



HUTCHISON CHINA MEDITECH LIMITED

Press Release

Chi-Med Initiates a Phase I/II Clinical Trial of Novel FGFR Inhibitor HMPL-453 in China

London: Thursday, June 22, 2017: Hutchison China MediTech Limited (“Chi-Med”) (AIM/Nasdaq: HCM) has just initiated a Phase I/II clinical trial of HMPL-453 in China. HMPL-453 is a novel, highly selective and potent small molecule inhibitor targeting fibroblast growth factor receptor (“FGFR”). The first drug dose was administered on June 19, 2017. This study complements the first-in-human Phase I clinical trial in Australia that was initiated earlier this year.

This Phase I/II study is a multi-center, single-arm, open-label, two-stage study to evaluate safety, tolerability, pharmacokinetics (“PK”) and preliminary efficacy of HMPL-453 monotherapy in patients with solid tumors harboring FGFR genetic alterations. The dose-escalation stage will enroll patients with locally advanced or metastatic solid tumors, for whom standard therapy either does not exist or has proven to be ineffective or intolerable, regardless genetic status, to determine the maximum tolerated dose (MTD) and recommended Phase II dose (“RP2D”).

The dose-escalation will be followed by a dose-expansion stage, which will further evaluate safety, tolerability and PK as well as preliminary anti-tumor efficacy at the RP2D. This stage will enroll primarily cancer patients harboring FGFR dysregulated tumors, including those with advanced bladder cancer, advanced cholangiocarcinoma and other solid tumors. For this second stage, the primary endpoint is objective response rate (ORR), with secondary endpoints including duration of response (DoR), disease control rate (DCR), progression free survival (PFS), overall survival (OS) and safety. Additional details about this study can be found at clinicaltrials.gov, using identifier [NCT03160833](https://clinicaltrials.gov/ct2/show/study/NCT03160833).

About bladder cancer and cholangiocarcinoma

Bladder cancer makes up approximately 90% of urothelial carcinomas. Bladder cancer is the sixth most common cancer in the U.S., and the ninth most common cancer in China, with about 80,000 new cases annually in both countries.^{[1],[2]} In the U.S. the five-year survival rate for those whose disease has metastasized is approximately 5%.^[1] Despite advances in the treatment of locally advanced or metastatic urothelial carcinoma, the prognosis for patients remains poor and more treatment options are needed.

A highly unmet medical need around the world, cholangiocarcinoma (bile duct cancer, “CCA”) accounts for approximately 3% of all gastrointestinal cancers and is the most common malignancy of the biliary tract (the combined system of the liver, gall bladder and bile ducts).^[3] CCA is classified as intrahepatic or extrahepatic based on anatomical location, with studies suggesting that the incidence of intrahepatic CCA in particular is increasing.^[4] Currently CCA has a bleak prognosis, with a 5-year survival rate of less than 5%.^[5]

About 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. To date, there are no approved therapies specifically targeting the FGFR signaling pathway.

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. Chi-Med is also conducting a Phase I study of HMPL-453 in Australia, for which additional details can be found at clinicaltrials.gov, using identifier [NCT02966171](https://clinicaltrials.gov/ct2/show/study/NCT02966171).

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: 0001). 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-453, 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 candidates HMPL-453 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.

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¹ National Cancer Institute. The Surveillance, Epidemiology, and End Results (SEER): Cancer Stat Facts: Bladder Cancer. Available at: <https://seer.cancer.gov/statfacts/html/urinb.html>. Accessed May 23, 2017.

² R. Zheng et al, National estimates of cancer prevalence in China 2011, Cancer Letters 2016 370(1) 33-38.

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