Press Release

HUTCHMED Initiates Registration Stage of the ESLIM-02 Phase II/III Trial of Sovleplenib for Warm Antibody Autoimmune Hemolytic Anemia in China

Hong Kong, Shanghai & Florham Park, NJ — Friday, March 22, 2024: HUTCHMED (China) Limited ("HUTCHMED") (Nasdaq/AIM:HCM; HKEX:13) today announces that it has initiated the registration stage of the Phase II/III clinical trial of sovleplenib in adult patients with warm antibody autoimmune hemolytic anemia ("wAIHA") in China.

This follows positive data from the proof-of-concept Phase II stage of the trial and subsequent consultation with the China National Medical Products Administration ("NMPA"). If positive, the data from the trial may be used to support a future New Drug Application ("NDA") filing. wAIHA is an autoimmune disorder that can lead to anemia and has limited treatment options. The first Phase III patient received their initial dose on March 20, 2024.

ESLIM-02 is a randomized, double blind, placebo-controlled Phase II/III clinical trial. The objective of the registration stage of the study is to confirm the safety and efficacy of sovleplenib in adult patients with wAIHA. The primary endpoint for the study is the proportion of patients who achieve a durable hemoglobin (Hb) response by Week 24. 21 patients have been enrolled in the study so far and approximately 90 more patients are expected to be enrolled to this registration stage. The lead principal investigators are Dr. Fengkui Zhang of Chinese Academy of Medical Sciences Blood Diseases Hospital, Dr. Bing Han of Chinese Academy of Medical Sciences Peking Union Medical College Hospital and Dr. Liansheng Zhang of Lanzhou University Second Hospital. Additional details may be found at clinicaltrials.gov, using identifier NCT05535933.

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 sovleplenib worldwide.

In addition to wAIHA, sovleplenib is also being studied in immune thrombocytopenia ("ITP"). ESLIM-01 (NCT05029635) is a randomized, double-blinded, placebo-controlled Phase III trial in China of sovleplenib in patients with primary ITP that met all its endpoints. ITP is an autoimmune disorder that can lead to increased risk of bleeding. The NMPA granted Breakthrough Therapy designation for this indication and accepted the New Drug Application (NDA) for review with Priority Review in January 2024. A dose-finding study in the U.S. is in planning (NCT06291415).

About wAIHA and Syk

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 the autoimmune hemolytic diseases,[3] accounting for about 75-80% of all adult AIHA cases.[4]

The accelerated clearance of antibody-coated RBCs by immunoglobulin Fc receptor ("FcR") bearing macrophages is thought to be the pathogenic mechanism in wAIHA.[5] Activation of the FcR is associated with a signaling subunit, FcRγ, whose phosphorylation subsequent to receptor binding results in the recruitment and activation of Syk.[6] Activated Syk mediates downstream signaling of the activated FcRs 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] Therefore, inhibition of Syk may have potential effects in the treatment of wAIHA through inhibition of phagocytosis and reduction of antibody production.

About HUTCHMED

HUTCHMED (Nasdaq/AIM:HCM; HKEX:13) is an innovative, commercial-stage, biopharmaceutical company. It is committed to the discovery, global development and commercialization of targeted therapies and immunotherapies for the treatment of cancer and immunological diseases. It has approximately 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 cancer drug candidates from in-house discovery to patients around the world, with its first three oncology medicines now marketed in China, the first of which is also marketed in the U.S. 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 the treatment of patients with 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 an NDA submission of sovleplenib for the treatment of patients with 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 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.

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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