

Press Release

HUTCHMED Highlights First Presentation of Results of the SAVANNAH Global Phase II Trial of Savolitinib plus TAGRISSO® at the 2022 WCLC Annual Meeting

— 49% ORR amongst SAVANNAH patients with higher MET levels —

Hong Kong, Shanghai & Florham Park, NJ — Wednesday, July 13, 2022: HUTCHMED (China) Limited ("[HUTCHMED](#)") (Nasdaq/AIM: HCM; HKEX: 13) today announces the first presentation of results from the ongoing SAVANNAH global Phase II trial at the upcoming International Association for the Study of Lung Cancer (IASLC) 2022 World Conference on Lung Cancer ("WCLC"), taking place August 6-9 in Vienna, Austria.

SAVANNAH is a global Phase II study of HUTCHMED and AstraZeneca's (LSE/STO/Nasdaq: AZN) savolitinib in combination with AstraZeneca's TAGRISSO® (osimertinib) in epidermal growth factor receptor ("EGFR")-mutated non-small cell lung cancer ("NSCLC") patients with mesenchymal epithelial transition receptor ("MET") driven tumors, following disease progression on treatment with TAGRISSO®. In addition to continuing TAGRISSO® treatment, patients received savolitinib 300mg once daily, 300mg twice daily, or 600mg once daily. A total of 294 patients are enrolled in the study.

The abstract presents results from an analysis of 193 efficacy evaluable patients who received savolitinib 300mg once daily plus TAGRISSO® 80mg once daily at data cut-off date of August 27, 2021. Qualifying MET aberrations are MET amplification as detected by FISH (MET copy number ≥ 5 and/or MET: CEP signal ratio ≥ 2 [FISH5+]) or MET overexpression as detected by IHC (3+ in $\geq 50\%$ tumor cells [IHC50+]). Additional analysis using an exploratory, higher cut-off level of MET aberration are presented. The higher cut-off levels for MET aberration are MET copy number ≥ 10 (FISH10+) and/or 3+ staining $\geq 90\%$ tumor cells (IHC90+). The prevalence of this higher cut-off levels of MET aberration was 34% of patients centrally tested for enrollment in this study.

Results showed a trend toward improved response rates with increasing level of MET aberration. Across all patients in this analysis, objective response rate ("ORR") was 32% [95% confidence interval ("CI"): 26-39%], median duration of response ("DoR") was 8.3 months [95% CI: 6.9-9.7 months], and median progression-free survival ("PFS") was 5.3 months [95% CI: 4.2- 5.8 months]. These results are consistent with the previously presented results from the TATTON global exploratory study in over 220 EGFR mutation positive NSCLC patients with MET amplified tumors following progression after treatment with any EGFR TKI.

Among the SAVANNAH patients who met the criteria for higher cut-off levels of MET aberration (n=108), ORR was 49% [95% CI: 39-59%], median DoR was 9.3 months [95% CI: 7.6-10.6 months], and mPFS was 7.1 months [95% CI: 5.3-8.0 months]. The safety profile of savolitinib plus TAGRISSO® was consistent with the known profiles of the combination and each treatment alone.

Findings based on the ongoing SAVANNAH study, and the previously presented TATTON Phase Ib/II study, supported the initiation of the SAFFRON global Phase III study in patients with EGFR-mutated, MET-driven, locally advanced or metastatic NSCLC whose disease progressed on first- or second-line treatment with TAGRISSO® as the most recent therapy. Patients will be prospectively selected for the higher level of MET aberration. The SAFFRON study will evaluate the efficacy and safety of savolitinib in combination with TAGRISSO® compared to pemetrexed plus platinum doublet-chemotherapy, the current standard-of-care treatment in this setting. Approximately 324 patients are planned to be randomized. If successful, the multi-regional clinical trial ("MRCT") may support registration for this combination globally. Two registrational studies are ongoing in China in EGFR mutation positive NSCLC with MET aberrations: the SANOVO study in treatment naïve patients, and SACHI study in patients whose disease progressed following treatment with any EGFR tyrosine kinase inhibitor ("TKI").

