HUTCHISON CHINA MEDITECH

Chi-Med Announces Progress in Savolitinib Lung Cancer Program and Update on Kidney Cancer Strategy

– Global SAVANNAH study of savolitinib / Tagrisso® combination in MET+ EGFRm NSCLC underway. Data presented at ESMO 2018 showed MET-amplification among the most frequent mechanisms of acquired resistance to AstraZeneca's Tagrisso® –

– China registration study of savolitinib monotherapy in MET Exon 14 deletion NSCLC patients set to complete enrollment mid-late 2019. First potential savolitinib NDA targeted in 2020 –

– The outcome of a molecular epidemiology study, along with rapidly changing treatment landscape, leading to change in savolitinib kidney cancer strategy –

London: Thursday, December 20, 2018: Hutchison China MediTech Limited ("Chi-Med") (AIM/Nasdaq: HCM) today provides a full update on the savolitinib development programs in both lung cancer and kidney cancer.

"This important progress on the savolitinib / *Tagrisso*® combination in lung cancer is a product of the close collaboration that Chi-Med has with AstraZeneca," commented Christian Hogg, Chief Executive Officer of Chi-Med. He added, "We are also making rapid progress in China on MET Exon 14 deletion lung cancer where we now expect to complete enrollment of our registration intent study in 2019. In addition, we continue to believe that there is a role for a selective MET inhibitor in kidney cancer, and will use the deep body of clinical and epidemiological data that we have amassed to adapt our savolitinib strategy to the fast changing treatment landscape."

Mene Pangalos, Executive Vice-President of AstraZeneca's Innovative Medicines and Early Development Biotech Unit, commented that, "Recent data in lung cancer has further confirmed the importance of MET as both a resistance mechanism to EGFR inhibitors and as a target in its own right. Savolitinib has the potential to provide benefit for cancer patients who have MET-driven tumors, including those with the Exon 14 deletion. The initiation of the SAVANNAH study is an important step in our goal of bringing novel targeted therapies forward which selectively inhibit key oncogenic drivers. I am delighted to see the successful collaboration with Chi-Med deliver more important data that has the potential to redefine the way in which MET-driven disease is treated."

LUNG CANCER DEVELOPMENT UPDATE:

TAGRISSO – *Tagrisso*® (osimertinib). Since its first approval in 2015, *Tagrisso*® has been established as a new standard of care in the treatment of Epidermal Growth Factor Receptor mutation ("EGFRm") non-small cell lung cancer ("NSCLC"), and has now been approved in over 80 countries. AstraZeneca recently announced that *Tagrisso*® would be added to China's national drug reimbursement program as second-line treatment for NSCLC patients in 2019;

- Understanding the mechanism of acquired resistance following EGFR tyrosine kinase inhibitor ("TKI") therapy is a key clinical question to inform the next treatment choice;
- At the European Society of Medical Oncology Congress ("ESMO") 2018, AstraZeneca presented the first results on the acquired resistance spectrum detected in patient plasma after progression in the first-line (FLAURA) and second-line T790M (AURA3) Phase III studies. In both studies, MET-amplification was among the most frequent mechanisms of acquired resistance to *Tagrisso*®. 15% of patients in the FLAURA study, and 19% of patients in AURA3, had evidence of MET amplification as a mechanism of acquired resistance in their plasma samples following progression on *Tagrisso*®; and
- The frequency of MET amplification is expected to be higher than the above plasma rates when assessed in tumor tissue due to the different diagnostic tests that are available.

TATTON – The combination of *Tagrisso*® / savolitinib is being explored as a treatment option for MET+ EGFRm NSCLC.

- Initial data from the TATTON (NCT02143466) study assessing the safety and preliminary efficacy of the Tagrisso®/savolitinib combination was presented at the World Conference on Lung Cancer ("WCLC") in 2017;
- Confirmed partial responses ("PRs") were seen in 10/33 (Objective Response Rate ("ORR") 33%) of patients with MET+ EGFRm NSCLC (local testing) who had been previously treated with a third generation EGFR TKIs, primarily *Tagrisso*®. The majority of these patients had received at least four lines of prior therapy;
- Confirmed PRs were seen in 14/23 (ORR 61%) of patients with MET+ T790M- EGFRm NSCLC (local testing) who had been previously treated with a first or second generation EGFR TKI. The majority of these patients had received one prior line of therapy; and
- Patients continue to be enrolled to the TATTON study and the clinical data has continued to mature, consistent with the WCLC 2017 presentation. A presentation of the complete TATTON dataset is planned for a scientific conference in 2019.

