grants BTD to new drugs that treat life-threatening diseases or serious conditions for which there are no effective treatment options, and where clinical evidence demonstrates significant advantages over existing therapies. Drug candidates with BTD may be considered for conditional approval and priority review when submitting a New Drug Application (NDA). This indicates that the development and review of amdizalisib for relapsed or refractory FL may be expedited, to address patients' unmet needs more quickly.

Christian Hogg, CEO of HUTCHMED, said, "The granting of BTD to amdizalisib by the NMPA underscores the promising clinical value of this highly selective and potent PI3Kδ inhibitor. There is a clear need for new therapies in this treatment setting, particularly with regard to specific toxicities and suboptimal efficacy with existing treatments across different lymphoma subtypes. We look forward to important clinical data on amdizalisib being presented at the ESMO Congress next week and are continuing to accelerate global development of this novel therapy."

Updated preliminary results from the ongoing Phase Ib expansion study in China will be presented as a Proffered Paper at the 2021 ESMO (European Society for Medical Oncology) Congress on September 20, 2021. To date, amdizalisib has been shown to be 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.

HUTCHMED has initiated an extensive, globally-focused clinical development pathway for amdizalisib. In April 2021, HUTCHMED initiated a Phase II registration study in China for amdizalisib in approximately 100 patients with relapsed or refractory FL and approximately 80 patients with marginal zone lymphoma ("MZL"). The trial is being conducted in over 35 sites in China. Additional details may be found at clinicaltrials.gov, using identifier NCT04849351.

Amdizalisib is also being evaluated in an ongoing Phase I/Ib study in the U.S. and Europe in patients with relapsed or refractory NHL (NCT03786926).

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 a promising target for drugs that aim to treat certain hematologic cancers.

FL accounts for approximately 17% of NHL. In 2020, there were an estimated 16,000 and 13,000 new cases of FL in China and the U.S., respectively[1,2,3]. Patients with relapsed or refractory FL do not have curative treatment options and have a high unmet need for optimal therapeutic options.

About Amdizalisib

Amdizalisib (HMPL-689) is a novel, selective and potent oral inhibitor targeting the isoform PI3Kδ. Amdizalisib'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, amdizalisib has the potential to demonstrate an optimal benefit-risk profile in this class.

HUTCHMED currently retains all rights to amdizalisib worldwide.

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 amdizalisib for patients with FL, MZL and NHL, the further clinical development for amdizalisib, 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 amdizalisib, 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 amdizalisib 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, The Stock Exchange of Hong Kong Limited 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] Source: NCCN® - https://www.nccn.org
[2] Source: SEER - https://seer.cancer.gov/statfacts/html/follicular.html
[3] Source: GLOBOCAN https://gco.iarc.fr/