



HUTCHISON CHINA MEDITECH

## Press Release

# Chi-Med Highlights Savolitinib Clinical Data to be Presented at Virtual WCLC

**Hong Kong, Shanghai, & Florham Park, NJ: Thursday, January 14, 2021:** Hutchison China MediTech Limited (“[Chi-Med](#)”) (Nasdaq/AIM: HCM) today announces that the final analysis of savolitinib in Phase Ib TATTON study Parts B and D will be presented at the upcoming virtual 2020 World Conference on Lung Cancer (WCLC 2020), taking place on January 28-31, 2021, virtually.

Further details of the featured poster presentation are as follows:

**Title:** Osimertinib + savolitinib in patients with EGFR<sup>m</sup> MET-amplified/overexpressed NSCLC: Phase Ib TATTON Parts B and D final analysis

**Lead Author:** Ji-Youn Han, Center for Lung Cancer, National Cancer Center, Goyang, Republic of Korea

**Session:** FP14 - Targeted Therapy - Clinically Focused

**Abstract # / Link:** #FP14.03 / [Link](#)

**Availability Date:** Thursday, January 28, 2021 (from midnight Singapore time)

## About Savolitinib

Savolitinib is an oral, potent, and highly selective small molecule inhibitor of MET, a receptor tyrosine kinase which has been shown to function abnormally in many types of solid tumors promoting tumor growth, angiogenesis, and metastasis. Savolitinib has been studied in over 1,000 patients to date. In clinical studies, it has shown promising clinical efficacy in patients with MET gene alterations in multiple tumor types with an acceptable safety profile.

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

## Savolitinib development in NSCLC:

*Phase II in MET Exon 14 alteration NSCLC (NCT02897479)* – In May 2020, data from an ongoing open-label, Phase II registration study was presented as part of the American Society of Clinical Oncology 2020 Virtual Scientific Program (“ASCO 2020”). In patients with MET Exon 14 skipping alteration NSCLC in the efficacy evaluable population, savolitinib demonstrated a 49.2% objective response rate (“ORR”), a 93.4% disease control rate (DCR) and a 9.6 months interim duration of response (“DoR”). 36% of patients in the study have pulmonary sarcomatoid carcinoma (PSC), an aggressive subtype of NSCLC. Data were not yet mature for DoR, progression-free survival (PFS) or overall survival (“OS”). Clinical data indicated an acceptable safety profile, with a low adverse event (AE) related discontinuations rate of 14.3%. This data supported the China new drug application (“NDA”) acceptance in May 2020.

*SAVANNAH Phase II study of savolitinib in combination with Tagrisso® in patients who have progressed following Tagrisso® due to MET amplification or overexpression (NCT03778229)* – The SAVANNAH study is a single-arm, open-label study in epidermal growth factor receptor (“EGFR”) mutation positive NSCLC patients with MET amplified/overexpressed tumors following progression after treatment with Tagrisso®, an EGFR-tyrosine kinase inhibitor owned by AstraZeneca.

## Savolitinib development in kidney cancer:

*MET-driven papillary renal cell carcinoma (“RCC”) (NCT03091192)* – In May 2020, data from 60 patients in the SAVOIR global study of savolitinib monotherapy compared with sunitinib monotherapy in MET-driven papillary RCC was presented at ASCO 2020. Savolitinib demonstrated encouraging activity, including an ORR of 27%

versus 7% for sunitinib, with no savolitinib responding patients with disease progression at data cut-off, and an encouraging OS hazard ratio of 0.51 (95% CI: 0.21–1.17; p=0.110) with median not reached at data cut-off.

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

Based on these data, AstraZeneca and Chi-Med are actively evaluating the opportunity to progress clinical work in papillary RCC for savolitinib.

### **Savolitinib development in other cancer indications:**

Savolitinib opportunities are also continuing to be explored in multiple other MET-driven tumor settings via investigator-initiated studies including gastric 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 nine 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](http://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. In addition, as certain studies rely on the use of Tagrisso® and Imfinzi® as combination therapeutics with savolitinib, such risks and uncertainties include assumptions regarding the safety, efficacy, supply and continued regulatory approval of Tagrisso® 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 press release, whether as a result of new information, future events or circumstances or otherwise.*

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