

Press Release

**HUTCHMED Highlights HMPL-523 Clinical Data Presented at the
2021 ASH Annual Meeting**

Hong Kong, Shanghai & Florham Park, NJ — Tuesday, December 14, 2021: HUTCHMED (China) Limited (“[HUTCHMED](#)”) (Nasdaq/AIM:HCM; HKEX:13) today announces new analyses on the ongoing studies of HMPL-523 presented at the 63rd American Society for Hematology’s (ASH) Annual Meeting and Exposition, held virtually and in person at the Georgia World Congress Center in Atlanta, Georgia.

Further details of the presentations are as follows:

Title: **Safety, Pharmacokinetics, and Preliminary Efficacy of HMPL-523 in Adult Patients with Primary Immune Thrombocytopenia: A Randomized, Double-Blind and Placebo-Controlled Phase Ib Study**

Presenter: Renchi Yang, MD, Hematology Hospital of the Chinese Academy of Medical Sciences

Session: 311. Disorders of Platelet Number or Function: Clinical and Epidemiological: Treatment of Immune Thrombocytopenia

Abstract No.: [149895](#)

Date & Time: Saturday, December 11, 2021 9:30am – 11am ET

Location: Georgia World Congress Center, C101 Auditorium and virtually

As of data cutoff date of September 30, 2021, a total of 34 patients were randomized to receive HMPL-523 and 11 patients to placebo. Among 16 patients who were randomized to receive the recommended phase II (“RP2D”) dose of 300mg once daily, 11 patients (68.8%) experienced response as defined by at least one incident of platelet count being $\geq 50 \times 10^9/L$ in the initial 8-week double blinded phase of the study, compared to one out of 11 patients (9.1%) randomized to receive placebo. During the subsequent 16-week open-label phase of the study, one additional patient initially randomized to receive the RP2D experienced a response. Four patients randomized to placebo crossed over to receive treatment at RP2D after the initial 8-week double blinded phase of the study; all four of these patients experienced response. In total, 16 out of 20 patients (80%) experienced response during both phases of the study. Durable response, defined as platelet count being $\geq 50 \times 10^9/L$ in at least 4 out of 6 last scheduled visits, were reported in 8 out of 20 patients (40%) who received RP2D in both phases of the study.

Safety data were presented for all 41 patients who received treatment at all doses, regardless of whether they were initially randomized to receive active treatment or crossed over during the open-label extension phase of the study. The median duration of treatment was 142 days (range: 23-170). No patients discontinued treatment due to treatment-related adverse events (“TRAE”), and no cases of treatment-related serious adverse events (“SAE”) were reported. There were 30 patients (73%) who experienced TRAEs, including 3 (7.3%) who experienced grade 3 or above TRAEs, one of whom received the RP2D. No TRAEs of grade 3 or above occurred in more than one patient.

These results supported the initiation of a Phase III registration study of HMPL-523 in adult patients with primary immune thrombocytopenia (“ITP”), ESLIM-01. The first patient in this study received their first dose on [October 27, 2021](#). Additional details may be found at [clinicaltrials.gov](#), using identifier [NCT05029635](#).

Title: **Preliminary Results from a Phase I Study of HMPL-523, a Selective, Oral Syk Inhibitor, in Patients with Relapsed or Refractory Lymphoma**

Presenter: Paolo Strati, MD, The University of Texas MD Anderson Cancer Center

Session: 623. Mantle Cell, Follicular, and Other Indolent B Cell Lymphomas: Clinical and Epidemiological: Poster II

Abstract No.: [2432](#)

Date & Time: Sunday, December 12, 2021 6:00pm – 8:00pm ET

Location: Georgia World Congress Center, Hall B5 and virtually

As of data cutoff date of August 25, 2021, 21 patients received a median of two cycles of treatment (range: 1-19). Among 16 response-evaluable patients, 4 responses were seen in patients in the 400-800 mg cohorts totaling 10 patients. Nine patients experienced disease progression, three in the 400-800mg cohorts and six in the 100-200mg cohorts.

Among 21 enrolled patients, 17 (81.0%) patients experienced TRAEs, including 7 (33.3%) who experienced grade 3 or above TRAEs. Specific to TRAE at grade 3 or above, neutropenia, which occurred in 2 patients, was the only TRAEs of grade 3 or above to have occurred in more than one patient. SAEs were reported in 6 patients (28.6%). Adverse events leading to discontinuation were reported in 2 (9.5%) patients. 7 patients withdrew from the study for reasons other than progressive disease.

These results support progressing HMPL-523 into the ongoing dose expansion phase of the study to evaluate its safety and efficacy in multiple subtypes of B-cell and T-cell lymphoma at the R2PD of 700 mg.

About HMPL-523

HMPL-523 is a novel, investigational, selective small molecule inhibitor for oral administration targeting spleen tyrosine kinase, also known as Syk. Syk is a major component in B-cell 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 HMPL-523 worldwide. The ESLIM-01 Phase III trial is underway to evaluate the efficacy and safety of HMPL-523 in treating adult patients with primary ITP, an autoimmune disorder that can lead to increased risk of bleeding. Additional details may be found at clinicaltrials.gov, using identifier [NCT05029635](https://clinicaltrials.gov/ct2/show/study/NCT05029635). HMPL-523 is also being studied in indolent non-Hodgkin's lymphoma and multiple subtypes of B-cell malignancies in China ([NCT02857998](https://clinicaltrials.gov/ct2/show/study/NCT02857998)), the U.S. and Europe ([NCT03779113](https://clinicaltrials.gov/ct2/show/study/NCT03779113)). A trial to study HMPL-523 in patients with warm autoimmune hemolytic anemia (wAIHA), another autoimmune disorder, is also planned.

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 4,500 personnel across all its companies, at the center of which is a team of over 1,400 in oncology/immunology. Since inception it has advanced eleven cancer drug candidates from in-house discovery into clinical studies 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](https://www.linkedin.com/company/hutchmed).

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 HMPL-523 for patients, its expectations as to whether any studies on HMPL-523 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 HMPL-523, 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 HMPL-523 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.

CONTACTS

Investor Enquiries

Mark Lee, Senior Vice President	+852 2121 8200
Annie Cheng, Vice President	+1 (973) 567 3786

Media Enquiries

Americas – Brad Miles,
Solebury Trout

+1 (917) 570 7340 (Mobile)

bmiles@troutgroup.com

Europe – Ben Atwell / Alex Shaw,
FTI Consulting

+44 20 3727 1030 / +44 7771 913 902 (Mobile) / +44 7779 545 055 (Mobile)

HUTCHMED@fticonsulting.com

Asia – Zhou Yi,
Brunswick

+852 9783 6894 (Mobile)

HUTCHMED@brunswickgroup.com

Nominated Advisor

Atholl Tweedie / Freddy Crossley,
Panmure Gordon (UK) Limited

+44 (20) 7886 2500