SAVANNAH – Based on these encouraging results, Chi-Med and AstraZeneca have initiated SAVANNAH, a global Phase II study of *Tagrisso*® / savolitinib combination in patients with MET+ EGFRm NSCLC who have progressed following *Tagrisso*®.

- SAVANNAH is a single arm study designed to enroll approximately 170 patients with MET+ EGFRm NSCLC, with at least 50% having progressed following first-line *Tagrisso*® therapy;
- The primary data completion is anticipated in 2021; and
- SAVANNAH will be closely aligned to benefit from the molecular profiling in the ORCHARD study announced by AstraZeneca during ESMO 2018. ORCHARD is an open-label, multi-center, multi-drug Phase II platform trial in patients with advanced EGFRm NSCLC whose disease has progressed on first-line therapy with *Tagrisso*®. Platform studies such as ORCHARD that offer targeted treatment options for all patients are typically expected to have high enrollment rates. By aligning the two studies, patients identified by ORCHARD to have MET+ EGFRm NSCLC and meet relevant inclusion criteria will be prioritized for the SAVANNAH study.

Further opportunities identified in EGFRm NSCLC:

- Separately, a Phase I study combining AstraZeneca's first generation EGFR TKI *Iressa*® with savolitinib has been completed in China and the results will be reported at a scientific meeting in 2019; and
- Chi-Med and AstraZeneca are reviewing the data from both the TATTON and *Iressa*® / savolitinib combination studies, and anticipate announcing plans for further studies during 2019.

MET Exon 14 deletion first-line NSCLC:

MET Exon 14 deletion first-line NSCLC is present in 2-3% of NSCLC patients. The China Phase II study of savolitinib monotherapy is currently enrolling in NSCLC patients with MET Exon 14 deletion who have failed prior systemic therapy, or are unwilling or unable to receive chemotherapy:

- Following early 2018 regulatory authority dialogue and a subsequent protocol amendment, our current China Phase II study, if successful, will be sufficient to support a New Drug Application ("NDA") submission in China;
- Enrollment is expected to complete during mid-late 2019;
- Preliminary data expected to be published at a major scientific conference during 2019; and
- Subject to positive Phase II outcome, we intend to submit China NDA in 2020.

We believe MET Exon 14 deletion NSCLC has the potential to be the first savolitinib approval world-wide.

KIDNEY CANCER DEVELOPMENT UPDATE:

Kidney cancer treatment landscape. The treatment landscape of renal cell carcinoma ("RCC") has evolved rapidly in recent years. Monotherapy treatment with second generation vascular endothelial growth factor receptor ("VEGFR") TKIs as well as programmed cell death protein-1 ("PD-1") monoclonal antibodies ("mAb") are improving patient outcomes with ORRs increasing to >30% and in first-line clear cell RCC ("ccRCC"). Lately, VEGFR TKI / PD-1 mAb combinations have been granted breakthrough therapy designation by the U.S. Food and Drug Administration (FDA) driven by their ORRs of >70% in first-line ccRCC patients.

Papillary renal cell carcinoma ("PRCC") continues to be a difficult sub-type of RCC to treat and has been shown to harbor MET-driven disease in between 40-70% of patients. As a result, while PRCC does favor the introduction of a MET TKI, enthusiasm for VEGFR TKI / PD-1 mAb monotherapy and combinations in PRCC is high.

Molecular Epidemiology ("MES") update – We have recently completed the largest MES study conducted on PRCC patients, which was aimed at developing a more comprehensive understanding of the role of MET-driven disease in PRCC. Archived tissue samples from over 200 PRCC patients in the US, Canada, France and Asia (Korea) were screened using our companion diagnostic to identify MET-driven disease. Historical medical records from these patients were then used to determine if MET-driven disease is predictive of worse outcome for patients treated with sunitinib, in terms of progression free survival ("PFS"), time to treatment failure (TTF) and overall survival (OS). Preliminary MES findings are as follows:

- MES analysis was conducted on patients who were diagnosed before December 31, 2015, so the impact of the recent evolution in treatment landscape (e.g. PD-1) was not observed;
- *Sutent*® (sunitinib) (VEGFR TKI) in first-line PRCC was effective, providing similar tumor control across MET positive and negative patients. *Sutent*® was heavily used as first-line PRCC therapy with minimal usage in second-line and above setting.
- Incidence of MET positive PRCC patients was lower than previous scientific publications and the savolitinib US Phase II study; and
- Full MES findings will be presented at a major scientific conference in 2019.

