HUTCHMED (China) Limited
和黃醫藥（中國）有限公司
(Incorporated in the Cayman Islands with limited liability)
(Stock Code: 13)

INSIDE INFORMATION

HUTCHMED Announces that the Sovleplenib Phase III ESLIM-01 Study Met Its Primary Endpoint in Primary Immune Thrombocytopenia in China

— Randomized, double-blind, controlled trial met primary endpoint of durable response rate and all secondary endpoints —

— Overall safety consistent with sovleplenib known profile —

— Plans for regulatory submission underway in China, where it was designated a Breakthrough Therapy —

— Results to be submitted to an upcoming medical meeting —

This announcement is made by HUTCHMED (China) Limited ("HUTCHMED") pursuant to Rule 13.09(2)(a) of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited and the Inside Information Provisions under Part XIVA of the Securities and Futures Ordinance (Cap. 571).

HUTCHMED today announces that the pivotal Phase III trial ESLIM-01 evaluating the investigational use of sovleplenib met its primary endpoint of durable response rate and all secondary endpoints in adult patients with primary immune thrombocytopenia ("ITP") in China. HUTCHMED plans to submit the New Drug Application ("NDA") around the end of 2023.

The National Medical Products Administration of China ("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. As such, the sovleplenib NDA may be considered for priority review for its use in ITP.

ESLIM-01 is 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. Enrollment was completed in December 2022. The trial 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 submitted for presentation at an upcoming scientific conference.

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 an autoimmune disorder that can lead to increased risk of bleeding. Encouraging proof of concept data was presented at ASH[1] 2021 and published in *The Lancet Haematology* in June 2023.[2]

"Sovleplenib offers a potential new treatment for patients with chronic adult primary ITP who have received at least one prior therapy, a heterogeneous disease that can persist for years and where there remains a significant need for new treatments," said Dr Michael Shi, Chief Medical Officer of HUTCHMED. "We are very pleased to see the positive outcomes of the ESLIM-01

study and would like to thank the patients, their families, and the healthcare professionals who participated in this study and helped reach this achievement."

Professor Ren-Chi Yang, MD, of the Institute of Hematology and Blood Diseases Hospital, Chinese Academy of Medical Sciences, who served as the ESLIM-01 co-Leading Principal Investigator ("PI") and Steering Committee ("SC") member, said, "By meeting the primary and all the secondary endpoints in this study while demonstrating a good level of tolerability and once daily oral dosing, I am optimistic that sovleplenib may be a potential choice to help ITP patients."

Professor Yu Hu, MD, at the Union Hospital, Tongji Medical College, Huazhong University of Science and Technology, co-Leading PI and SC member commented, "Many patients with recurrent or refractory ITP feel burdened by their disease in their daily lives and by the management of their current medications. I welcome the opportunity to offer my patients another treatment option to live better with their disease."

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 20 patients who received the recommend Phase II dose of 300mg once daily ("RP2D"), 8 (40%) 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 20 patients had been previously treated with glucocorticoid steroid, and 15 previously treated with thrombopoietin or thrombopoietin receptor agonists. Median time to response to treatment was 1.1 weeks for the 16 patients who received the RP2D during the first 8 weeks of the study, as defined by first platelet count equal to or exceeding $30x10^9$/L. Among the 41 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 three (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.[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 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 and marketed in China. For more information, please visit: www.hutch-med.com or follow us on LinkedIn.

Forward-Looking Statements

This announcement 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 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 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 announcement, whether as a result of new information, future events or circumstances or otherwise.

Inside Information

This announcement contains inside information for the purposes of Article 7 of Regulation (EU) No 596/2014 (as it forms part of retained EU law as defined in the European Union (Withdrawal) Act 2018).

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[1] ASH = American Society of Hematology.

[2] Liu X, Zhou H, Hu Y, et al. Sovleplenib (HMPL-523), a novel Syk inhibitor, for patients with primary immune thrombocytopenia in China: a randomised, double-blind, placebo-controlled, phase 1b/2 study. *Lancet Haematol*. 2023;10(6):e406-e418. doi:10.1016/S2352-3026(23)00034-0.

[3] Zufferey A, Kapur R, Semple JW. Pathogenesis and Therapeutic Mechanisms in Immune Thrombocytopenia (ITP). *J. Clin. Med*. 2017, 6(2), 16.

[4] McMillan R, Bussel JB, 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, Mathias SD, Cella D, 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, Nandigam R, Bennett D, 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, Bennett D, Logie JW, 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, Watson S, Erqou S, 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, Arnold DM, Bussel JB, 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, Costello PS, Fitzer-Attas CJ 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).

By Order of the Board

Edith Shih
Non-executive Director and Company Secretary

Hong Kong, August 21, 2023

As at the date of this announcement, the Directors of the Company are:

Executive Directors:
Mr TO Chi Keung, Simon
(Chairman)
Dr Weiguo SU
(Chief Executive Officer and Chief Scientific Officer)
Mr CHENG Chig Fung, Johnny
(Chief Financial Officer)

Non-executive Directors:
Dr Dan ELDAR
Ms Edith SHIH
Ms Ling YANG

Independent Non-executive Directors:
Mr Paul Rutherford CARTER
(Senior Independent Director)
Mr Graeme Allan JACK
Professor MOK Shu Kam, Tony