Initiation of HMPL-523 Phase I clinical trial in haematological cancer in Australia

London: Friday, 15 January 2016: Hutchison China MediTech Limited (“Chi-Med”) (AIM: HCM) today announces that Hutchison MediPharma Limited (“HMP”), its drug R&D subsidiary, has initiated a Phase I trial in Australia in patients with haematological malignancies. HMPL-523 is a novel, highly selective and potent small molecule oral inhibitor targeting spleen tyrosine kinase, also known as Syk, a key component in B-cell receptor signalling. Preparations and site selection began in late 2015 and the first patient was dosed on 13 January 2016. This trial follows the successful completion of a first-in-human Phase I clinical trial in healthy volunteers in October 2015.

The new study is a Phase I, open-label, dose escalation study of HMPL-523 as monotherapy administered orally to patients with relapsed or refractory haematological malignancies who are unable to tolerate standard therapy or for whom there is no effective therapy. Two stages for this study are planned: a dose escalation stage and a dose-expansion stage. The primary objectives of the study are to evaluate safety and tolerability, and to determine the maximum tolerated dose and/or recommended Phase II dose of HMPL-523 in this patient population. Other objectives include the evaluation and characterisation of the pharmacokinetics of HMPL-523 and its metabolites, and to make preliminary assessments of the anti-tumour activity of HMPL-523 in certain sub-populations in the dose expansion phase of the trial.

The successful completion of the first-in-human study in healthy volunteers in 2015 has established the safety profile of HMPL-523. HMP now hopes that this Phase I study in haematological malignancies could provide clinical proof-of-concept that modulation of the B-cell signalling pathway through inhibition of Syk will provide patients with a clinical benefit.

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Notes to Editors

About B-cell signalling

As one of the major cellular components of the immune system, B-cells play pivotal roles in several immune system related diseases, such as autoimmune diseases including rheumatoid arthritis, systemic lupus erythematosus and allergy, as well as haematological cancers (i.e. B-cell malignancies) including lymphoma and leukaemia. Targeted B-cell
receptor signalling therapies, including monoclonal antibodies and small molecules, have been proven to be clinically effective for the treatment of rheumatoid arthritis as well as B-cell malignancies, leading to scientific and commercial success.

Syk is a key protein involved in the B-cell signalling pathway.

**About haematological cancers**

Haematological cancers are classified as leukaemia (affecting blood and bone marrow), lymphoma (affecting the lymphatic system) and myeloma (affecting bone marrow). According to Frost & Sullivan, there were approximately 954,000 new cases of haematological cancers worldwide in 2014, which is expected to increase to approximately 1.1 million new cases annually by 2020. The global market for haematological cancer treatments is projected to grow from approximately $19.2 billion in 2014 to $25.7 billion by 2020. Treatment of haematological cancers is determined on a case-by-case basis and primarily involves chemotherapy, radiation, targeted therapy and/or stem cell transplantation and, more recently, immunotherapy and gene therapy.

**About small molecule B-cell signalling pathway inhibitors in haematological cancer**

The advantages of small molecule B-cell receptor signalling therapy has driven research and development by major pharmaceutical companies. Notable success has been achieved in B-cell malignancies in oncology, such as lymphoma and leukaemia, where small molecule inhibitors are now being used to target kinases down-stream from Syk in the B-cell signalling pathway, namely Bruton’s tyrosine kinase (“BTK”) and PI3Kδ. In 2013 and 2014, ibrutinib (BTK/AbbVie) and idelalisib (PI3Kδ/Gilead) respectively both received Breakthrough Therapy designation and accelerated approval from the U.S. Food and Drug Administration in haematological cancer indications.

In early clinical studies in haematological cancer, where off-target toxicities are less limiting, several small molecule Syk inhibitors have begun to show promise. Fostamatinib, entospletinib (Gilead) and TAK-659 (Takeda) have all exhibited efficacy against various subtypes of non-Hodgkin’s lymphoma, in either a single agent or combination setting, thereby indicating that Syk is a relevant target for these diseases.

**About the HMPL-523 Phase I study in healthy volunteers**

HMPL-523 is an oral small molecule therapy targeting Syk. A first-in-human, dose-escalating, Phase I study to assess safety, tolerability and pharmacokinetics of HMPL-523 was completed in healthy volunteers in Australia. HMPL-523 was administered up to 800mg as a single dose and up to 400mg multiple dose in 14 cohorts. The treatment was generally well tolerated without material off-target toxicities. HMPL-523 exhibited a linear pharmacokinetic profile and a dose dependent suppression of B-cell activation.

**About HMP**

HMP is a novel drug R&D company focusing on discovering, developing and commercialising innovative therapeutics in oncology and autoimmune diseases. With a team of over 280 scientists and staff, its pipeline is comprised of novel oral compounds for cancer and inflammation in development in North America, Europe, Australia and Greater China. HMP is a subsidiary of Chi-Med. For more information, please visit: www.hmplglobal.com.
About Chi-Med

Chi-Med is a China-based, globally-focused healthcare group which researches, develops, manufactures and sells pharmaceuticals and health-related consumer products. Its Innovation Platform 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 announcement contains forward-looking statements that reflect Chi-Med’s current expectations regarding future events, including its plans to initiate clinical studies for its drug candidates in the targeted indications, 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 enrolment 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 a drug candidate to meet the primary or secondary endpoint of a study, the ability of a drug candidate to obtain regulatory approval in different jurisdictions, the ability of a drug candidate to gain commercial acceptance after obtaining regulatory approval 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. Chi-Med undertakes no obligation to update or revise the information contained in this announcement, whether as a result of new information, future events or circumstances or otherwise.