



HUTCHISON CHINA MEDITECH

Press Release

Chi-Med's NDA for Savolitinib in Non-Small Cell Lung Cancer Granted Priority Review in China

Hong Kong, Shanghai & Florham Park, NJ: Tuesday, July 28, 2020: Hutchison China MediTech Limited ("[Chi-Med](#)") (Nasdaq/AIM: HCM) today announced that the China National Medical Products Administration ("NMPA") has granted Priority Review status to the New Drug Application ("NDA") for savolitinib for the treatment of non-small cell lung cancer ("NSCLC") with MET Exon 14 skipping mutations. This is the first NDA filing for savolitinib globally and first for a selective MET inhibitor in China.

With over 774,000 new cases every year, China accounted for 37% of the world's annual incidence of lung cancer in 2018.¹ Approximately 80-85% of lung cancer cases are NSCLC.² It is estimated that 2-3% of NSCLC patients have MET Exon 14 skipping mutations; these mutations lead to poor prognosis.³ The annual incidence of MET Exon 14 skipping mutation NSCLC is estimated to be 12,000 to 20,000 in China.

About Priority Review in China

The NMPA's Priority Review procedure encourages research and development of potential new medicines with clear clinical value, medicines or vaccines that address urgent clinical needs, as well as medicines that address serious infectious diseases, certain rare diseases, and select pediatric conditions or formulations. A potential new medicine may have clear clinical value if it is being developed for serious conditions that are life threatening, debilitating, or impact quality of life. NDAs undergoing Priority Review would receive preferential allocation of NMPA resources during the review process.⁴

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 (LSE, STO, NYSE: AZN) for savolitinib. Savolitinib's global development plan includes NSCLC and kidney cancer, and additional MET-driven tumors are being explored.

Savolitinib development in NSCLC:

Phase II in MET Exon 14 mutation 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 mutation 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 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 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. Based on these data, AstraZeneca and Chi-Med are actively evaluating the opportunity to progress clinical work in papillary RCC for monotherapy savolitinib.

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.

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.

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.

CONTACTS

Investor Enquiries

Mark Lee, Senior Vice President	+852 2121 8200
Annie Cheng, Vice President	+1 (973) 567 3786

Media Enquiries

Americas – Brad Miles, Solebury Trout	+1 (917) 570 7340 (Mobile) bmiles@troutgroup.com
Europe – Ben Atwell / Alex Shaw, FTI Consulting	+44 20 3727 1030 / +44 7771 913 902 (Mobile) / +44 7779 545 055 (Mobile) Chi-Med@fticonsulting.com

Asia – Joseph Chi Lo / Zhou Yi, Brunswick

+852 9850 5033 (Mobile), jlo@brunswickgroup.com /
+852 9783 6894 (Mobile), yzhou@brunswickgroup.com

Nominated Advisor

Freddy Crossley / Atholl Tweedie,
Panmure Gordon (UK) Limited

+44 (20) 7886 2500

¹ Global Cancer Observatory. China Fact Sheet. gco.iarc.fr/today/data/factsheets/populations/160-china-fact-sheets.pdf.

² American Cancer Society. www.cancer.org/cancer/lung-cancer/about/what-is.html.

³ 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.
doi: [10.1200/JCO.2015.63.4600](https://doi.org/10.1200/JCO.2015.63.4600).

⁴ National Medical Products Administration, "Drug Marketing Authorization Priority Review Process."
<http://www.nmpa.gov.cn/WS04/CL2138/378606.html>.