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HUTCHMED (China) Limited

和黃醫藥（中國）有限公司

(Incorporated in the Cayman Islands with limited liability)

(Stock Code: 13)

VOLUNTARY ANNOUNCEMENT

HUTCHMED Announces China NMPA Approval of SYVIK® (sovleplenib) for the Treatment of Primary Immune Thrombocytopenia and Warm Antibody Autoimmune Hemolytic Anemia

— SYVIK® becomes the first novel Syk inhibitor approved in China —

— Simultaneous approvals in two underserved autoimmune indications supported by positive ESLIM-01 trial in ITP and ESLIM-02 trial in wAIHA —

— Expands HUTCHMED's commercial portfolio into immunology, establishing a new presence beyond oncology —

HUTCHMED (China) Limited ("HUTCHMED") today announces that the China National Medical Products Administration ("NMPA") has granted simultaneous approval for two New Drug Applications (NDAs) of SYVIK® (sovleplenib), a novel, selective oral small molecule inhibitor targeting spleen tyrosine kinase ("Syk"):

- Immune Thrombocytopenia ("ITP"): For the treatment of adult patients with chronic primary ITP who have had an insufficient response to at least one prior therapy; and
- Warm Antibody Autoimmune Hemolytic Anemia ("wAIHA"): For the treatment of adult patients with wAIHA who who have had an insufficient response to prior corticosteroid therapy.

The approval for ITP is supported by data from ESLIM-01 (NCT05029635), a randomized, double-blinded, placebo-controlled Phase III trial in China of SYVIK® in 188 adult patients who had received at least one prior line of standard therapy. Results from ESLIM-01 study were published in *The Lancet Haematology*. SYVIK® demonstrated a clinically meaningful early and sustained durable platelet response in patients with primary ITP compared to placebo, with durable response rate of 48.4% compared to zero with placebo (p<0.0001). Overall response rates were 68.3% at 0–12 weeks and 70.6% at 0–24 weeks with SYVIK®, compared to 14.5% and 16.1% with placebo (p<0.0001). SYVIK® demonstrated a tolerable safety profile and improvement in quality of life.

The approval for wAIHA is supported by data from ESLIM-02 (NCT05535933), a randomized, double-blind, placebo-controlled Phase II/III study in adult patients with primary or secondary wAIHA who had relapsed or were refractory to prior glucocorticoid treatment. Results from the Phase II part of ESLIM-02 were published in *The Lancet Haematology*. Results from the Phase III part were presented at the European Hematology Association ("EHA") 2026 Congress. SYVIK® demonstrated a significantly higher durable response rate during weeks 5–24 compared to placebo (66% vs 15%, p<0.0001). During the 24-week double-blind treatment period, SYVIK® demonstrated superior efficacy across several key metrics; specifically, the overall response rate — defined as hemoglobin ≥100 g/L with an increase of ≥20 g/L from baseline without rescue therapy — was significantly increased (70% vs 22%, p<0.0001). SYVIK® demonstrated a favorable safety profile with no treatment-related deaths or discontinuations in the SYVIK® group.

Mr Johnny Cheng, Acting Chief Executive Officer and Chief Financial Officer of HUTCHMED, said: "The simultaneous approvals of SYVIK® for both ITP and wAIHA represent a significant milestone for HUTCHMED as our first in-house discovered immunology drug approved for commercialization. Patients with these chronic autoimmune blood conditions often face disease relapses and tolerability challenges associated with prolonged standard treatments. SYVIK® has demonstrated clinically meaningful efficacy, rapid onset, and sustained durable responses with a favorable safety profile across the pivotal ESLIM-01 and ESLIM-02 studies. We are committed to making this new targeted treatment option accessible to patients across China, addressing critical unmet needs and helping patients better manage these challenging conditions."

In addition to the regulatory approvals in China, sovleplenib was granted Orphan Drug Designation by the US FDA for the treatment of primary ITP and autoimmune hemolytic anemia in October 2026. This designation underscores the clinical value of sovleplenib and its potential to address significant unmet medical needs on a global scale. HUTCHMED retains full worldwide rights to sovleplenib and continues to evaluate strategic pathways to support its global development.

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 US, 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 wAIHA

Autoimmune hemolytic anemia ("AIHA") is an autoimmune disorder characterized by the destruction of red blood cells ("RBCs") due to the production of antibodies against RBC. The incidence of AIHA is estimated to be 0.8-3.0/100,000 adults per year with an estimated prevalence of 17 per 100,000 adults and a death rate of 8-11%.[11,12] wAIHA is the most common form of AIHA,[13] accounting for about 75-80% of all adult AIHA cases.[14]

The accelerated clearance of antibody-coated RBCs by immunoglobulin Fc-gamma receptor (FcγR) bearing macrophages is thought to be the pathogenic mechanism in wAIHA.[15] Activated Syk mediates downstream signaling of the activated Fc receptors in phagocytic cells, resulting in phagocytosis of RBCs.[16] In addition, activation of Syk through the B-cell receptor mediates activation and differentiation of B-lymphocytes into antibody secreting plasma cells.[17] Inhibition of Syk may have potential effects in the treatment of wAIHA through inhibition of phagocytosis and reduction of antibody production.

About SYVIK®

SYVIK® (sovleplenib) is a novel, selective inhibitor of Syk. 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.

HUTCHMED currently retains all rights to sovleplenib worldwide.

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. Since inception it has focused on bringing drug candidates from in-house discovery to patients around the world, with its first five medicines marketed in China, the first of which is also approved around the world including in the US, Europe and Japan. 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 US 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, the further clinical development for sovleplenib, its expectations as to whether any studies on sovleplenib 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 sovleplenib, including as a combination therapy, to meet the primary or secondary endpoint of a study, to obtain regulatory approval in other jurisdictions and to gain commercial acceptance after obtaining regulatory approval; the potential market of sovleplenib for a targeted indication; and 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 US 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.

Medical Information

This announcement 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.

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By Order of the Board

Edith Shih
Non-executive Director and Company Secretary

Hong Kong, November 19, 2026

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

Chairman and Non-executive Director:
Dr Dan ELDAR

Executive Directors:
Dr Weiguo SU
(Chief Executive Officer and Chief Scientific Officer)
Mr CHENG Chig Fung, Johnny
(Acting Chief Executive Officer and Chief Financial Officer)

Non-executive Directors:
Ms Edith SHIH
Ms Ling YANG

Independent Non-executive Directors:
Dr Renu BHATIA
(Senior and Lead Independent Non-executive Director)
Dr Chaohong HU
Professor TAN Shao Weng, Daniel
Mr WONG Tak Wai