Further details from SAVANNAH will be available at WCLC. Further details of the savolitinib WCLC updates are as follows:

Title: **MET Biomarker-based Preliminary Efficacy Analysis in SAVANNAH: savolitinib+osimertinib in EGFRm NSCLC Post-Osimertinib**

Presenter: Myung-Ju Ahn, Division of Hematology-Oncology, Department of Medicine, Samsung Medical Center, Sungkyunkwan University School of Medicine, Seoul, Korea

Other Authors: Filippo De Marinis, Laura Bonanno, Byoung Chul Cho, Tae-Min Kim, Susanna Cheng, Silvia Novello, Claudia Proto, Sang-We Kim, Jong Seok Lee, Giulio Metro, James Chih-Hsin Yang, Wanning Xu, Ryan Hartmaier, Aino Telaranta-Keerie, Lynne Poole, Lecia Sequist

Session: EP08.02 - Metastatic Non-small Cell Lung Cancer - Molecular Targeted Treatments

Abstract No.: [EP08.02-140](#)

Title: **SAFFRON: Ph3 Savolitinib + Osimertinib vs Chemotherapy in EGFRm NSCLC with MET Overexpression/Amplification Post-Osimertinib**

Presenter: Shun Lu, Lung Cancer Center, Shanghai Chest Hospital, Shanghai Jiao Tong University, Shanghai, China

Other Authors: Wanning Xu, Aino Telaranta-Keerie, Nan Jia, Ryan Hartmaier

Session: EP08.02 - Metastatic Non-small Cell Lung Cancer - Molecular Targeted Treatments

Abstract No.: [EP08.02-138](#)

Title: **SANOVO: A Phase 3 Study of Savolitinib or Placebo in Combination with Osimertinib in Patients with EGFR-mutant and MET Overexpressed NSCLC**

Presenter: Qing Zhou, Guangdong General Hospital

Other Authors: Jingchang Li, Jianghong Wang, Lin Yang, Jian Fang, Xiaorong Dong, Tienan Yi, Xuhong Min, Fei Xu, Jianhua Chen, Diansheng Zhong, Jun Bai, Laiyu Liu, Aiping Zeng, Junfang Tang, Hongcheng Wu, Xian Luo, Jie Yu, Weiguo Su, Yi-Long Wu

Session: EP08.02 - Metastatic Non-small Cell Lung Cancer - Molecular Targeted Treatments

Abstract No.: [EP08.02-063](#)

About NSCLC, EGFR and MET Aberrations

Lung cancer is the leading cause of cancer death among men and women, accounting for about one-fifth of all cancer deaths.¹ More than a third of the world's lung cancer patients are in China.² Lung cancer is broadly split into NSCLC and small cell lung cancer, with 80-85% classified as NSCLC.³ The majority of NSCLC patients are diagnosed with advanced disease while approximately 25-30% present with resectable disease at diagnosis.^{4,5}

Approximately 10-25% of NSCLC patients in the U.S. and Europe and 30-40% of patients in Asia have EGFR-mutated NSCLC.^{6,7,8} These patients are particularly sensitive to treatment with an EGFR TKI which blocks the cell-signaling pathways that drive the growth of tumor cells.⁹ While an EGFR TKI can provide a durable survival benefit to most patients, the majority will ultimately develop resistance to their first-line treatment, underscoring a great unmet need to tackle acquired resistance in this patient population.¹⁰

MET is a tyrosine kinase receptor.¹¹ Aberration of MET (amplification or overexpression) is present in both treatment naïve patients as well as being one of the primary mechanisms of acquired resistance to EGFR TKIs for metastatic EGFR-mutated NSCLC.^{12,13} Approximately 2-3% of NSCLC patients have tumors with MET exon 14 skipping alterations, a targetable mutation in the MET gene.¹⁴ Among patients who experience disease progression post-osimertinib treatment, approximately 15-50% present with MET aberration.^{15,16,17,18,19} The prevalence of MET amplification and overexpression may differ depending on the sample type, detection method and assay cut-off used.

About Savolitinib (ORPATHYS® in China)

Savolitinib is an oral, potent, and highly selective MET TKI that has demonstrated clinical activity in advanced solid tumors. It blocks atypical activation of the MET receptor tyrosine kinase pathway that occurs because of mutations (such as exon 14 skipping alterations or other point mutations) or gene amplification.

Savolitinib is [marketed](#) in China under the brand name ORPATHYS® for the treatment of patients with NSCLC with MET exon 14 skipping alterations who have progressed following prior systemic therapy or are unable to receive chemotherapy. It is currently under clinical development for multiple tumor types, including lung, kidney, and gastric cancers, as a single treatment and in combination with other medicines.

