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Chi-Med Initiates a Ph I Trial of HMPL-523 for AML

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This study complements the ongoing Phase Ib dose expansion program of HMPL-523 in a broad range of hematological cancers in Australia.



Hutchison China MediTech Limited (Chi-Med) 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, multicentre 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.

This study complements the ongoing Phase Ib dose expansion program of HMPL-523 in a broad range of hematological cancers in Australia. 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’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 Chi-Med is now planning for proof-of-concept development in the U.S.