



HUTCHISON CHINA MEDITECH

Press Release

Chi-Med Initiates an International Phase I/Ib Trial of HMPL-523 in Patients with Advanced Relapsed or Refractory Lymphoma

London: Friday, October 4, 2019: Hutchison China MediTech Limited (“[Chi-Med](#)”) (AIM/Nasdaq: HCM) has initiated an international Phase I/Ib study of HMPL-523, its novel spleen tyrosine kinase (“Syk”) inhibitor, in patients with relapsed or refractory lymphoma. The first patient was dosed on September 26, 2019 in the U.S.

The international clinical study, with sites in the U.S. and Europe, is a multi-center, open-label, two-stage study, including dose escalation and expansion, investigating the effects of HMPL-523 administered orally to patients with relapsed or refractory lymphoma. The primary outcome measures are safety and tolerability. Secondary outcomes include pharmacokinetic (PK) measurements and preliminary efficacy such as objective response rate (ORR). The lead investigator of the study is Dr. Nathan Fowler, Associate Professor, Department of Lymphoma/Myeloma, The University of Texas MD Anderson Cancer Center, Houston, TX. Additional details may be found at clinicaltrials.gov, using identifier [NCT03779113](#).

This study complements the ongoing Phase Ib dose expansion program of HMPL-523 in Australia (clinicaltrials.gov identifier: [NCT02503033](#)) and China (clinicaltrials.gov identifiers: [NCT02857998](#) and [NCT03483948](#)) addressing a broad range of hematological cancers. 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 2018¹. Outside of oncology, HMPL-523 is in Phase I study in patients with Immune Thrombocytopenia (ITP) in China (clinicaltrials.gov identifier: [NCT03951623](#)).

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. Because B cell malignancies are heterogeneous and patients commonly experience relapse despite current therapies, there is a recognized need for new therapeutics.

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 470 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, including in combination with azacitidine, 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. In addition, as one of the Phase I studies in China relies on the use of azacitidine as combination therapeutics with HMPL-523, such risks and uncertainties include assumptions regarding the safety, efficacy, supply and continued regulatory approval of azacitidine. 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>.