Press Release

HUTCHMED Announces Positive Topline Results of Phase III Part of ESLIM-02 Trial of Sovleplenib for Warm Antibody Autoimmune Hemolytic Anemia in China

— Delivers rapid, durable responses in wAIHA, the more common form of this potentially life-threatening disease —

Hong Kong, Shanghai & Florham Park, NJ — Wednesday, January 7, 2026: HUTCHMED (China) Limited ("HUTCHMED") (Nasdaq/AIM:HCM; HKEX:13) today announces that the Phase III registration part of the ESLIM-02 clinical trial of sovleplenib, a novel spleen tyrosine kinase ("Syk") inhibitor, in adult patients with warm antibody autoimmune hemolytic anemia ("wAIHA") in China has met its primary endpoint of durable hemoglobin (Hb) response rate within weeks 5 to 24 of treatment.

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%.[1,2] wAIHA is the most common form of AIHA,[3] accounting for about 75-80% of all adult AIHA cases.[4]

ESLIM-02 is a randomized, double blind, placebo-controlled China Phase II/III study in adult patients with primary or secondary wAIHA who had relapsed or were refractory to at least one prior line of standard treatment. Results from the Phase II part of the study published in The Lancet Haematology in January 2025 demonstrated encouraging hemoglobin benefit compared with placebo, with overall response rate of 43.8% vs 0% in the first 8 weeks, and overall response rate of 66.7% during the 24 weeks of sovleplenib treatment (including patients that crossed over from placebo) with a favorable safety profile.[5] Additional details may be found at clinicaltrials.gov, using identifier NCT05535933.

Professor Fengkui Zhang of the Chinese Academy of Medical Sciences Blood Diseases Hospital, and one of the leading principal investigators of the ESLIM-02 study, said: "Warm antibody autoimmune hemolytic anemia is a highly heterogeneous and often chronically relapsing disease. Patients often experience symptoms like fatigue significantly impacting patients' quality of life. In severe cases, the disease can become life-threatening if not managed effectively. The positive topline results from ESLIM-02 highlight sovleplenib's potential to deliver rapid and durable hemoglobin responses in wAIHA patients who have limited options after failing standard therapies. This could represent a meaningful advancement for managing this challenging condition."

Professor Bin Han of Peking Union Medical College Hospital and Professor Liansheng Zhang of The Second Hospital of Lanzhou University were also co-leading Principal Investigators of the study. Full results of the ESLIM-02 study will be submitted for presentation at an upcoming scientific conference. HUTCHMED plans to submit the New Drug Application ("NDA") for sovleplenib for wAIHA to the China National Medical Products Administration (NMPA) in the first half of 2026.

About Sovleplenib and wAIHA

Sovleplenib is a novel, investigational, selective small molecule inhibitor for oral administration targeting the spleen tyrosine kinase, also known as Syk. Syk is a major component in B-cell receptor and Fc receptor signaling and is an established target for the treatment of multiple subtypes of B-cell lymphomas and autoimmune disorders.

The accelerated clearance of antibody-coated RBCs by immunoglobulin Fc-gamma receptor (FcγR) bearing macrophages is thought to be the pathogenic mechanism in wAIHA.[6] Activated Syk mediates downstream signaling of the activated Fc receptors in phagocytic cells, resulting in phagocytosis of RBCs.[7] In addition, activation of Syk through the B-cell receptor mediates activation and differentiation of B-lymphocytes into antibody secreting plasma cells.[8] Inhibition of Syk may have potential effects in the treatment of wAIHA through inhibition of phagocytosis and reduction of antibody production.

In addition to wAIHA, sovleplenib is also being studied in immune thrombocytopenia ("ITP"). Positive results from ESLIM-01 (NCT05029635), a Phase III trial in China of sovleplenib in patients with primary ITP, have been published in *The Lancet Haematology*. An NDA resubmission for sovleplenib for second-line ITP is planned in the first half of 2026.

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 three 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 press release 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 for the treatment of wAIHA 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 a new drug application submission of sovleplenib for the treatment of wAIHA or other indications in China or other jurisdictions, its potential to gain approvals from regulatory authorities on an expedited basis or at all, the efficacy and 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 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 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.

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