

Press Release

HUTCHMED Initiates ESLIM-01, a Phase III Trial of HMPL-523 in Patients with Immune Thrombocytopenia in China

Hong Kong, Shanghai & Florham Park, NJ — Thursday, October 28, 2021: HUTCHMED (China) Limited (“[HUTCHMED](#)”) (Nasdaq/AIM:HCM; HKEX:13) today announces that it has initiated a Phase III trial in China of HMPL-523, a novel, investigational spleen tyrosine kinase (“Syk”) inhibitor, in adult patients with primary immune thrombocytopenia (“ITP”), an autoimmune disorder that can lead to increased risk of bleeding. The first patient received their first dose on October 27, 2021.

The study is a randomized, double blinded, placebo-controlled Phase III clinical trial evaluating the efficacy and safety of HMPL-523 in treating adult patients with ITP. The primary endpoint of the study is the durable response rate. Secondary and exploratory endpoints include overall response rate (ORR), incidence of treatment emergent adverse events, and patient quality of life improvement. Approximately 180 patients are expected to be enrolled. Additional details may be found at clinicaltrials.gov, using identifier [NCT05029635](#).

Christian Hogg, CEO of HUTCHMED, said, “There is a clear need for new therapies in treating ITP, a condition that can profoundly impact patients’ quality of life. With the current treatment options, patients often develop resistance and thereby are prone to relapse. We hope HMPL-523 will provide an important alternative that can induce durable response for patients in this treatment setting.”

The rationale for this Phase III study is based on encouraging data from the Phase Ib study of HMPL-523 in adult patients with ITP. The safety, pharmacokinetics and preliminary efficacy data for the Phase Ib study are expected to be presented at the 63rd American Society of Hematology (ASH) Annual Meeting in December 2021.

About HMPL-523

HMPL-523 is a novel, investigational, selective small molecule inhibitor for oral administration targeting spleen tyrosine kinase, also known as Syk. Syk is a major component in B-cell receptor signaling and is an established target for the treatment of multiple subtypes of B-cell lymphomas and autoimmune disorders.

HUTCHMED currently retains all rights to HMPL-523 worldwide. In addition to ITP, HMPL-523 is also being studied in indolent non-Hodgkin’s lymphoma and multiple subtypes of B-cell malignancies in China, the U.S. and Europe ([NCT02857998](#); [NCT03779113](#)). A trial to study HMPL-523 in patients with warm autoimmune hemolytic anemia (wAIHA), another autoimmune disorder, is also planned.

About ITP and Syk

ITP is an autoimmune disorder characterized by immunologic destruction of platelets and decreased platelet production. Patients with ITP exhibit symptoms of petechiae, purpura, and gastrointestinal and/or urinary mucosal tract bleeding.¹ ITP is also associated with fatigue (reported in up to 39% of adults with ITP) and impaired quality of life, across domains of emotional, functional and reproductive health, and work or social life.²⁻⁶ The incidence of primary ITP in adults is 3.3 per 100,000 adults per year with a prevalence of 9.5 per 100,000 adults.⁷

Adult ITP is a heterogeneous disease that can persist for years, even with best available care, and treatments are infrequently curative. Despite availability of several treatments with differing mechanisms of action, chronicity of disease continues to be a problem. Many patients develop resistance to treatment and thereby are prone to relapse.⁸ Thus, there remains a significant population of patients who have limited sensitivity to currently available agents and are in need of new treatments.

As platelet destruction in ITP is mediated by Syk-dependent phagocytosis of FcγR-bound platelets, Syk inhibition represents a promising approach to management of ITP.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 more than 4,500 personnel across all its companies, at the center of which is a team of over 1,400 in oncology/immunology. Since inception it has advanced eleven 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](https://www.linkedin.com/company/hutchmed).

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-523 for patients, its expectations as to whether any studies on HMPL-523 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-523, 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-523 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.

CONTACTS

Investor Enquiries

Mark Lee, Senior Vice President +852 2121 8200
Annie Cheng, Vice President +1 (973) 567 3786

Media Enquiries

Americas – Brad Miles, Solebury Trout +1 (917) 570 7340 (Mobile)
bmiles@troutgroup.com
Europe – Ben Atwell / Alex Shaw, FTI Consulting +44 20 3727 1030 / +44 7771 913 902 (Mobile) / +44 7779 545 055 (Mobile)
HUTCHMED@fticonsulting.com
Asia – Zhou Yi, Brunswick +852 9783 6894 (Mobile)
HUTCHMED@brunswickgroup.com

Nominated Advisor

Atholl Tweedie / Freddy Crossley, Panmure Gordon (UK) Limited +44 (20) 7886 2500

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