CALYPSO study in PRCC – An independently sponsored Phase II study of savolitinib monotherapy and in combination with *Imfinzi*® (durvalumab), AstraZeneca's anti Programmed death-ligand 1 ("PD-L1") mAb, is underway in both PRCC and ccRCC patients (NCT02819596; U.K./Spain; sponsor: Queen Mary's University, London).

- CALYPSO explores combination (savolitinib / *Imfinzi*®) use in an all-comer PRCC population (both MET-driven and MET-independent; PD-L1 expression agnostic); and
- Preliminary data from this study is planned for presentation at a future scientific conference.

SAVOIR Phase III study – SAVOIR (NCT03091192) is a global Phase III registration study of savolitinib versus *Sutent*® in MET-driven metastatic PRCC patients. The study was initiated in June 2017 with a primary endpoint for efficacy of PFS. The SAVOIR protocol was designed, with regulatory endorsement, to include an adjustment at the time of MES readout to enable rebalancing the ratio of first-line vs. second-line and above MET positive PRCC patients.

MES implications on SAVOIR study:

- Likelihood of SAVOIR success in first-line MET positive PRCC is now considered as low given outcome of MES;
- Rebalancing SAVOIR to second-line and above patients is operationally not practical given minimal use of Sutent® beyond first-line as well as lower than expected incidence of MET positive patients; and
- The outcome of a molecular epidemiology study, along with recent novel therapy approvals, is leading to a change in savolitinib kidney cancer strategy.

As a result, the savolitinib registration strategy for PRCC is being reassessed, to take into account these findings as well as the rapidly changing RCC treatment landscape. Enrollment in the SAVOIR study has been suspended.

About Savolitinib

Savolitinib is a potential first-in-class inhibitor of c-MET, an enzyme which has been shown to function abnormally in many types of solid tumors. Chi-Med designed savolitinib to be a potent and highly selective oral inhibitor, which, through chemical structure modification, addresses human metabolite-related renal toxicity, the primary issue that halted development of several other selective c-MET inhibitors. In clinical studies to date, involving over 700 patients, savolitinib has shown promising signs of clinical efficacy in patients with c-MET gene alterations in PRCC, NSCLC, colorectal cancer (CRC) and gastric cancer with an acceptable safety profile. Chi-Med is currently testing savolitinib in partnership with AstraZeneca in Phase Ib/II studies, in multiple solid tumor indications, both as a monotherapy and in combinations.

About Chi-Med

Chi-Med (AIM/Nasdaq: HCM) is an innovative biopharmaceutical company which researches, develops, manufactures and markets pharmaceutical products. Its Innovation Platform, Hutchison MediPharma, has about 400 scientists and staff focusing on discovering, developing and commercializing targeted therapeutics in oncology and autoimmune diseases. It has a portfolio of eight cancer drug candidates currently in clinical studies around the world. Chi-Med's Commercial Platform manufactures, markets, and distributes prescription drugs and consumer health products, covering an extensive network of hospitals across China.

Dual-listed on the AIM market of the London Stock Exchange and the Nasdaq Global Select Market, Chi-Med is headquartered in Hong Kong and majority owned by the multinational conglomerate CK Hutchison Holdings Limited (SEHK: 1). For more information, please visit: www.chi-med.com.

Forward-Looking Statements

This announcement 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 savolitinib, plans to initiate clinical studies for savolitinib, 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 savolitinib to meet the primary or secondary endpoint of a study, to obtain regulatory approval in different jurisdictions and to gain commercial acceptance after obtaining regulatory approval, the potential market of savolitinib for a targeted indication and the sufficiency of funding. In addition, as certain studies rely on the use of Tagrisso®, Iressa® and Imfinzi® as combination therapeutics with savolitinib, such risks and uncertainties include assumptions regarding the safety, efficacy, supply and continued regulatory approval of Tagrisso®, Iressa® and Imfinzi®. 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 announcement, whether as a result of new information, future events or circumstances or otherwise.

Inside Information

This announcement contains inside information for the purposes of Article 7 of Regulation (EU) No 596/2014.

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