

# Press Release

# Chi-Med Presents Clinical Data at ASCO 2017 Annual Meeting

- FRESCO Phase III trial results for fruquintinib in colorectal cancer in an oral presentation -

- Five abstracts in total accepted for fruquintinib, savolitinib and sulfatinib -

**London: Thursday, May 18, 2017:** Hutchison China MediTech Limited ("Chi-Med") (AIM/Nasdaq: HCM) today announces that new clinical data on three of its novel tyrosine kinase inhibitors, fruquintinib, savolitinib and sulfatinib, will be presented at the 2017 American Society of Clinical Oncology ("ASCO") Annual Meeting, to be held in Chicago, Illinois from June 2 to 6, 2017.

The five presentations, one oral presentation and four poster presentations, cover the following studies:

# Fruquintinib:

• The full results of the FRESCO Phase III study in 416 patients with locally advanced or metastatic colorectal cancer ("CRC") will be highlighted in an oral presentation on June 5, 2017. Primary endpoint median overall survival was 9.30 months for fruquintinib versus 6.57 months in the control group, with a hazard ratio of 0.65 and p< 0.001. Fruquintinib was well tolerated, with manageable on-target treatment related adverse events consistent with previous studies.

### Savolitinib:

- c-MET amplification ("amp") is a major acquired resistance ("AR") pathway to Tagrisso<sup>®</sup> (osimertinib). AstraZeneca PLC ("AstraZeneca") will highlight an analysis of 23 EGFR-mutant non-small-cell lung cancer ("NSCLC") patients with AR to Tagrisso<sup>®</sup>. Analysis shows that about 30% (7/23 patients) of AR is c-MET amp and that among the 7 patients with c-MET amp, 3 patients received combination Tagrisso<sup>®</sup>/savolitinib therapy; all 3 had partial response ("PR") under RECIST (Response Evaluation Criteria in Solid Tumors) guidelines.
- Savolitinib included in PAPMET Phase II study (sponsored by NIH/NCI) of multiple c-MET and vascular endothelial growth factor receptor ("VEGFR") tyrosine kinase inhibitors in metastatic papillary renal cell carcinoma patients. PAPMET will evaluate four therapies in a 1:1:1:1 randomization, sunitinib, cabozantinib, crizotinib and savolitinib in an about 275-patient study which began in 2016 and as at January 30, 2017 had registered 26 patients. PAPMET will study efficacy, safety and correlation of clinical outcome with tumor molecular driver alterations such as c-MET.
- Update on the VIKTORY trial, a biomarker-based umbrella trial in gastric cancer. From June 2014 to January 2017, a total of 432 metastatic gastric cancer patients were enrolled in VIKTORY, a total of 23 patients (5.3%) were guided into savolitinib monotherapy treatment (4/23 patients) or savolitinib/docetaxel combination therapy (19/23) based on molecular screening outcomes.

# Sulfatinib:

• Preliminary results of a Phase II study in advanced medullary thyroid cancer ("MTC") and radioiodine ("RAI")-refractory differentiated thyroid cancer ("DTC"). Sulfatinib is an oral, novel angio-immuno kinase inhibitor that selectively targets VEGFR, fibroblast growth factor receptor-1 ("FGFR") and colony-stimulating factor-1 receptor ("CSF-1R"). As at December 31, 2016 a total of 18 patients had been enrolled with 1/6 MTC patients and 3/12 RAI-DTC patients reporting confirmed PRs, and all other patients stable disease, under RECIST.

#### **Presentation Details**

Abstracts for the presentations are available at <u>abstracts.asco.org</u>, as listed below:

# Fruquintinib:

Title:	A randomized, double-blind, placebo-controlled, multi-centered phase III trial comparing fruquintinib versus placebo plus best supportive care in Chinese patients with metastatic colorectal cancer (FRESCO)	
Abstract #:	3508	
Presenter:	Dr. Jin Li, Oncologist and Director of the Tumor Department, Shanghai East Hospital, Tongji University School of Medicine	
Authors:	J Li, S Qin, RH Xu, J Xu, L Shen, Y Bai, Y Deng, L Yang, ZD Chen, H Zhong, H Pan, W Guo, Y Shu, Y Yuan, J Zhou	
Session:	Gastrointestinal (Colorectal) Cancer – Oral Abstract Session	
Date & Time:	Monday, June 5, 2017, 5:24 PM CDT	
Location:	Hall D2	
Savolitinib:		
Title:	MET amplification (amp) as a resistance mechanism to osimertinib	
Abstract #:	9020	
Authors:	Z Piotrowska, K Thress, M Mooradian, RS Heist, CG Azzoli, J Temel, C Rizzo, R Nagy, R Lanman, S Gettinger, T Evans, A Hata, A Shaw, LV Sequist	
Session:	Lung Cancer—Non-Small Cell Metastatic	
Date & Time:	Saturday, June 3, 08:00 - 11:30 AM CDT	
Location:	Hall A	
Title:	A randomized, phase II efficacy assessment of multiple MET kinase inhibitors in metastatic papillary renal carcinoma (PRCC): SWOG S1500	
Abstract #:	TPS4599	
Authors:	SK Pal, C Tangen, IM Thompson, B Shuch, NB Haas, DJ George, M Stein, M Plets, PN Lara	
Session:	Genitourinary (Nonprostate) Cancer	
Date & Time:	Sunday, June 4, 08:00 – 11:30 AM CDT	
Location:	Hall A	
Title:	VIKTORY trial: Report on AZD1775/paclitaxel in TP53 mutation (+) GC, selumetinib/paclitaxel in ras aberrant GC, AZD5363/paclitaxel in PIK3CA mt and biomarker negative, savolitinib/docetaxel in met (+), and vistusertib/paclitaxel in RICTOR(+) GC	
Abstract #:	4024	
Authors:	J Lee, ST Kim, PG Mortimer, S Hollingsworth, E Harrington, C Shepherd, E Kilgour, SH Park, H Lee, SY Oh, JH Kang, JO Park, YS Park, HY Lim, KM Kim, WK Kang	

