Press Release

HUTCHMED Receives Breakthrough Therapy Designation in China for HMPL-523 for Treatment of Primary Immune Thrombocytopenia

Hong Kong, Shanghai & Florham Park, NJ — Wednesday, January 12, 2022: HUTCHMED (China) Limited ("HUTCHMED") (Nasdaq/AIM:HCM; HKEX:13) today announces that the Center for Drug Evaluation of China's National Medical Products Administration ("NMPA") has granted Breakthrough Therapy Designation ("BTD") to HMPL-523, a novel, investigational spleen tyrosine kinase ("Syk") inhibitor, for the treatment of chronic adult primary immune thrombocytopenia ("ITP") patients who have received at least one prior therapy.

NMPA grants BTD to new drugs that treat life-threatening diseases or serious conditions for which there are no effective treatment options, and where clinical evidence demonstrates significant advantages over existing therapies. Drug candidates with BTD may be considered for conditional approval and priority review when submitting a New Drug Application (NDA).

Christian Hogg, Chief Executive Officer of HUTCHMED, said, "ITP is an autoimmune bleeding disorder that can often be serious and can have a significant, multifaceted impact on patients' health and quality of life. The granting of BTD to HMPL-523 in ITP highlights the unmet need in this treatment setting and the promising clinical value of this novel oral Syk inhibitor. With this designation, we are hopeful that can accelerate the development of HMPL-523 in China."

The BTD is supported by the encouraging results from the Phase Ib study of HMPL-523, which were presented at the 63rd American Society of Hematology (ASH) Annual Meeting in December 2021. The data also supported the initiation of a Phase III trial, ESLIM-01, in China of HMPL-523 in adult patients with ITP in October 2021. Approximately 180 patients are expected to be enrolled. Additional details may be found at clinicaltrials.gov, using identifier NCT05029635.

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. The ESLIM-01 Phase III trial is underway to evaluate the efficacy and safety of HMPL-523 in treating adult patients with primary ITP, an autoimmune disorder that can lead to increased risk of bleeding. Additional details may be found at clinicaltrials.gov, using identifier NCT05029635. HMPL-523 is also being studied in indolent non-Hodgkin's lymphoma and multiple subtypes of B-cell malignancies in China (NCT02857998), the U.S. and Europe (NCT03779113).

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 estimated to be 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 the 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 the 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 11 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-523 for patients with ITP and other indications, 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.

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