

Press Release

HUTCHMED Highlights Sovleplenib Phase III ESLIM-01 Study and Hematological Malignancy Programs Data to be Presented at the upcoming EHA2024 Congress

Hong Kong, Shanghai & Florham Park, NJ — Friday, May 17, 2024: HUTCHMED (China) Limited (“[HUTCHMED](#)”) (Nasdaq/AIM:HCM; HKEX:13) today announces that topline and subgroup results from the ESLIM-01 Phase III study of sovleplenib, as well as new and updated data related to novel investigational hematological malignancy therapies HMPL-306, HMPL-760 and tazemetostat, will be presented at the upcoming European Hematology Association (“EHA”) Hybrid Congress, taking place on June 13-16, 2024 in Madrid, Spain and online.

ESLIM-01 is a randomized, double-blinded, placebo-controlled Phase III trial in China of sovleplenib in adult patients with primary Immune Thrombocytopenia (“ITP”) who have received at least one prior line of standard therapy ([NCT05029635](#)). In 188 patients randomized to receive oral sovleplenib or placebo, sovleplenib demonstrated a clinically meaningful early and sustained durable platelet response in patients with primary ITP with durable response rate of 48.4% compared to zero with placebo (p<0.0001). The median time to response was 1.1 weeks with sovleplenib. It demonstrated a tolerable safety profile with grade 3 or above treatment-emergent adverse events (TEAEs) in 25.4% of patients with sovleplenib and 24.2% with placebo. Sovleplenib also significantly improved quality of life in physical functioning and energy/fatigue (p<0.05).

Most patients were heavily pretreated with a median of four prior lines of ITP therapy and a majority (71.3%) of the patients had received prior TPO/TPO-RA¹ treatment. Further post-hoc subgroup analysis of the study demonstrated consistent clinical benefits across ITP patients regardless of prior lines of ITP therapies or prior TPO/TPO-RA exposure, regardless of TPO/TPO-RA treatment types and number of prior regimens.

In addition to the promising data in ITP, results from Phase II part of the ongoing ESLIM-02 Phase II/III study ([NCT05535933](#)) of sovleplenib for warm antibody autoimmune hemolytic anemia (wAIHA) will also be presented at the congress demonstrating encouraging hemoglobin (Hb) 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). A favorable safety profile was also demonstrated.

Details of the presentations are as follows:

Abstract title	Presenter / Lead author	Presentation details
Efficacy and Safety of The Syk Inhibitor Sovleplenib (HMPL-523) in Adult Patients with Primary Immune Thrombocytopenia in China (ESLIM-01): A Randomized, Double-Blind, Placebo-Controlled Phase 3 Study	Renchi Yang Institute of Hematology and Blood Diseases Hospital, Chinese Academy of Medical Sciences, Tianjin, China	#S316 Oral Presentation (Platelet disorders in the spotlight: Clinical and translational) Friday, June 14, 2024 15:00 – 15:15 CEST, Hall Mallo
Sovleplenib for the Treatment of Warm Antibody Autoimmune Hemolytic Anemia (wAIHA): Results from the Randomized, Double-Blind, Placebo-Controlled, Phase 2 Part of the Study	Fengkui Zhang Institute of Hematology and Blood Diseases Hospital, Chinese Academy of Medical Sciences, Tianjin, China	#S297 Oral Presentation (Thalassemias and rare anemias) Sunday, June 16, 2024 12:00 – 12:15 CEST, Hall Mallo
Sovleplenib in Primary Immune Thrombocytopenia (ITP) Patients by Prior Lines of Therapy: Subgroup Analysis of a Multicenter, Randomized, Double-Blind, Placebo-Controlled Phase 3 Study (ESLIM-01)	Xiaofan Liu Institute of Hematology and Blood Diseases Hospital, Chinese Academy of Medical Sciences, Tianjin, China	#P1629 Poster Session Friday, June 14, 2024
Sovleplenib in Primary Immune Thrombocytopenia (ITP) Pts with Prior TPO/TPO-RA Treatment: Subgroup Analysis of a Multicenter, Randomized, Double-Blind, Placebo-Controlled Phase 3 Study (ESLIM-01)	Heng Mei Union Hospital, Tongji Medical College, Huazhong University of Science and Technology, Wuhan, China	#P1631 Poster Session Friday, June 14, 2024
Safety and Efficacy of Syk Inhibitor Sovleplenib in Heavily Pre-Treated Hodgkin Lymphoma Patients	Paolo Strati The University of Texas MD Anderson Cancer Center, Houston, U.S.	#P1102 Poster Session Friday, June 14, 2024
HMPL-306 in Patients with Relapsed or Refractory Myeloid Hematological Malignancies Harboring IDH1 and/or IDH2 Mutations: Final Result of Dose Expansion in Phase 1 Study	Xiaojun Huang Peking University People’s Hospital, Beijing, China	#P532 Poster Session Friday, June 14, 2024

Abstract title	Presenter / Lead author	Presentation details
Phase 1 Study of HMPL-306 in Patients with Advanced Acute Myeloid Leukemia with Isocitrate Dehydrogenase (IDH) Mutations: Preliminary Results of the Dose Escalation Cohorts	Pau Montesinos Hospital Universitario La Fe, Valencia, Spain	#P549 Poster Session Friday, June 14, 2024
Phase II Study of EZH2 Inhibitor Tazemetostat plus Amdizalisib, a PI3K Inhibitor, in Patients with Relapsed/Refractory Lymphomas	Mingci Cai Ruijin Hospital affiliated to Shanghai Jiao Tong University School of Medicine, Shanghai, China	#P2080 e-Poster Presentation Friday, June 14, 2024
Results from a Phase 1 Dose Escalation Study of HMPL-760, a Third Generation, Highly Selective, Reversible BTK Inhibitor in Chinese Patients with Relapsed/Refractory (R/R) Lymphomas	Ying Qian Ruijin Hospital affiliated to Shanghai Jiao Tong University School of Medicine, Shanghai, China	#P2054 e-Poster Presentation Friday, June 14, 2024
A Phase 1b Study to Evaluate the Safety and Preliminary Efficacy of Sovleplenib, a Syk Inhibitor, in Adult Subjects with Immune Thrombocytopenia	Waleed Ghanima University of Oslo, Oslo, Norway	#PB3341 Publication Only

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 medicines 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 but not limited to its expectations regarding the therapeutic potential of sovleplenib, HMPL-306, HMPL-760 and tazemetostat, the further clinical development for sovleplenib, HMPL-306, HMPL-760, tazemetostat and amdizalisib, its expectations as to whether any studies on sovleplenib, HMPL-306, HMPL-760, tazemetostat and amdizalisib 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 sovleplenib, HMPL-306, HMPL-760, tazemetostat and amdizalisib, 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 sovleplenib, HMPL-306, HMPL-760 and tazemetostat 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 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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REFERENCES

¹ TPO = Thrombopoietin; TPO-RAs = Thrombopoietin receptor agonists.