Session: Gastrointestinal (Noncolorectal) Cancer

Date & Time:	Saturday, June 3, 08:00 – 11:30 AM CDT
Location:	Hall A
Sulfatinib:	
Title:	A phase II multicenter trial of the multitargeted kinase inhibitor sulfatinib in advanced medullary thyroid cancer (MTC) and radioiodine (RAI)-refractory differentiated thyroid cancer (DTC)
Abstract #:	6037
Authors:	J Chen, Q Ji, J Cao, D Ji, C Bai, Y Lin, B Pan, G Sun, J Li, C Qi, Y Hua
Session:	Head and Neck Cancer
Date & Time:	Monday, June 5, 1:15 PM CDT
Location:	Hall A

Once presented, the presentations will be available at <u>www.chi-med.com/news/</u>. Further information about ASCO is available at <u>asco.org</u>.

### About Fruquintinib

Fruquintinib is a highly selective small molecule drug candidate that has been shown to inhibit VEGFR 24 hours a day via an oral dose, without known off-target toxicities. Its tolerability, along with its clean drugdrug interaction profile, enables rational combination with other cancer therapies such as in our ongoing clinical trials of fruquintinib in combination with chemotherapy and targeted therapy.

At an advanced stage, tumors secrete large amounts of VEGF, a protein ligand, to stimulate formation of excessive vasculature (angiogenesis) around the tumor to provide greater blood flow, oxygen, and nutrients to the tumor. VEGF and VEGFR play a pivotal role in tumor-related angiogenesis, and the inhibition of the VEGF/VEGFR pathway. This represents an important therapeutic strategy in blocking the development of new blood vessels essential for tumors to grow and invade.

Fruquintinib is currently under joint development in China by Chi-Med and its partner Eli Lilly and Company ("Lilly"). Chi-Med and Lilly jointly announced top-line results from the FRESCO CRC trial on March 3, 2017. In addition, fruquintinib is being studied in China in a Phase III pivotal trial in NSCLC, known as FALUCA; and a Phase II study using fruquintinib combined with Iressa<sup>®</sup> (gefitinib) in the first-line setting for patients with advanced or metastatic NSCLC. Other studies currently being planned, and soon to be initiated, include a Phase III study in gastric cancer in combination with paclitaxel in China, new studies in the United States, and certain exploratory studies in combination with other oncology agents.

#### About Savolitinib

Savolitinib (AZD6094/HMPL-504) is a potential global first-in-class inhibitor of c-MET (also known as mesenchymal epithelial transition factor) receptor tyrosine kinase, an 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 specifically designed to address issues observed in the clinic with first-generation c-MET inhibitors, including renal toxicity.

Savolitinib was discovered by Chi-Med and is being developed in collaboration with AstraZeneca. AstraZeneca and Chi-Med are currently testing savolitinib in multiple tumor types worldwide including kidney, lung and gastric cancers, both as a monotherapy or in combination with other targeted and immunotherapy agents.

#### About Sulfatinib

Sulfatinib is an oral, novel angio-immunokinase inhibitor that selectively inhibits the tyrosine kinase activity associated with VEGFR, FGFR and CSF-1R, three key tyrosine kinase receptors involved in tumor angiogenesis and immune evasion. Inhibition of the VEGFR signaling pathway can act to stop angiogenesis, the growth of the vasculature around the tumor, and thereby starve the tumor of the nutrients and oxygen it needs to grow rapidly. Aberrant activation of the FGFR signaling pathway, which can be increased by anti-VEGFR therapy treatment, is shown to be associated with cancer progression by promoting tumor growth, angiogenesis and formation of the myeloid derived suppressor cells. Inhibition of the CSF-1R signaling pathway blocks the activation of tumor-associated macrophages, which are involved in suppressing immune responses against tumors.

Six sulfatinib clinical trials are underway in China and the United States, including two Phase III studies and one Phase II study in neuroendocrine tumors patients (SANET-p, SANET-ep and SANET-1), one Phase II study in thyroid cancer patients and one Phase II study in biliary tract cancer patients.

#### About Chi-Med

Chi-Med is an innovative biopharmaceutical company which researches, develops, manufactures and sells pharmaceuticals and healthcare products. Its Innovation Platform, Hutchison MediPharma Limited, 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: <u>www.chi-med.com</u>.

#### 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 for the clinical development of fruquintinib, savolitinib and sulfatinib, plans to initiate clinical studies for fruquintinib, savolitinib and sulfatinib, 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 candidates fruguintinib, savolitinib and sulfatinib to meet the primary or secondary endpoint of a study, to obtain regulatory approval in different jurisdictions, to gain commercial acceptance after obtaining regulatory approval, the potential market of fruquintinib, savolitinib and sulfatinib for a targeted indication and the sufficiency of funding. In addition, as certain studies rely on the use of Iressa<sup>®</sup> (gefitinib) as a combination therapeutic with fruquintinib and docetaxel and Tagrisso<sup>®</sup> (osimertinib) as a combination therapeutic with savolitinib, such risks and uncertainties include assumptions regarding the safety, efficacy, supply and continued regulatory approval of Iressa<sup>®</sup>, docetaxel and Tagrisso<sup>®</sup>. 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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