

Press Release

HUTCHMED Highlights Savolitinib SAVANNAH Phase II and Other Data at European Lung Cancer Congress 2025

— SAVANNAH Phase II trial demonstrated high and durable response rates with savolitinib plus TAGRISSO® in MET-high lung cancer, representing a promising chemo-free oral treatment strategy to address mechanisms of resistance in the advanced setting —

— Long-term survival benefit and safety observed in savolitinib Phase IIIb study in METex14 NSCLC —

Hong Kong, Shanghai & Florham Park, NJ — Thursday, March 20, 2025: HUTCHMED (China) Limited (“[HUTCHMED](#)”) (Nasdaq/AIM: HCM; HKEX: 13) today announces that new and updated data from several studies of compounds discovered by HUTCHMED, savolitinib and surufatinib, will be presented at the European Lung Cancer Congress (ELCC) 2025, taking place on March 26-29, 2025 in Paris, France.

Title: SAVANNAH: Savolitinib (savo) + osimertinib (osi) in patients (pts) with EGFRm advanced NSCLC and MET overexpression (OverExp) and/or amplification (Amp) following progressive disease (PD) on osi

Lead Author: Myung-Ju Ahn, Samsung Medical Center, Sungkyunkwan University School of Medicine, Seoul, Republic of Korea

Session: [Proffered Paper session 1](#)

Abstract Number: #20

Date & Time: Wednesday, March 26, 2025, 16:45 Central European Time

Location: South Paris Room

Results from the SAVANNAH Phase II trial (NCT03778229) showed savolitinib (300mg BID¹) plus TAGRISSO® demonstrated a clinically meaningful and durable objective response rate (“ORR”) in patients with epidermal growth factor receptor mutated (“EGFRm”) non-small cell lung cancer (“NSCLC”) with high levels of MET overexpression and/or amplification whose disease progressed on treatment with first line TAGRISSO®.

Savolitinib plus TAGRISSO® demonstrated confirmed ORR of 56% (95% CI²: 45%–67%) and 55% (95% CI: 43%–66%), median duration of response (“DoR”) of 7.1 (95% CI: 5.6–9.6) and 9.9 (95% CI: 6.0–13.7) months, and median progression-free survival (“PFS”) of 7.4 (95% CI: 5.5–7.6) and 7.5 (95% CI: 6.4–11.3) months by investigator and blinded independent central review (BICR) assessment, respectively.

Safety results and discontinuation rates due to adverse events were consistent with the established profiles of each medicine and no new safety concerns were reported. In all patients treated with savolitinib (300mg BID) plus TAGRISSO®, Grade 3 or higher adverse events (AEs) occurred in 57% and Grade 3 or higher treatment related adverse events (TRAEs) occurred in 32% of the patients.

Savolitinib is an oral, potent and highly selective MET tyrosine kinase inhibitor (“TKI”) being jointly developed and commercialized by AstraZeneca and HUTCHMED. In 2023, savolitinib and TAGRISSO® received Fast Track Designation from the US Food and Drug Administration (FDA) in this setting.

Title: Final Overall Survival and Long-term Safety Outcomes of Savolitinib in Patients with Locally Advanced or Metastatic NSCLC Harboring MET Exon 14 (METex14) Mutation: An Update from a Phase 3b Study

Lead Author: Yongfeng Yu, Shanghai Chest Hospital, Shanghai Jiao Tong University School of Medicine, Shanghai, China

Session: [Poster Display session](#)

Abstract Number: #80P

Date & Time: Friday March 28, 2025, 13:00 Central European Time

Location: Poster area

Updated results from the savolitinib Phase IIIb study in China demonstrated survival benefits and long-term safety in MET exon 14 skipping alteration NSCLC, particularly in treatment-naïve patients (NCT04923945). Among the 166 patients who received savolitinib treatment, the median follow-ups for 87 treatment-naïve patients and 79 previously treated patients were 34.5 and 25.1 months, respectively. In 87 treatment-naïve patients, median overall survival (“OS”) was 28.3 months (95% CI: 17.5–not evaluable), and the 36-month OS rate was 44.7%. In 79 previously treated patients, median OS was 25.3 months (95% CI: 20.5–30.5), and the 24-month OS rate was 51.7%. Post-hoc OS subgroup analysis suggested that patients with baseline brain metastasis also gain survival benefit with median OS of 15.3 months and 25.3 months in treatment-naïve patients (10/87 patients) and previously treated (21/79 patients) with brain metastasis, respectively. No new safety signal was observed.

Savolitinib is approved in China under the brand name ORPATHYS® for this patient population.

