

Press Release

Chi-Med Initiates a Phase I Trial of HMPL-523 in Patients with Immune Thrombocytopenia (ITP) in China

London: Friday, August 23, 2019: Hutchison China MediTech Limited (“Chi-Med”) (AIM/Nasdaq: HCM) has initiated a Phase I study of HMPL-523, its novel spleen tyrosine kinase (“Syk”) inhibitor, in patients with immune thrombocytopenia (“ITP”), an autoimmune disorder that can lead to increased risk of bleeding. The first ITP patient was dosed on August 12, 2019 in China.

The study is a randomized, double-blinded, placebo-controlled Phase Ib clinical trial investigating the safety, tolerability, pharmacokinetics and preliminary efficacy of HMPL-523 in adult patients with ITP. The primary endpoint is the number of patients with any adverse event. The secondary endpoints are maximum plasma concentration (C_{max}), area under the concentration-time curve in a selected time interval (AUC_{0-t}), and rate of clinical remission at week 8. The trial is comprised of a dose escalation stage and a dose expansion stage. Approximately 50 to 60 patients will be enrolled. Additional details may be found at clinicaltrials.gov, using identifier [NCT03951623](https://clinicaltrials.gov/ct2/show/study/NCT03951623).

This study complements the ongoing Phase Ib dose expansion program of HMPL-523 in Australia (clinicaltrials.gov identifier: [NCT02503033](https://clinicaltrials.gov/ct2/show/study/NCT02503033)) and China (clinicaltrials.gov identifiers: [NCT02857998](https://clinicaltrials.gov/ct2/show/study/NCT02857998) and [NCT03483948](https://clinicaltrials.gov/ct2/show/study/NCT03483948)) addressing a broad range of hematological cancers. These cancers include acute myeloid leukemia, chronic lymphocytic leukemia/small lymphocytic lymphoma, mantle cell lymphoma, follicular lymphoma, marginal zone lymphoma, diffuse large B-cell lymphoma and Waldenstrom’s macroglobulinemia. Preliminary results of the dose escalation stage in a Phase I study in China of HMPL-523 in patients with relapsed or refractory B-cell lymphomas were presented in 2018.¹ A Phase I dose escalation study in Australia in healthy volunteers was also completed, showing that HMPL-523 was generally well tolerated (clinicaltrials.gov identifier: [NCT02105129](https://clinicaltrials.gov/ct2/show/study/NCT02105129)).

About HMPL-523

HMPL-523 is a novel, highly selective and potent 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 therapeutic target in multiple subtypes of B-cell lymphomas and autoimmune disorders.

About ITP

ITP is a type of thrombocytopenic defined as isolated low platelet count (thrombocytopenia) with normal bone marrow and the absence of other causes of thrombocytopenia. Patients with ITP exhibit symptoms of petechiae, purpura, and gastrointestinal and/or urinary mucosal tract bleeding.² 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.³⁻⁷ 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.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 a new approach to treatment.

About Chi-Med

Chi-Med (AIM/Nasdaq: HCM) is an innovative biopharmaceutical company which researches, develops, manufactures and markets pharmaceutical products. Its Innovation Platform, Hutchison MediPharma, has about 440 scientists and staff focusing on discovering, developing and commercializing targeted therapeutics and immunotherapies in oncology and autoimmune diseases. It has a portfolio of eight cancer drug candidates currently in clinical studies around the world. Chi-Med’s Commercial Platform manufactures, markets, and distributes prescription drugs and consumer health products, covering an extensive network of hospitals across China.

Chi-Med is headquartered in Hong Kong and is dual-listed on the AIM market of the London Stock Exchange and the Nasdaq Global Select Market. For more information, please visit: www.chi-med.com.

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 Chi-Med’s current expectations regarding future events, including its expectations for the clinical development of HMPL-523, plans to initiate clinical studies for HMPL-523 as a monotherapy or in combinations, its expectations as to whether such studies 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, 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 drug candidate HMPL-523 as a monotherapy or in combinations to meet the primary or secondary endpoint of a study, to obtain regulatory approval in different jurisdictions, to gain commercial acceptance after obtaining regulatory approval, the potential market of HMPL-523 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 Chi-Med’s filings with the U.S. Securities and Exchange Commission and on AIM. Chi-Med 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 Zhu, J *et al.*, [Preliminary Results from a Phase 1 Study of HMPL-523, a Highly Selective Syk Inhibitor, in Chinese Patients with Mature B-Cell Lymphomas](#). *Blood*. 2018; 132:5324. Published 2018 Nov 21. doi: <https://doi.org/10.1182/blood-2018-99-111648>.

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³ McMillan R, Bussell JB, George JN, Lalla D, Nichol JL. Self-reported health-related quality of life in adults with chronic immune thrombocytopenic purpura. *Am J Hematol.* 2008 Feb;83(2):150-4.

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⁷ Sarpatwari A, Watson S, Erqou S, Anderson H, Grainger J, Higgins JP, Newland AC. Health-related lifestyle in adults and children with primary immune thrombocytopenia (ITP). *Br J Haematol.* 2010 Oct;151(2):189-91.

⁸ Lambert MP, Gernsheimer TB. Clinical updates in adult immune thrombocytopenia. *Blood.* 2017 May 25;129(21):2829-2835.

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