In 2011, following its discovery and initial development by HUTCHMED, AstraZeneca and HUTCHMED entered a global licensing and collaboration agreement to jointly develop and commercialize savolitinib. Joint development of savolitinib in China is led by HUTCHMED, while AstraZeneca leads development outside of China. HUTCHMED is responsible for the marketing authorization, manufacturing and supply of savolitinib in China. AstraZeneca is responsible for the commercialization of savolitinib in China and worldwide. Sales of savolitinib are recognized by AstraZeneca.

Savolitinib development in NSCLC

[Phase II study of savolitinib monotherapy in MET Exon 14 skipping alteration NSCLC \(NCT02897479\)](#) – The conditional approval in China for MET Exon 14 skipping alteration NSCLC was based on the results of a Phase II study that were published in *The Lancet Respiratory Medicine*²⁰. At a median follow up of 17.6 months, savolitinib demonstrated an ORR of 42.9% (95% confidence interval [CI] 31.1-55.3) and median PFS of 6.8 months (95% CI 4.2-9.6) in the overall trial population. Disease control rate (“DCR”) in the overall trial population was 82.9% (95% CI 72.0-90.8). The safety and tolerability profile of savolitinib was consistent with previous trials, and no new safety signals were identified. Continued approval is contingent upon the successful completion of a confirmatory trial in this patient population ([NCT04923945](#)).

Based on results of the TATTON and SAVANNAH studies below, several Phase III studies of savolitinib in combination with TAGRISSO® have been initiated, including SACHI, SANOVO and SAFFRON.

- *[SACHI Phase III study of savolitinib in combination with TAGRISSO® in patients who have progressed following EGFR TKI treatment due to MET amplification \(NCT05015608\)](#)* – Initiated in the second half of 2021, this is a randomized, open-label study in China in EGFR mutated NSCLC patients with MET amplified tumors following progression after treatment with any EGFR TKI.
- *[SANOVO Phase III study of savolitinib in combination with TAGRISSO® in treatment-naïve patients with EGFR mutant positive NSCLC with MET overexpression \(NCT05009836\)](#)* – Initiated in the second half of 2021, this is a randomized, double-blinded study in China in untreated, unresectable or metastatic patients with EGFR mutated NSCLC with MET overexpressed tumors.
- *[SAVANNAH Phase II study of savolitinib in combination with TAGRISSO® in patients who have progressed following TAGRISSO® due to MET amplification or overexpression \(NCT03778229\)](#)* – This is an open-label, global study in EGFR mutated NSCLC patients with MET amplified/overexpressed tumors following progression after treatment with TAGRISSO®. Results were accepted for presentation at the upcoming WCLC annual meeting.
- *[SAFFRON Phase III study of savolitinib in combination with TAGRISSO® in patients who have progressed following TAGRISSO® due to MET amplification or overexpression \(NCT05261399\)](#)* – This is a global Phase III study in patients with EGFR mutated, MET-driven, locally advanced or metastatic NSCLC whose disease progressed on first- or second-line treatment with TAGRISSO® as the most recent therapy. Patients will be prospectively selected for the higher level of MET aberration. The SAFFRON study will evaluate the efficacy and safety of savolitinib in combination with TAGRISSO® compared to pemetrexed plus platinum doublet-chemotherapy, the current standard-of-care treatment in this setting. Approximately 324 patients are planned to be randomized. If successful, the MRCT may support registration for this combination globally.
- *[TATTON Phase Ib/II studies of savolitinib in combination with TAGRISSO® in patients who have progressed following EGFR TKI treatment due to MET amplification \(NCT02143466\)](#)* – This global exploratory study included over 220 EGFR mutated NSCLC patients with MET amplified tumors following progression after treatment with any EGFR TKI. Results were published in *Lancet Oncology*²¹ and final analysis was presented at the 2021 World Conference on Lung Cancer²². Three cohorts with patients treated following progression on first- or second-generation EGFR TKI demonstrated an ORR of 64.7-66.7% and a median PFS of 9.0-11.1 months. The cohort of patients treated following progression on a first- and third-generation EGFR TKI demonstrated an ORR of 33.3% (95% CI 22.4-45.7), with a median PFS of 5.5 months (95% CI 4.1-7.7). The combination demonstrated encouraging anti-tumor activity and an acceptable risk-benefit profile.

