Press Release

HUTCHMED Announces NDA Acceptance in China for Sovleplenib for the Treatment of Primary Immune Thrombocytopenia with Priority Review Status

— NDA accepted and granted Priority Review following its Breakthrough Therapy designation granted in January 2022 —

— NDA is supported by data from successful Phase III ESLIM-01 trial in patients with adult primary immune thrombocytopenia who have received at least one previous therapy —

Hong Kong, Shanghai & Florham Park, NJ — Thursday, January 11, 2024: HUTCHMED (China) Limited ("HUTCHMED") (Nasdaq/AIM:HCM; HKEX:13) today announces that the New Drug Application ("NDA") for sovleplenib for the treatment of adult patients with primary immune thrombocytopenia ("ITP") has been accepted for review and granted priority review by the China National Medical Products Administration ("NMPA"). Sovleplenib is a novel, selective, oral inhibitor targeting spleen tyrosine kinase ("Syk"), being developed for the treatment of hematological malignancies and immune diseases.

The NDA is supported by data from ESLIM-01, a randomized, double-blinded, placebo-controlled Phase III trial in China of sovleplenib in 188 adult patients with primary ITP who have received at least one prior line of standard therapy. In August 2023, HUTCHMED announced that the trial had met its primary endpoint of demonstrating a clinically meaningful and a statistically significant increase in durable response rate in patients treated with sovleplenib as compared to patients treated with placebo. Secondary endpoints including response rate and safety were also met. Full results will be published in due course. Results from the proof of concept study that led to the ESLIM-01 study were published in *The Lancet Haematology.*

The NMPA granted Breakthrough Therapy designation ("BTD") to sovleplenib for the indication studied in ESLIM-01 in January 2022. The NMPA granted this designation to sovleplenib as a new drug that could treat a serious condition for which there are no effective treatment options, and where clinical evidence demonstrates significant advantages over existing therapies.

"We are pleased to have initiated the rolling submission of an NDA for sovleplenib in China as we look to bring this novel treatment to ITP patients," said Dr. Weiguo Su, Executive Director, Chief Executive Officer and Chief Scientific Officer of HUTCHMED. "Our submission includes data from the successful Phase III ESLIM-01 trial in China which demonstrated a durable response rate of sovleplenib for patients. There is a significant need for new therapies in adult primary ITP which can significantly impair the quality of life for patients."

About Sovleplenib

Sovleplenib is a novel, selective inhibitor of Syk for once daily oral administration. Syk is a major component in B-cell receptor and FcR signaling and is an established target for the treatment of multiple subtypes of B-cell lymphomas and autoimmune disorders.

Results from the Phase I/II study in China study published in *The Lancet Haematology* showed a rapid and durable increase in platelet counts in previously treated patients with ITP. Among the patients who received the recommend Phase II dose of 300mg once daily ("RP2D"), 40% of patients experienced durable response, as defined by platelet count equal to or exceeding $50x10^9$/L in four out of six visits during week 14 to 24 of the study. All RP2D patients had been previously treated with glucocorticoid steroid, and 80% were previously treated with thrombopoietin or thrombopoietin receptor agonists. Among the patients who received treatment at all doses through week 24 of the study, treatment-emergent adverse events ("TEAE") led to dose reduction or interruption in 7% patients, and no dose discontinuation. No TEAEs of grade 3 or above occurred in more than one patient through week 24 of the study.

Sovleplenib is currently under clinical investigation and its safety and efficacy have not been evaluated by any regulatory authority.

HUTCHMED currently retains all rights to sovleplenib worldwide. In addition to ITP, sovleplenib is also being studied in warm antibody autoimmune hemolytic anemia (NCT05535933) and indolent non-Hodgkin's lymphoma (NCT03779113).

About ITP

ITP is an autoimmune disorder characterized by immunologic destruction of platelets and decreased platelet production. Patients with ITP are at increased risk of excessive bleeding and bruising.[1] ITP is also associated with fatigue (reported in up to 39% of adults with ITP) and impaired quality of life.[2,3,4,5,6] The incidence of primary ITP in adults is 3.3/100,000 adults per year with a prevalence of 9.5 per 100,000 adults.[7] Based on this prevalence rate, approximately 110,000 patients are estimated to be living with primary ITP in China, in addition to 56,000 patients in the U.S., Germany, France, Italy, Spain, UK, and Japan. It has been estimated that as many as 145,000 patients are living with chronic ITP in major pharmaceutical markets excluding China.[8]

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.[9] 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.[10]

About HUTCHMED

HUTCHMED (Nasdaq/AIM: HCM; HKEX: 13) is an innovative, commercial-stage, biopharmaceutical company. It is committed to the discovery, 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, HUTCHMED has focused on bringing cancer drug candidates from in-house discovery to patients around the world, with its first three oncology medicines now approved 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 submission of a NDA for sovleplenib for the treatment of ITP with the NMPA and the timing of such submission, therapeutic potential of sovleplenib for the treatment of patients with ITP and the further development of sovleplenib 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 NDA approval of sovleplenib for the treatment of patients with ITP or other indications in China or other jurisdictions, its potential to gain approvals from regulatory authorities on an expedited basis or at all, the safety profile of sovleplenib, HUTCHMED's ability to fund, implement and complete its further clinical development and commercialization plans for sovleplenib, the timing of these events, 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.

CONTACTS

Investor Enquiries	+852 2121 8200 / ir@hutch-med.com
Media Enquiries	
Ben Atwell / Alex Shaw, FTI Consulting	+44 20 3727 1030 / +44 7771 913 902 (Mobile) / +44 7779 545 055 (Mobile) / HUTCHMED@fticonsulting.com
Zhou Yi, Brunswick	+852 9783 6894 (Mobile) / HUTCHMED@brunswickgroup.com
Nominated Advisor	
Atholl Tweedie / Freddy Crossley / Daphne Zhang, Panmure Gordon	+44 (20) 7886 2500

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