

Press Release

HUTCHMED Initiates Phase I Study of its novel SHP2 inhibitor HMPL-415 for Advanced Malignant Solid Tumors in China

Hong Kong, Shanghai & Florham Park, NJ — Monday, July 10, 2023: HUTCHMED (China) Limited (“[HUTCHMED](#)”) (Nasdaq/AIM:HCM; HKEX:13) today announces that it has initiated a Phase I study in China of HMPL-415, an investigational novel selective allosteric inhibitor targeting Src homology-2 domain-containing protein tyrosine phosphatase-2 (“SHP2”). The first patient received their first dose on July 6, 2023.

The clinical trial is a multi-center, open-label study to evaluate the safety, tolerability, pharmacokinetics and preliminary efficacy profile of HMPL-415 as a single agent in patients with advanced malignant solid tumors. This study is expected to enroll up to approximately 80 patients, including patients as part of the dose escalation stage, and further patients at the determined recommended Ph II dose (RP2D). The leading principal investigators are Dr. Tianshu Liu of Zhongshan Hospital Fudan University and Dr. Nong Yang of Hunan Cancer Hospital. Additional details may be found at clinicaltrials.gov, using identifier [NCT05886374](#).

About HMPL-415

HMPL-415 is a novel, highly potent and selective allosteric inhibitor targeting SHP2. SHP2 is a non-receptor protein tyrosine phosphatase ubiquitously expressed mainly in the cytoplasm of several tissues. SHP2 modulates diverse cell signaling events that control metabolism, cell growth, differentiation, cell migration, transcription and oncogenic transformation. It interacts with diverse molecules in the cell, and regulates key signaling events including RAS/ERK, PI3K/AKT, JAK/STAT and PD-1 pathways downstream of several receptor tyrosine kinases (RTKs) upon stimulation by growth factors and cytokines. Dysregulation of SHP2 expression or activity causes many developmental diseases, and hematological and solid tumors.¹

HUTCHMED currently retains all rights to HMPL-415 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 it 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 HMPL-415, the further clinical development for HMPL-415, its expectations as to whether any studies on HMPL-415 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 and the 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-415, including as a combination therapy, to meet the primary or secondary endpoint of a study, to obtain regulatory approval in different jurisdictions and to gain commercial acceptance after obtaining regulatory approval; the potential market of HMPL-415 for a targeted indication; the sufficiency of funding; and the impact of COVID-19 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 Asmamaw, M.D., Shi, X.J., Zhang, L.R. et al. A comprehensive review of SHP2 and its role in cancer. Cell Oncol. 45, 729–753 (2022). <https://doi.org/10.1007/s13402-022-00698-1>