



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 Sovleplenib Granted US FDA Orphan Drug Designation for Primary Immune Thrombocytopenia

- Orphan Drug Designation granted for the treatment of primary immune thrombocytopenia —
- Underscores the potential of soveplenib to address significant unmet medical needs in patients with this rare and serious autoimmune condition —
- Eligible for development incentives including 7 years of US market exclusivity upon regulatory approval —

HUTCHMED (China) Limited ("[HUTCHMED](#)") today announces that the US Food and Drug Administration ("FDA") has granted Orphan Drug Designation to soveplenib for the treatment of primary immune thrombocytopenia ("ITP"), an autoimmune disorder that can lead to increased risk of bleeding. Sovleplenib is a novel, selective, oral spleen tyrosine kinase ("Syk") inhibitor.

The FDA's Orphan Drug Designation program provides orphan status to drugs and biologics intended for the safe and effective treatment, diagnosis, or prevention of rare diseases or conditions that affect fewer than 200,000 people in the United States. If approved by the FDA for the designated indication, drugs with Orphan Drug Designation are eligible for 7 years of US market exclusivity upon approval, tax credits for qualified clinical trials, user fee waivers under the Prescription Drug User Fee Act, and specialized regulatory guidance from the FDA during clinical development.

In China, New Drug Applications ("NDAs") for soveplenib in primary ITP and warm antibody autoimmune hemolytic anemia are currently under regulatory review by the National Medical Products Administration (NMPA), supported by positive data from the pivotal ESLIM-01 and ESLIM-02 trials in China, respectively.

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 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.

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 four 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 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, unexpected adverse events or safety issues; the ability of sovleplenib 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 market of sovleplenib for a targeted indication; the sufficiency of funding; HUTCHMED’s ability to successfully develop and commercialize sovleplenib. 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.

- ¹ Zufferey A, et al. Pathogenesis and Therapeutic Mechanisms in Immune Thrombocytopenia (ITP). *J. Clin. Med.* 2017, 6(2), 16.
- ² 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.
- ³ 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.
- ⁴ 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.
- ⁵ 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.
- ⁶ 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.
- ⁷ Lambert MP, Gernsheimer TB. Clinical updates in adult immune thrombocytopenia. *Blood.* 2017 May 25;129(21):2829-2835.
- ⁸ Clarivate Landscape & Forecast for Immune Thrombocytopenic Purpura, 2018.
- ⁹ Provan D, et al. Updated international consensus report on the investigation and management of primary immune thrombocytopenia. *Blood Adv.* 2019;3(22):3780-3817.
- ¹⁰ 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).

By Order of the Board

Edith Shih

Non-executive Director and Company Secretary

Hong Kong, October 29, 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