Chi-Med Initiates a Phase II Trial of HMPL-453 in Patients with Advanced Malignant Mesothelioma in China


The clinical study is a single-arm, multi-center, open-label study, evaluating the efficacy, safety and pharmacokinetics of HMPL-453 in historically confirmed patients with advanced malignant mesothelioma that failed at least one line of systemic therapy.

The primary outcome measure is overall response rate (ORR). Secondary outcome measures include preliminary efficacy such as disease control rate (DCR), time to response (TTR), duration of response (DoR), progression-free survival (PFS), and overall survival (OS). The lead investigator of the study is Shun Lu, Professor at Shanghai Chest Hospital, Jiao Tong University. Additional details may be found at clinicaltrials.gov, using identifier NCT04290325.

About Fibroblast Growth Factor Receptors (FGFR)

FGFRs are a sub-family of receptor tyrosine kinases. Activation of FGFR signaling pathways is central to several biological processes. In normal physiology, FGF/FGFR signaling is involved in embryonic development (organogenesis and morphogenesis), tissue repair, angiogenesis, neuroendocrine and metabolism homeostasis. Given its complexity and critical role in a number of important physiological processes, aberrant FGFR signaling has been found to be a driving force in tumor growth, promotion of angiogenesis, as well as conferring resistance to anti-tumor therapies.

About HMPL-453

HMPL-453 is a novel, highly selective and potent small molecule inhibitor targeting fibroblast growth factor receptors 1, 2 and 3. In pre-clinical studies, HMPL-453 demonstrated superior potency and better kinase selectivity as compared to other drugs in the same class, as well as a favorable safety profile. Enrollment has been completed for the dose escalation of the Phase I study of HMPL-453 in China, for which additional details can be found at clinicaltrials.gov, using identifier NCT03160833.

About Chi-Med

Chi-Med (Nasdaq/AIM: HCM) is an innovative biopharmaceutical company committed, over the past twenty years, to the discovery and global development of targeted therapies and immunotherapies for the treatment of cancer and immunological diseases. It has a portfolio of eight cancer drug candidates currently in clinical studies around the world and extensive commercial infrastructure in its home market of China. For more information, please visit: www.chi-med.com.

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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-453, including plans to initiate clinical studies for HMPL-453, 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-453 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-453 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.