



HUTCHISON CHINA MEDITECH LIMITED

Completion of Phase I clinical trial of novel Syk Inhibitor HMPL-523 for autoimmune diseases in healthy volunteers

London: Friday, 30 October 2015: Hutchison China MediTech Limited (“Chi-Med”) (AIM: HCM) today announces that Hutchison MediPharma Limited (“HMP”), its drug R&D subsidiary, has successfully completed its first-in-human Phase I clinical trial of HMPL-523. HMPL-523 is a novel, highly selective and potent small molecule inhibitor targeting spleen tyrosine kinase, also known as Syk, a key component in B-cell receptor signalling.

The first-in-human Phase I study of HMPL-523 was a dose-escalating study conducted to assess the safety, tolerability and pharmacokinetics of both single and repeat doses of HMPL-523 in healthy volunteers in Australia. The study began in June 2014, and completed ten single dose cohorts, with eight patients per cohort, from 5mg single dose through 800mg single dose. In April 2015, the multiple ascending dose section of the Phase I study commenced in which HMPL-523 was administered once daily for 14 consecutive days. Four dose cohorts have now completed this section of the study, again with eight patients per cohort, from 200mg multiple dose through to 400mg multiple dose. At 400mg daily, HMPL-523 drug exposures are believed to be well above the predicted efficacious dose level and, consequently, there is no intention to escalate further in healthy volunteers.

The preliminary safety profile of HMPL-523 was in-line with our expectations. No material off-target toxicities such as hypertension and severe diarrhoea were observed with HMPL-523 in this study. Furthermore, HMPL-523 exhibited a linear pharmacokinetic profile and a dose dependent suppression of B-cell activation. Full results of the Phase I study will be published in due course.

Christian Hogg, CEO of Chi-Med, said, “We have now established what we believe is a dose range for the further development of HMPL-523. This will now allow Chi-Med to move this important, potentially first-in-class compound into global Phase II proof-of-concept studies against multiple indications both in autoimmune diseases and oncology.”

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Notes to Editors

About HMPL-523

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 (“mAb”) and small molecules, have been proven to be clinically effective for the treatment of rheumatoid arthritis (“RA”) as well as B-cell malignancies, leading to scientific and commercial success.

HMPL-523 is an oral small molecule therapy targeting Syk, a major component in the B-cell signalling pathway. If proven safe and effective, we believe HMPL-523 will be an attractive therapy due to its convenience of use as compared to the intravenous B-cell receptor blocking mAb rituximab (Roche) and the TNF α blocking mAb drugs like infliximab (Janssen), adalimumab (AbbVie) and etanercept (Amgen/Pfizer). Furthermore, oral small molecules such as HMPL-523 are generally cleared more quickly from the body as compared to mAbs, thereby reducing the risk of infections which result from sustained suppression of the immune system.

The total global market for RA drugs is predicted to grow from approximately US\$34 billion in 2014 to US\$45 billion by 2020, according to Frost & Sullivan.

About small molecule B-cell signalling pathway inhibitors in immunology

Clinical efficacy in RA has been established by a first generation small molecule Syk inhibitor, fostamatinib (Rigel/AstraZeneca). Unfortunately, poor kinase selectivity linked to critical off-target side effects such as hypertension, severe diarrhoea, and neutropenia limited fostamatinib’s dose and led to failure in Phase III studies and ultimately discontinuation in RA.

We designed HMPL-523 to be highly selective to eliminate these off-target toxicities thereby creating the opportunity for safe combination with other therapies to maximise efficacy. Furthermore, the pharmacokinetic properties of HMPL-523 are unique, with pre-clinical studies indicating extensive tissue distribution. We believe high tissue distribution is important, particularly in tissue-oriented autoimmune diseases, and research on HMPL-523 has confirmed this by demonstrating strong efficacy in RA and lupus pre-clinical models with relatively low plasma concentrations. Consequently, in addition to our planned global Phase II development in RA, we intend to evaluate HMPL-523 as a treatment for lupus.

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 PI3K δ . In 2013 and 2014, ibrutinib (BTK/AbbVie) and idelalisib (PI3K δ /Gilead) both received Breakthrough Therapy designation and accelerated approval from the FDA in the U.S. in haematological cancer indications. Given the important role of B-cell receptor signalling in haematological cancer, we intend to initiate a Phase I study in Australia in haematological cancer patients in late 2015.

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 sub-

types 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 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 around 250 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.