Savolitinib development in kidney cancer

SAMETA Phase III study in combination with IMFINZI® PD-L1 inhibitor in MET-driven, unresectable and locally advanced or metastatic papillary renal cell carcinoma (“RCC”) (NCT05043090) – Based on the encouraging results of the SAVOIR monotherapy and CALYPSO combination therapy studies below, we initiated SAMETA, a global Phase III, open-label, randomized, controlled study of savolitinib plus IMFINZI® versus sunitinib monotherapy versus IMFINZI® monotherapy in patients with MET-driven, unresectable and locally advanced or metastatic papillary RCC.

SAVOIR randomized, controlled study of savolitinib monotherapy in MET-driven locally advanced or metastatic PRCC (NCT03091192) – Data from 60 patients in this global study of savolitinib monotherapy compared with sunitinib monotherapy in MET-driven papillary RCC was presented at the American Society of Clinical Oncology (“ASCO”) 2020 Program and published simultaneously in *JAMA Oncology*²³. Savolitinib demonstrated encouraging activity, including an ORR of 27% versus 7% for sunitinib, with no savolitinib responding patients experiencing 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 the median not reached at data cut-off.

CALYPSO study of savolitinib in combination with IMFINZI® PD-L1 inhibitor in RCC (NCT02819596) – This investigator initiated open-label Phase I/II study of savolitinib in combination with IMFINZI®, a PD-L1 antibody owned by AstraZeneca, evaluated the safety and efficacy of the savolitinib/IMFINZI® combination in patients with RCC. An analysis of 41 papillary RCC patients was presented at the 2021 ASCO Annual Meeting²⁴, showing a confirmed response rate in 8 out of the 14 MET-driven patients, or 57%, with a median DoR of 9.4 months, median PFS of 10.5 months and median OS of 27.4 months. No new safety signals were seen.

Savolitinib development in gastric cancer and other cancer indications

Phase II study of savolitinib monotherapy in advanced or metastatic MET amplified gastric cancer (“GC”) or adenocarcinoma of the gastroesophageal junction (“GEJ”) (NCT04923932) – This is an open-label, two-cohort, multi-center study to evaluate the efficacy, safety and pharmacokinetics of savolitinib in locally advanced or metastatic GC or GEJ patients whose disease progressed after at least one line of standard therapy.

This trial follows multiple Phase II studies that have been conducted in Asia to study savolitinib in MET-driven GC patients, including VIKTORY²⁵. VIKTORY is an investigator-initiated Phase II umbrella study in GC in South Korea in which a total of 715 patients were successfully sequenced into molecular-driven patient groups, including those with MET amplified GC. Patients whose tumors harbor MET amplification were treated with savolitinib monotherapy, reporting an ORR of 50% (10/20, 95% CI: 28.0, 71.9).

Savolitinib opportunities are also continuing to be explored in multiple other MET-driven tumor settings via investigator-initiated studies including colorectal cancer.

About HUTCHMED

HUTCHMED (Nasdaq/AIM:HCM; HKEX:13) is an innovative, commercial-stage, biopharmaceutical company. It is committed to the discovery and global development and commercialization of targeted therapies and immunotherapies for the treatment of cancer and immunological diseases. It has more than 4,900 personnel across all its companies, at the center of which is a team of over 1,800 in oncology/immunology. Since inception it has advanced 12 cancer drug candidates from in-house discovery into clinical studies around the world, with its first three oncology drugs now approved and marketed. For more information, please visit: www.hutch-med.com or follow us on [LinkedIn](#).

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 HUTCHMED’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 HUTCHMED’s data to support New Drug Application approval of savolitinib for the treatment of patients with NSCLC in China, the U.S., E.U., Japan or other jurisdictions, the safety profile of savolitinib, the potential for savolitinib to become a new standard of care for patients with NSCLC and other types of cancer, its ability to implement and complete its further clinical development plans for savolitinib, the potential commercial launch of savolitinib in the U.S., E.U., Japan, 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 HUTCHMED's filings with the U.S. Securities and Exchange Commission, on AIM and with The Stock Exchange of Hong Kong Limited. HUTCHMED 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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