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Press Release

HUTCHMED Initiates Phase I Trial of Menin Inhibitor HMPL-506 in Patients with Hematological Malignancies in China

Hong Kong, Shanghai & Florham Park, NJ - Friday, June 7, 2024: HUTCHMED (China) Limited ("HUTCHMED") (Nasdaq/AIM:HCM; HKEX:13) today announces that it has initiated Phase I clinical trial of its menin inhibitor HMPL-506 in patients with hematological malignancies in China. The first patient received their first dose on May 31, 2024.

This is a Phase I, multicenter, open-label clinical study to evaluate the safety, pharmacokinetics and efficacy of HMPL-506 in patients with hematological malignancies. The study is divided into two phases, a dose escalation phase and a dose expansion phase. The study is expected to enroll at least 60 patients. The lead principal investigators are Dr. Jianxiang Wang and Dr. Hui Wei of Chinese Academy of Medical Sciences Blood Diseases Hospital. Additional details may be found at clinicaltrials.gov, using identifier NCT06387082.

About HMPL-506 and Menin

HMPL-506 is a novel, investigational, selective small molecule inhibitor for oral administration targeting the menin protein. The menin protein is a scaffold protein that controls gene expression and cell signaling. Mixed-lineage leukemia ("MLL", also known as KMT2A) rearrangement and nucleophosmin 1 ("NPM1") mutation play key roles in acute myeloid leukemia ("AML"). MLL-rearranged AML accounts for approximately 5% of adult AML and NPM1-mutant AML accounts for approximately 30% of AML.[1],[2],[3] Current research has demonstrated that the inhibition of menin-MLL interaction is a feasible therapeutic strategy in MLL-rearranged and/or NPM1-mutant AML.[4],[5],[6],[7] Currently there is no menin inhibitor approved worldwide. HUTCHMED currently retains all rights to HMPL-506 worldwide.

According to the National Cancer Institute (NCI), there will be approximately 20,380 new cases of AML in the U.S. in 2023 and the five-year relative survival rate is 31.7%.[8] There were an estimated 19,700 new cases of AML in China in 2018 and is estimated to reach 24,200 in China in 2030.[9]

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 approximately 5,000 personnel across all its companies, at the center of which is a team of about 1,800 in oncology/immunology. Since inception it has focused on bringing cancer drug candidates from in-house discovery to patients around the world, with its first three oncology drugs marketed in China, the first of which is also marketed in the U.S. 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-506 for the treatment of patients with hematological malignancies and the further development of HMPL-506 in this and other indications. Forward-looking statements involve risks and uncertainties. Such risks and uncertainties include, among other things, assumptions regarding the timing and outcome of clinical studies and the sufficiency of clinical data to support an NDA submission of HMPL-506 for the treatment of patients with hematological malignancies or other indications in China or other jurisdictions, its potential to gain approvals from regulatory authorities on an expedited basis or at all, the efficacy and safety profile of HMPL-506, HUTCHMED's ability to fund, implement and complete its further clinical development and commercialization plans for HMPL-506 and the timing of these events. 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] Ibrahim S, Estey EH, Pierce S, et al. 11q23 abnormalities in patients with acute myelogenous leukemia and myelodysplastic syndrome as detected by molecular and cytogenetic analyses. Am J Clin Pathol, 2000, 114(5):793-7.

[2] Grimwade D, Hills RK, Moorman AV, et al. Refinement of cytogenetic classification in acute myeloid leukemia: determination of prognostic significance of rare recurring chromosomal abnormalities among 5876 younger adult patients treated in the United Kingdom Medical Research Council trials. Blood, 2010,116(3):354-65.

[3] Falini B, Mecucci C, Tiacci E, et al. Cytoplasmic nucleophosmin in acute myelogenous leukemia with a normal karyotype. N Engl J Med. 2005;352(3):254-66.

[4] Krivtsov AV, Evans K, Gadrey JY, et al. A Menin-MLL Inhibitor Induces Specific Chromatin Changes and Eradicates Disease in Models of MLL-Rearranged Leukemia. Cancer Cell 2019;36:660-73 e11.

[5] Uckelmann HJ, Kim SM, Wong EM, et al. Therapeutic targeting of preleukemia cells in a mouse model of NPM1 mutant acute myeloid leukemia. Science 2020;367:586-90.

[6] Borkin D, He S, Miao H, et al. Pharmacologic inhibition of the Menin-MLL interaction blocks progression of MLL leukemia in vivo. Cancer Cell 2015;27:589-602.

[7] Klossowski S, Miao H, Kempinska K, et al. Menin inhibitor MI-3454 induces remission in MLL1-rearranged and NPM1-mutated models of leukemia. J Clin Invest 2020;130:981-97.

[8] National Cancer Institute - seer.cancer.gov/statfacts/html/amyl.html.

[9] Lin J, Yao D, Qian J, et al. IDH1 and IDH2 mutation analysis in Chinese patients with acute myeloid leukemia and myelodysplastic syndrome. Ann Hematol. 2012;91(4):519-525. doi:10.1007/s00277-011-1352-7.

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