HUTCHISON CHINA MEDITECH

Press Release

Chi-Med Announces NDA Acceptance in China for Savolitinib in the Treatment of Non-Small Cell Lung Cancer with MET Exon 14 Skipping Mutations

— First NDA filing of savolitinib globally —

— Chi-Med seeking first-in-class Chinese marketing authorization for a selective MET inhibitor —

London: Friday, May 29, 2020: Hutchison China MediTech Limited ("Chi-Med") (Nasdaq/AIM: HCM) today announced that the New Drug Application ("NDA") for savolitinib for the treatment of non-small cell lung cancer ("NSCLC") with MET Exon 14 skipping mutations has been accepted for review by the China National Medical Products Administration (NMPA).

The NDA is supported by data from an open-label, Phase II registration study. Interim data were presented on the first 50 treated patients at the Chinese Society of Clinical Oncology Annual Meeting in September 2019. An updated analysis with 70 patients in the study will be presented by Professor Shun Lu as part of the American Society of Clinical Oncology ("ASCO") 2020 Virtual Scientific Meeting, available on May 29, 2020 at 8:00 a.m. Eastern Time ("*Phase II Study of Savolitinib in Patients with Pulmonary Sarcomatoid Carcinoma and Other Types of Non-Small Cell Lung Cancer Harboring MET Exon 14 Skipping Mutations*", abstract #9519).

"With today's NDA acceptance, savolitinib is one step closer to benefitting a specific group of NSCLC patients who have limited treatment options today and we are very proud of that. After many years of collaboration with AstraZeneca, we hope that this NDA is the first of many globally for savolitinib." Mr Christian Hogg, Chief Executive Officer of Chi-Med, commented.

It is estimated that 2-3% of NSCLC patients have MET Exon 14 skipping mutations, which predicts poor prognosis.[1] Annual incidence of lung cancer in China accounted for 37.0% of the world's annual incidence of lung cancer in 2018.[2]

In 2011, Chi-Med entered into a global licensing and joint development and commercialization agreement with AstraZeneca (LSE, STO, NYSE: AZN) for savolitinib. Savolitinib's global development plan includes NSCLC and kidney cancer, and additional MET-driven tumors are being explored.

About Savolitinib

Savolitinib is a small molecule inhibitor of MET, a receptor tyrosine kinase enzyme which has been shown to function abnormally in many types of solid tumors. It was developed as a potent and highly selective oral inhibitor. In clinical studies to date, involving over 1,000 patients, savolitinib has shown promising clinical efficacy in patients with MET gene alterations in multiple tumor types with an acceptable safety profile.

Savolitinib in NSCLC:

Phase II in MET Exon 14 deletion NSCLC (NCT02897479) – NDA accepted and data to be presented at ASCO 2020.

SAVANNAH Phase II study of savolitinib in combination with Tagrisso® in patients who have progressed following Tagrisso® due to MET amplification (NCT03778229) – The SAVANNAH study is a single-arm, open-label study in epidermal growth factor receptor (EGFR) mutation positive NSCLC patients following first- or second-line Tagrisso® therapy.

Savolitinib in kidney cancer:

CALYPSO Phase II of savolitinib in combination with Imfinzi® PD-L1 inhibitor in renal cell carcinoma ("RCC") (NCT02819596) – The CALYPSO study is an investigator initiated open-label Phase I/II study of savolitinib in combination with Imfinzi®, an anti-PD-L1 antibody owned by AstraZeneca. The study is evaluating the safety and efficacy of the savolitinib/Imfinzi® combination in patients with papillary RCC ("PRCC") and clear cell RCC.

SAVOIR Phase III in MET-positive PRCC (NCT03091192) – In December 2018, enrollment was terminated in SAVOIR, a global Phase III registration study of savolitinib monotherapy compared with sunitinib monotherapy in MET-positive PRCC. The early termination was driven by factors external to the SAVOIR study. Data from the approximately 60 patients randomized in SAVOIR prior to termination matured during 2019 and will be presented by Professor Toni K. Choueiri at ASCO 2020 Virtual Scientific meeting in an oral abstract session, available on May 29, 2020 at 8:00 a.m. Eastern Time ("*SAVOIR: A Phase III Study of Savolitinib Versus Sunitinib in Patients with MET-driven Papillary Renal Cell Carcinoma",* abstract #5002). Based on these data, AstraZeneca and Chi-Med are actively evaluating the opportunity to restart clinical work in PRCC for monotherapy savolitinib.

Savolitinib in other cancer indications:

Investigator-initiated studies of savolitinib have been undertaken in gastric cancer, prostate cancer and colorectal cancer.

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.

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 regarding the therapeutic potential of savolitinib for the treatment of patients with NSCLC, the further clinical development of savolitinib in this and other indications, its expectations as to whether clinical studies of savolitinib 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 the sufficiency of its data to support NDA approval of savolitinib for the treatment of patients with NSCLC in China, its potential to gain expeditious approvals for savolitinib in other jurisdictions such as the U.S., E.U. or Japan, the safety profile of savolitinib, the potential for savolitinib to become a new standard of care for NSCLC patients, its ability to implement and complete its further clinical development plans for savolitinib, its potential commercial launch of savolitinib in China and other jurisdictions, the timing of these events, and the impact of the COVID-19 pandemic on general economic, regulatory and political conditions. 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]Awad M et al. “MET Exon 14 Mutations in Non–Small-Cell Lung Cancer Are Associated With Advanced Age and Stage-Dependent MET Genomic Amplification and c-Met Overexpression.” Journal of Clinical Oncology 2016 34:7, 721-730.
[2] Global Cancer Observatory.