Press Release

HUTCHMED Completes Patient Enrollment of Phase II Registration Trial of Amdizalisib in Follicular Lymphoma in China

Hong Kong, Shanghai & Florham Park, NJ — Monday, February 27, 2023: HUTCHMED (China) Limited ("HUTCHMED") (Nasdaq/AIM:HCM, HKEX:13) today announces that it has completed patient enrollment of Phase II registration trial of amdizalisib in patients with relapsed or refractory follicular lymphoma ("FL"), a subtype of non-Hodgkin's lymphoma ("NHL"). The last patient was enrolled on February 24, 2023.

The clinical trial is a multi-center, single-arm, open-label clinical study to evaluate the efficacy and safety of amdizalisib once a day oral monotherapy in patients with relapsed/refractory FL or marginal zone lymphoma ("MZL"). 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). A total of 108 relapsed/refractory FL patients were enrolled. The trial is being conducted in over 35 sites in China. Additional details may be found at clinicaltrials.gov, using identifier NCT04849351.

Topline results on the FL patients in this trial are expected to be reported in the second half of 2023, followed by submission of results for presentation at an appropriate medical conference. If positive, HUTCHMED would initiate plans to apply for marketing authorization of amdizalisib for relapsed/refractory FL from the China National Medical Products Administration (NMPA).

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 a 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 Amdizalisib

Amdizalisib (HMPL-689) is a novel, selective and potent oral inhibitor targeting the isoform PI3Kδ. Amdizalisib's pharmacokinetic ("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.

In addition to the current Phase II trial and the supportive Phase I trial in China, amdizalisib is also being evaluated in combination with tazemetostat (a methyltransferase inhibitor of EZH2) in patients with relapsed or refractory lymphoma in a Phase II study in China.

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 and global development and commercialization of targeted therapies and immunotherapies for the treatment of cancer and immunological diseases. It has more than 5,000 personnel across all its companies, at the center of which is a team of about 1,800 in oncology/immunology. Since inception, HUTCHMED has focused on bringing cancer drug candidates from in-house discovery to patients around the world, with its first three oncology drugs now approved and marketed in China. 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 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, 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] Source: NCCN® - https://www.nccn.org
[2] Source: SEER - https://seer.cancer.gov/statfacts/html/follicular.html
[3] Source: GLOBOCAN - https://gco.iarc.fr/