Press Release

HUTCHMED Highlights Publication of Phase III ESLIM-01 Results in The Lancet Haematology

— Publication shows treatment demonstrated durable response rate of 48.4% vs. 0% with placebo —

— Presentations at EHA showcased subgroup analyses demonstrating consistent benefits regardless of prior lines of therapies or prior TPO/TPO-RA[1] exposure —

— Data supported regulatory submission in China accepted in January 2024 —

Hong Kong, Shanghai & Florham Park, NJ — Monday, June 17, 2024: HUTCHMED (China) Limited ("HUTCHMED") (Nasdaq/AIM:HCM; HKEX:13) today announces that results from ESLIM-01, HUTCHMED's Phase III trial of sovleplenib (HMPL-523), in adult patients with primary immune thrombocytopenia ("ITP") in China, were published in *The Lancet Haematology*. Additional details and subgroup results of the study were also presented on June 14 at the European Hematology Association ("EHA") 2024 Hybrid Congress as an oral and two poster presentations.

Sovleplenib is a novel, selective, oral inhibitor targeting spleen tyrosine kinase ("Syk") for the treatment of hematological malignancies and immune diseases. Syk is a component in Fc receptor ("FcR") and B-cell receptor signaling pathway. ITP is a complex autoimmune bleeding disorder, leading to a reduced platelet level in the peripheral blood. ITP can also impact on patients' quality of life due to fatigue, restrictions on activities and anxiety. The ESLIM-01 trial results published by *The Lancet Haematology* suggest that sovleplenib could be a potential treatment option for patients with ITP who received at least one prior therapy.

ESLIM-01 is a 2:1 randomized, double-blind, Phase III study conducted in 188 adult patients with primary ITP who had received at least one previous anti-ITP treatment (NCT05029635). The study demonstrated a clinically meaningful early and sustained durable platelet response in patients with primary ITP, with a tolerable safety profile and improvement in quality of life. The primary endpoint was met, with durable response rate of 48.4% (61/126) with sovleplenib compared to zero with placebo (p<0.0001), which was consistent across most pre-defined subgroups. In addition, overall response rates were 68.3% at 0–12 weeks and 70.6% at 0–24 weeks with sovleplenib, compared to 14.5% and 16.1% with placebo (p<0.0001). The median time to response was 8 days with sovleplenib compared to 30 days with placebo.

Further post-hoc subgroup analysis of the study demonstrated consistent clinical benefits across ITP patients regardless of prior lines of ITP therapies or prior TPO/TPO-RA exposure, including TPO/TPO-RA treatment types and number of prior regimens. Most patients were heavily pretreated with a median of four prior lines of ITP therapy. In patients who received four or more prior lines of therapy, the durable response rate was 47.7% with sovleplenib compared to 0% with placebo (p<0.0001). In addition, a majority of the patients had received prior TPO/TPO-RA. 74.6% of patients in the sovleplenib group had received prior treatment with TPO/TPO-RA, and analysis in this subgroup also demonstrated a significantly higher durable response rate of 46.8% with sovleplenib compared to zero with placebo (p<0.0001).

The safety profile of sovleplenib in ESLIM-01 was consistent with previously reported studies. The majority of treatment-emergent adverse events ("TEAEs") were mild or moderate in severity (grade 1 or 2). Grade 3 or above TEAEs were reported in 25.4% of patients with sovleplenib and 24.2% with placebo. Sovleplenib also significantly improved quality of life in physical functioning and energy/fatigue (p<0.05).[2]

The China National Medical Products Administration ("NMPA") granted Breakthrough Therapy designation for this indication and accepted the New Drug Application ("NDA") for review with Priority Review in January 2024. A dose-finding study in the U.S. is being planned (NCT06291415). HUTCHMED also initiated the registration stage of the Phase II/III clinical trial of sovleplenib in adult patients with warm antibody autoimmune hemolytic anemia ("wAIHA") in China in March 2024 (NCT05535933). HUTCHMED retains all rights to sovleplenib worldwide.

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.[3] ITP is also associated with fatigue (reported in up to 39% of adults with ITP) and impaired quality of life.[4,5,6,7,8] 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.[9] 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.[10]

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.[11] 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.[12]

About Sovleplenib

Sovleplenib is a novel, selective inhibitor of Syk for once daily oral administration. Syk, a non-receptor tyrosine kinase, 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.

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

HUTCHMED 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 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 it has focused on bringing cancer drug candidates from in-house discovery to patients around the world, with its first three oncology medicines 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 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, and the timing of these events. 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.

Medical Information

This press release contains information about products that may not be available in all countries, or may be available under different trademarks, for different indications, in different dosages, or in different strengths. Nothing contained herein should be considered a solicitation, promotion or advertisement for any prescription drugs including the ones under development.

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 / Freddie Wooding, Panmure Gordon	+44 (20) 7886 2500

REFERENCES

[1] TPO = Thrombopoietin; TPO-RAs = Thrombopoietin receptor agonists.
[2] Hu Y, et al. Efficacy and safety of the Syk inhibitor sovleplenib (HMPL-523) in adult patients with primary immune thrombocytopenia in China (ESLIM-01): a randomized, double-blind, placebo-controlled phase 3 study [published online ahead of print, 2024 Jun 14]. *Lancet Haematol*. 2024.
[3] Zufferey A, et al. Pathogenesis and Therapeutic Mechanisms in Immune Thrombocytopenia (ITP). *J. Clin. Med*. 2017, 6(2), 16.
[4] McMillan R, et al. Self-reported health-related quality of life in adults with chronic immune thrombocytopenic purpura. *Am J Hematol*. 2008 Feb;83(2):150-4.
[5] Snyder CF, et al. Health-related quality of life of immune thrombocytopenic purpura patients: results from a web-based survey. *Curr Med Res Opin*. 2008 Oct;24(10):2767-76.
[6] Doobaree IU, et al. Thromboembolism in adults with primary immune thrombocytopenia: a systematic literature review and meta-analysis. *Eur J Haematol*. 2016 Oct;97(4):321-30.
[7] Sarpatwari A, et al. Thromboembolic events among adult patients with primary immune thrombocytopenia in the United Kingdom General Practice Research Database. *Haematologica*. 2010 Jul;95(7):1167-75.
[8] Sarpatwari A, et al. Health-related lifestyle in adults and children with primary immune thrombocytopenia (ITP). *Br J Haematol*. 2010 Oct;151(2):189-91.
[9] Lambert MP, Gernsheimer TB. Clinical updates in adult immune thrombocytopenia. *Blood*. 2017 May 25;129(21):2829-2835.
[10] Clarivate Landscape & Forecast for Immune Thrombocytopenic Purpura, 2018.
[11] Provan D, et al. Updated international consensus report on the investigation and management of primary immune thrombocytopenia. *Blood Adv*. 2019;3(22):3780-3817.
[12] Crowley MT, et al. A critical role for Syk in signal transduction and phagocytosis mediated by Fcγ receptors on macrophages. *J. Exp. Med*. 186(7), 1027–1039 (1997).