



HUTCHISON CHINA MEDITECH

## Press Release

### Chi-Med Initiates a Phase I Trial of HMPL-523 in Combination with Azacitidine in Elderly Patients with Acute Myeloid Leukemia in China

**London: Thursday, October 18, 2018:** 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 combination with azacitidine, an approved nucleoside metabolic inhibitor, in elderly patients with acute myeloid leukemia (“AML”) in China.

This is a Phase I, open-label, non-randomized, multicenter study to evaluate the safety, pharmacokinetics and preliminary efficacy of the combination in previously untreated elderly patients with AML who are not eligible for standard induction therapy. The primary outcome measures are overall response rate (ORR) and adverse events (AE). The two-stage study will have a dose escalation and dose expansion stage. Additional details about this study may be found at [clinicaltrials.gov](https://clinicaltrials.gov), using identifier [NCT03483948](https://clinicaltrials.gov/ct2/show/study/NCT03483948).

This study complements the ongoing Phase Ib dose expansion program of HMPL-523 in a broad range of hematological cancers in Australia ([clinicaltrials.gov](https://clinicaltrials.gov) identifier: [NCT02503033](https://clinicaltrials.gov/ct2/show/study/NCT02503033)) and China ([clinicaltrials.gov](https://clinicaltrials.gov) identifier: [NCT02857998](https://clinicaltrials.gov/ct2/show/study/NCT02857998)). These include chronic lymphocytic leukemia, small lymphocytic lymphoma, mantle cell lymphoma, follicular lymphoma, marginal zone lymphoma, diffuse large B-cell lymphoma and Waldenstrom's macroglobulinemia. Chi-Med targets to present dose escalation results at a major scientific conference later in 2018 or in 2019. Chi-Med's U.S. Investigational New Drug (IND) application for HMPL-523 in hematological cancers was cleared by the Food and Drug Administration (FDA) at the end of June 2018 and hence Chi-Med is now planning for proof-of-concept development in the U.S.

#### About Syk

Syk is a non-receptor cytoplasmic tyrosine kinase primarily expressed in cells of hematopoietic lineage. Constitutive activation of Syk in AML has been reported and targeted inhibition of Syk demonstrated anti-leukemia activity in AML mouse models. Syk has also been shown to directly phosphorylate the FLT3 receptor, modulating its activation and possibly promoting its role in leukemogenesis.

#### About AML

AML, a cancer of blood and bone marrow characterized by rapid disease progression, is the most common acute leukemia. Undifferentiated blast cells proliferate in the bone marrow rather than mature into normal blood cells. AML occurs in children and adults of all ages, but is primarily a disease of older adults, with a median age at diagnosis of 67 years. AML is universally fatal without treatment, with a median survival of approximately two months.<sup>1</sup> The vast majority of patients do not respond to chemotherapy and progress to relapsed/refractory AML. The five-year survival rate for AML is approximately 27%.<sup>2</sup>

Combination chemotherapy regimens with or without hematopoietic stem cell transplantation (HSCT) are a mainstay of therapy for patients with newly diagnosed AML. Older patients with newly diagnosed AML who are ineligible for intensive chemotherapy typically have poor outcomes and few available treatment options. There is a clear need for new treatments for AML.

#### About Chi-Med

Chi-Med is an innovative biopharmaceutical company which researches, develops, manufactures and sells pharmaceuticals and healthcare products. Its Innovation Platform, Hutchison MediPharma Limited, focuses on discovering and developing innovative therapeutics in oncology and autoimmune diseases for the global market. Its Commercial Platform manufactures, markets, and distributes prescription drugs and consumer health products in China.

Chi-Med is majority owned by the multinational conglomerate CK Hutchison Holdings Limited (SEHK: 1). For more information, please visit: [www.chi-med.com](http://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 the new Phase I study 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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### Nominated Advisor

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<sup>1</sup> Oran B and Weisdorf D. 2012. Survival for older patients with acute myeloid leukemia: a population-based study. *Haematologica* 97:1916-1924.

<sup>2</sup> Noone AM, Howlader N, Krapcho M, Miller D, Brest A, Yu M, Ruhl J, Tatalovich Z, Mariotto A, Lewis DR, Chen HS, Feuer EJ, Cronin KA (eds). SEER Cancer Statistics Review, 1975-2015, National Cancer Institute. Bethesda, MD, [https://seer.cancer.gov/csr/1975\\_2015/](https://seer.cancer.gov/csr/1975_2015/), based on November 2017 SEER data submission, posted to the SEER web site, April 2018.