



HUTCHISON CHINA MEDITECH LIMITED

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Chi-Med and AstraZeneca Initiate SAVOIR, a Global Phase III Trial of Savolitinib in Papillary Renal Cell Carcinoma

London: Thursday, June 29, 2017: Chi-Med and AstraZeneca today announce that they have initiated a global pivotal Phase III, open-label, randomized multi-center registration study of the highly selective inhibitor of c-MET receptor tyrosine kinase, savolitinib, in c-MET-driven papillary renal cell carcinoma ("PRCC"). This is the first pivotal study ever conducted in c-MET-driven PRCC and the first molecularly selected trial in renal cell carcinoma ("RCC").

"The launch of the SAVOIR trial, designed to support product registration in the U.S. and Europe, continues to advance our strategy to deliver innovative medicines to major markets worldwide," said Christian Hogg, Chief Executive Officer of Chi-Med. "Based on the results of our Phase II study, we believe savolitinib has the potential to bring meaningful clinical benefit to patients with c-MET-driven PRCC. We also expect to further understand the correlations between c-MET alterations and patient outcomes through epidemiological analyses using our newly developed companion diagnostic assay."

Susan Galbraith, SVP IMED Oncology, AstraZeneca commented that "It is exciting to achieve this milestone in savolitinib's development. The data building across our early development studies are encouraging, that savolitinib has the potential to be an important treatment option for c-MET driven cancers including kidney, lung and gastric cancers."

The initiation of this Phase III trial has triggered a US\$5 million milestone payment to Hutchison MediPharma Limited (a 99.8% subsidiary of Chi-Med) from AstraZeneca under the terms of the license and collaboration agreement signed between them in 2011 (as amended).

In addition to SAVOIR, Chi-Med and AstraZeneca are conducting a number of Phase Ib and II studies of savolitinib in kidney cancer, lung cancer and gastric cancer. These studies involve savolitinib as a monotherapy or in combination with other targeted therapy, such as Tagrisso® (osimertinib) or Iressa® (gefitinib). Additional studies combining with Imfinzi® (durvalumab) and Taxotere® (docetaxel) are also in progress.

About SAVOIR

SAVOIR is a global Phase III, open-label, randomized, controlled trial evaluating the efficacy and safety of savolitinib, compared with sunitinib, in patients with c-MET-driven, unresectable, locally advanced or metastatic PRCC. Approximately 180 patients will be randomized at 50 to 75 sites across five to ten countries. c-MET status is confirmed by the novel targeted next-generation sequencing (NGS) assay developed for savolitinib. Patients will be randomized in a 1:1 ratio to receive either continuous treatment with savolitinib 600 mg (400 mg if <50 kg) orally, once daily, or intermittent treatment with sunitinib 50 mg orally once daily (4 weeks on/2 weeks off), on a 6-week cycle.

The primary objective is to evaluate the primary efficacy endpoint progression free survival ("PFS") of savolitinib as compared with sunitinib. Secondary endpoints include overall survival, objective response rate ("ORR"), duration of response, best percentage change in tumor size, disease control rate, and safety and tolerability. The impact of savolitinib compared with sunitinib on disease symptoms and quality of life, along with the pharmacokinetics of savolitinib will also be assessed. Additional details about this study may be found at clinicaltrials.gov, using identifier [NCT03091192](https://clinicaltrials.gov/ct2/show/study/NCT03091192).

About Savolitinib

Savolitinib (AZD6094/HMPL-504) is a potential first-in-class selective 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 other selective c-MET inhibitors, such as renal toxicity.

Savolitinib was discovered by Chi-Med and is being developed in collaboration with AstraZeneca. Savolitinib is currently being studied 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 c-MET-Driven PRCC

Worldwide, about 366,000 new patients are diagnosed with kidney cancer annually. RCC accounts for approximately 80-85% of kidney cancer and has several histological sub-types with different genetic and biochemical characteristics. PRCC is the most common of the non-clear cell renal carcinomas accounting for 10-15% of RCC. However, the biology and molecular characteristics of PRCC are different from those of clear cell RCC ("ccRCC"). Multiple studies indicate that PRCC is c-MET-driven in 40-70% of patients.

There are no therapies approved for patients with PRCC, who currently receive treatments approved for RCC such as sunitinib. These RCC agents were mostly approved on the basis of studies where the majority of subjects were ccRCC patients and where the benefits to the PRCC minority were more modest. Currently the National Comprehensive Cancer Network Guidelines advise PRCC patients to enter clinical trials.

About Savolitinib in PRCC

In February 2017, the results of a global Phase II multicenter study in advanced PRCC was presented at the 2017 American Society of Clinical Oncology Genitourinary Cancers Symposium, which indicated a clear efficacy signal with savolitinib monotherapy in c-MET-driven patients. Median PFS of 6.2 months in c-MET-driven patients as compared with 1.4 months ($p < 0.0001$) in c-MET-independent patients. ORR was 18.2% in c-MET-driven patients vs. 0% ($p = 0.002$) in c-MET independent patients. An encouraging durable response and safety profile were reported in savolitinib treated patients. Further details are available at www.chi-med.com/asco-gu-2017-savolitinib-ph2-in-prcc-pres/.

Studies of c-MET-driven disease in gastric cancer and lung cancer suggest that c-MET amplification and/or overexpression can be a negative prognostic for disease progression. Over the course of 2017, Chi-Med and AstraZeneca are also conducting a comprehensive molecular epidemiology study of approximately 300 PRCC patient samples to further understand the correlations between c-MET alterations and patient outcomes, including any predictive biomarkers.

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: www.chi-med.com.

About AstraZeneca in Oncology

AstraZeneca has a deep-rooted heritage in oncology and offers a quickly growing portfolio of new medicines that has the potential to transform patients' lives and the Company's future. With at least 6 new medicines to be launched between 2014 and 2020 and a broad pipeline of small molecules and biologics in development, we are committed to advance new oncology as one of AstraZeneca's six Growth Platforms focused on lung, ovarian, breast and blood cancers. In addition to our core capabilities, we actively pursue innovative partnerships and investments that accelerate the delivery of our strategy, as illustrated by our investment in Acerta Pharma in hematology.

By harnessing the power of four scientific platforms – immuno-oncology, the genetic drivers of cancer and resistance, DNA damage response and antibody drug conjugates – and by championing the development

of personalized combinations, AstraZeneca has the vision to redefine cancer treatment and one day eliminate cancer as a cause of death.

About AstraZeneca

AstraZeneca is a global, science-led biopharmaceutical company that focuses on the discovery, development and commercialization of prescription medicines, primarily for the treatment of diseases in three main therapy areas – oncology, cardiovascular & metabolic diseases and respiratory. The Company also is selectively active in the areas of autoimmunity, neuroscience and infection. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. For more information, please visit www.astrazeneca.com and follow us on Twitter [@AstraZeneca](https://twitter.com/AstraZeneca).

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, to gain commercial acceptance after obtaining regulatory approval, the potential market of savolitinib for a targeted indication and the sufficiency of funding. 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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