Press Release

HUTCHMED Initiates a Phase I Trial of HMPL-653 in Patients with Advanced Malignant Solid Tumors and TGCT in China

Hong Kong, Shanghai & Florham Park, NJ — Thursday, January 20, 2022: HUTCHMED (China) Limited ("HUTCHMED") (Nasdaq/AIM:HCM; HKEX:13) today announces that it has initiated a Phase I trial in China of HMPL-653, an investigational novel, highly selective, and potent colony-stimulating factor 1 receptor ("CSF-1R") inhibitor. The first patient received their first dose on January 18, 2022.

The Phase I trial is a multicenter, open-label, single-arm study to evaluate the safety, tolerability, pharmacokinetics and preliminary efficacy of HMPL-653 in the treatment of patients with advanced or metastatic solid tumors and tenosynovial giant cell tumors ("TGCT"). Approximately 110 patients are expected to be enrolled in the dose escalation and expansion phase of this study. The primary endpoints are dose limiting toxicity, safety, tolerability, recommended phase II dose and maximum tolerated dose. The secondary endpoints include pharmacokinetics, objective response rate, progression free survival, disease control rate, and overall survival. The lead principal investigator is Dr Cheng Ying of the Jilin Cancer Hospital, which is the lead institution for this study.

About HMPL-653

HMPL-653 is an investigational novel, highly selective, and potent CSF-1R inhibitor designed to target malignant driven tumors as a monotherapy or in combination with other drugs.

CSF-1R is usually expressed on the surface of macrophages and can promote growth and differentiation of macrophages after binding with its ligand, CSF-1. A number of studies have shown that blocking the CSF-1R signaling pathway could effectively modulate the tumor microenvironment, relieve tumor immunosuppression, and synergize with other anti-cancer therapies such as immune checkpoint inhibitors to achieve tumor inhibition. It has been demonstrated in several clinical studies that other CSF-1R inhibitors, by inhibiting CSF-1R activity, could be used to treat TGCT, and to treat a variety of malignancies through combination with immuno-oncology and/or other therapeutic agents. Currently no CSF-1R inhibitor has been approved in China.

HUTCHMED currently retains all rights to HMPL-653 worldwide.

About TGCT

TGCT is a very rare type of soft tissue tumor caused by abnormal proliferation and inflammation of giant cells, monocytes and inflammatory cells. These tumors are mainly characterized by the expression of CSF-1. Targeting CSF-1R has become an effective therapeutic strategy for TGCT. The incidence of TGCT is approximately between 1.8 and 50 per 1 million people.[1] Surgery is the standard treatment for TGCT patients. However, among patients with diffuse or recurrent/refractory TGCT, tumors are wrapped in peripheral organs such as bone, tendon, ligament and joint, which makes removal by surgery difficult. The recurrence rate of diffuse-type cases is estimated to be 21% to 50%.[2] There is a high unmet need for effective and safe treatment for these patients.

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 4,600 personnel across all its companies, at the center of which is a team of about 1,500 in oncology/immunology. Since inception it has advanced 12 cancer drug candidates from in-house discovery into clinical studies 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-653 for patients, its expectations as to whether any studies on HMPL-653 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-653, 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-653 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] Rockberg J, Bach BA, Amelio J, et al. J Bone Joint Surg Am. 2015;97:1756-66.
[2] Gouin F, Noailles T. Orthop Traumatol Surg Res. 2017;103(1S):S91-S97.