



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 Highlights Sovleplenib ESLIM-02 Phase III Data in Warm Antibody Autoimmune Hemolytic Anemia Presented at EHA 2026 Congress

— Sovleplenib demonstrated rapid and durable hemoglobin response with favorable safety profile —

— The ESLIM-02 study underscores sovleplenib's potential to address critical unmet needs in a treatment landscape currently devoid of approved targeted therapies —

HUTCHMED (China) Limited ("[HUTCHMED](#)") today announces results from the Phase III part of the ESLIM-02 study of sovleplenib in patients with warm antibody autoimmune hemolytic anemia ("wAIHA") in China were presented on Thursday, June 11, 2026 during the European Hematology Association ("EHA") Congress in Stockholm, Sweden.

Supported by data from the ESLIM-02 study, a New Drug Application ("NDA") for sovleplenib for the treatment of adult patients with wAIHA who have had an insufficient response to at least one previous glucocorticoid treatment has been accepted for review and granted priority review by the China National Medical Products Administration ("NMPA") in April 2026. The NMPA granted Breakthrough Therapy Designation to sovleplenib for the treatment of wAIHA in March 2026. The ESLIM-02 presentation was selected for the official EHA Press Program.

Professor Bing Han of Peking Union Medical College Hospital, and co-leading Principal Investigator of the ESLIM-02 study, said: "The wAIHA treatment paradigm has remained stagnant for decades, with patients often trapped in a cycle of high-dose steroids and frequent relapses. The ESLIM-02 data are transformative as they demonstrate that targeting the Syk pathway can achieve both rapid and durable control of hemolysis. We are particularly encouraged by the robust data across all patient subgroups, regardless of their prior treatments. Sovleplenib's ability to significantly reduce the need for rescue therapies and blood transfusions represents a major step forward in restoring the quality of life for these patients."

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 ([NCT05535933](#)). Results from the Phase II part of the study were [published in The Lancet Haematology](#) in January 2025. In Phase III part of the study, 90 patients were randomized 1:1 to receive either sovleplenib (n=44) or placebo (n=46) at a dose of 300 mg once daily for 24 weeks.

The study met its primary endpoint, with sovleplenib demonstrating 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, sovleplenib demonstrated superior efficacy across several key metrics; specifically, the overall response rate—defined as hemoglobin (Hb) ≥ 100 g/L with an increase of ≥ 20 g/L from baseline without rescue therapy—was significantly increased (70% vs 22%, $p<0.0001$). The use of protocol-defined rescue therapy was significantly reduced with sovleplenib (16% vs 54%, $p=0.0001$), fewer patients received red blood cell transfusion (11% vs 43%) and higher patients with tapering or discontinuation of glucocorticoids or other baseline concomitant anti-wAIHA therapies (50% vs 15%, $p=0.003$).

Median time to response was 3.1 weeks for soveplelenib versus 6.3 weeks for placebo, while the median cumulative duration of response among overall responders was 16.1 versus 6.1 weeks, respectively. Additionally, an improvement in hemolytic markers was observed with soveplelenib compared with placebo, showing an alleviation of active hemolysis.

These efficacy findings remained consistent across all sensitivity analyses, and all subgroup analyses further supported the primary endpoint results. Notably, in patients who had received prior rituximab therapy, the durable response rate continued to favor soveplelenib over placebo (69% vs 16%, $p=0.0022$).

Soveplelenib demonstrated a favorable safety profile. Grade ≥ 3 treatment-emergent adverse events (“TEAE”) were reported in 43% patients in the soveplelenib arm and 59% patients in the placebo arm. The most common Grade ≥ 3 TEAEs, occurring in at least 10% of patients, were warm autoimmune hemolytic anemia (18% vs 43%) and upper respiratory tract infection (2% vs 11%). There were no TEAE-related deaths or treatment discontinuations reported in the soveplelenib group.

Details of the presentation are as follows:

Title: A randomized, double-blind, placebo-controlled Phase 3 study of ESLIM-02 for efficacy and safety of soveplelenib (HMPL-523) in patients with warm autoimmune hemolytic anemia in China

Lead Author: Bing Han, Peking Union Medical College Hospital, Chinese Academy of Medical Science, Beijing, China

Session: Oral Session (Targeted therapies in rare red cell and metabolic disorders)

Presentation ID: S301

Date & Time: Thursday, 11 June 2026, 17:00 CEST

Location: A13 Hall

About Soveplelenib and wAIHA

Soveplelenib is a novel, investigational, selective small molecule inhibitor for oral administration targeting 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 (Fc γ R) bearing macrophages is thought to be the pathogenic mechanism in wAIHA.¹ Activated Syk mediates downstream signaling of the activated Fc receptors in phagocytic cells, resulting in phagocytosis of RBCs.² In addition, activation of Syk through the B-cell receptor mediates activation and differentiation of B-lymphocytes into antibody secreting plasma cells.³ 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, soveplelenib is also being studied in immune thrombocytopenia (“ITP”). Positive results from ESLIM-01 (NCT05029635), a Phase III trial in China of soveplelenib in patients with primary ITP, have been [published in *The Lancet Haematology*](#). The NMPA accepted for review the resubmitted NDA filing for the treatment of ITP and granted it priority review in February 2026. According to IQVIA, China has 430,000 existing patients with 41,000 new ITP patients each year. About half of ITP patients fail to have satisfactory results from currently approved treatments such as TPO (thrombopoietin) / TPO-RAs (thrombopoietin receptor agonists).

HUTCHMED currently retains all rights to soveplelenib 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 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 but not limited to its expectations regarding the therapeutic potential of soveplepenib, the further clinical development for soveplepenib, its expectations as to whether any studies on soveplepenib 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. 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 soveplepenib, including as combination therapies, to meet the primary or secondary endpoint of a study, to obtain regulatory approval in different jurisdictions and to gain commercial acceptance after obtaining regulatory approval; the potential markets of soveplepenib for a targeted indication, and the sufficiency of funding. 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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- ¹ Barros MM, Blajchman MA, Bordin JO. Warm autoimmune hemolytic anemia: recent progress in understanding the immunobiology and the treatment. *Transfus Med Rev.* 2010; 24(3):195 - 210. doi: 10.1016/j.tmr.2010.03.002.
 - ² Barcellini W, Fattizzo B, Zaninoni A. Current and emerging treatment options for autoimmune hemolytic anemia. *Expert Rev Clin Immunol.* 2018; 14(10):857 - 872. doi: 10.1080/1744666x.2018.1521722.
 - ³ Davidzohn N, Biram A, Stoler - Barak L, Grenov A, Dassa B, Shulman Z. SYK degradation restrains plasma cell formation and promotes zonal transitions in germinal centers. *J Exp Med.* 2020; 217(3):e20191043. doi: 10.1084/jem.20191043.

By Order of the Board

Edith Shih

Non-executive Director and Company Secretary

Hong Kong, June 12, 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