

Press Release

HUTCHMED Completes Patient Enrollment of ESLIM-01, a Phase III Trial of Sovleplenib in Primary Immune Thrombocytopenia in China

Hong Kong, Shanghai & Florham Park, NJ — Tuesday, January 3, 2023: HUTCHMED (China) Limited (“[HUTCHMED](#)”) (Nasdaq/AIM:HCM, HKEX:13) today announces that it has completed patient enrollment of ESLIM-01, a pivotal Phase III clinical trial of soveleplenib for the treatment of adult patients with primary immune thrombocytopenia (“ITP”) in China. The last patient was enrolled on December 31, 2022.

The ESLIM-01 study, initiated in October 2021, is a randomized, double blinded, placebo-controlled Phase III clinical trial evaluating the efficacy and safety of soveleplenib in treating adult patients with ITP. The primary endpoint of the study is the durable response rate. Secondary and exploratory endpoints include overall response rate (ORR), incidence of treatment emergent adverse events, and patient quality of life improvement. A total of 188 patients were enrolled. Additional details may be found at clinicaltrials.gov, using identifier [NCT05029635](#).

Topline results from the ESLIM-01 trial are expected to be reported in the second half of 2023, followed by submission of results for presentation at an appropriate medical congress. If positive, HUTCHMED would initiate plans to apply for marketing authorization of soveleplenib by the China National Medical Products Administration (NMPA).

About Sovleplenib

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.

HUTCHMED currently retains all rights to soveleplenib worldwide. In addition to ITP, soveleplenib is also being studied in warm antibody autoimmune hemolytic anemia ([NCT05535933](#)), indolent non-Hodgkin's lymphoma and multiple subtypes of B-cell malignancies in China, the U.S. and Europe ([NCT02857998](#); [NCT03779113](#)).

About ITP and Syk

ITP is an autoimmune disorder characterized by immunologic destruction of platelets and decreased platelet production. Patients with ITP exhibit symptoms of petechiae, purpura, and gastrointestinal and/or urinary mucosal tract bleeding.¹ ITP is also associated with fatigue (reported in up to 39% of adults with ITP) and impaired quality of life, across domains of emotional, functional and reproductive health, and work or social 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

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.⁸ 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.⁹

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. It has more than 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 drug candidates from in-house discovery to patients around

the world, with its first three oncology drugs now approved and marketed in China. 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 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 patients, 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 different jurisdictions and to gain commercial acceptance after obtaining regulatory approval; the potential market of sovleplenib for a targeted indication; the sufficiency of funding; 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 press release, whether as a result of new information, future events or circumstances or otherwise.

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- ¹ Zufferey A, Kapur R, Semple JW. Pathogenesis and Therapeutic Mechanisms in Immune Thrombocytopenia (ITP). J. Clin. Med. 2017, 6(2), 16.
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⁴ 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.
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⁷ Lambert MP, Gernsheimer TB. Clinical updates in adult immune thrombocytopenia. Blood. 2017 May 25;129(21):2829-2835.
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⁹ 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).