Title: Final overall survival (OS) of surufatinib plus PD-1/PD-L1 antibodies as maintenance therapy following first line (1L) platinum-based chemotherapy (Chemo) plus PD-1/PD-L1 antibodies in patients (pts) with extensive-stage small cell lung cancer (ES-SCLC)

Lead Author: Yi Hu, Chinese PLA General Hospital, Beijing, China

Session: [Poster Display session](#)

Abstract Number: #310P

Date & Time: Friday March 28, 2025, 13:00 Central European Time

Location: Poster area

Results from the exploratory study suggests surufatinib plus immunotherapy as maintenance therapy following first line chemo-immunotherapy demonstrated durable survival benefit for patients with extensive-stage small cell lung cancer (“SCLC”) patients (NCT05509699). At data cut-off on July 31, 2024, a total of 21 patients were enrolled in this single arm Phase IIa part of the study and received at least one dose of surufatinib plus PD-1/PD-L1 antibodies treatment. The median follow-up duration was 17.1 months for maintenance and 22.5 months for first line (induction + maintenance) therapy. The 12-month and 18-month OS rates were both 57.1% for maintenance therapy; and 85.7% and 57.1% for first line therapy.

About NSCLC and SAVANNAH

Lung cancer is the leading cause of cancer death among men and women, accounting for about one-fifth of all cancer deaths. Lung cancer is broadly split into SCLC or NSCLC, the latter accounting for about 80% of cases. Approximately 10 to 15% of patients with NSCLC in the US and Europe and 30 to 40% of patients in Asia have an epidermal growth factor receptor (“EGFR”) mutation. While EGFR TKIs have significantly improved outcomes in the first line setting, treatment resistance and disease progression are extremely common, and a significant unmet need exists in later-line settings for effective and well-tolerated treatment options.

SAVANNAH is an ongoing randomized, global Phase II trial studying the efficacy of savolitinib added to TAGRISSO® in patients with EGFRm, locally advanced or metastatic NSCLC with MET overexpression and/or amplification who progressed following treatment with TAGRISSO®. Based on the original single-arm trial design, patients were treated with savolitinib 300 or 600mg QD³ or 300mg BID, in combination with oral TAGRISSO® 80mg QD. In 2022, a comparison of savolitinib 300 mg BID and TAGRISSO® 80 mg QD to savolitinib 300mg BID and placebo was added to the trial to evaluate contribution of components.

The trial enrolled over 360 patients in more than 80 centers globally, including in North America, Europe, South America and Asia. The primary endpoint is ORR and key secondary endpoints include PFS and DoR.

In [August 2022](#), positive interim results from the SAVANNAH trial were presented at the International Association for the Study of Lung Cancer 2022 World Conference on Lung Cancer (WCLC).

The global SAFFRON Phase III trial is currently ongoing to further assess the savolitinib plus TAGRISSO® combination versus platinum-based doublet chemotherapy in patients with EGFRm, MET-overexpressed and/or amplified, locally advanced or metastatic NSCLC following TAGRISSO®. Patients are being prospectively selected using the high MET level cut-off identified in SAVANNAH.

About Savolitinib

Savolitinib is an oral, potent, and highly selective MET TKI that has demonstrated clinical activity in advanced solid tumors. MET is a tyrosine kinase receptor that has an essential role in normal cell development. Savolitinib

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), gene amplification or protein overexpression. MET overexpression and/or amplification can lead to tumor growth and the metastatic progression of cancer cells, and is a known mechanism of acquired resistance to EGFR TKIs. The prevalence of MET depends on the sample type, detection method and assay cut-off used.

Savolitinib is approved in China and is marketed under the brand name ORPATHYS® by our partner, AstraZeneca, for the treatment of adult patients with locally advanced or metastatic NSCLC with MET exon 14 skipping alteration, representing the first selective MET inhibitor approved in China. It has been [included](#) in the National Reimbursement Drug List of China (“NRDL”) since March 2023.

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.

About Surufatinib

Surufatinib is a novel, oral angio-immuno kinase inhibitor that selectively inhibits the tyrosine kinase activity associated with vascular endothelial growth factor receptors (VEGFRs) and fibroblast growth factor receptor (FGFR), which both inhibit angiogenesis, and colony stimulating factor-1 receptor (CSF-1R), which regulates tumor-associated macrophages, promoting the body’s immune response against tumor cells. Its unique dual mechanism of action may be very suitable for possible combinations with other immunotherapies, where there may be synergistic anti-tumor effects.

Surufatinib is marketed in China by HUTCHMED under the brand name SULANDA®, and was first included in the NRDL in January 2022 for the treatment of non-pancreatic and pancreatic neuroendocrine tumors (NETs).

About HUTCHMED

HUTCHMED (Nasdaq/AIM:HCM; HKEX:13) is an innovative, commercial-stage, biopharmaceutical company. It is committed to the discovery, global development and commercialization of targeted therapies and immunotherapies for the treatment of cancer and immunological diseases. Since inception, it has focused on bringing drug candidates from in-house discovery to patients around the world, with its first three medicines marketed in China, and the first of which is also approved around the world including in the US, Europe and Japan. 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 the savolitinib or surufatinib for the treatment of patients with lung cancer and the further clinical development of the savolitinib or surufatinib in this and other indications. Forward-looking statements involve risks and uncertainties. Such risks and uncertainties include, among other things, assumptions regarding the timing and outcome of clinical studies and the sufficiency of clinical data to support New Drug Application approval of the savolitinib or surufatinib in lung cancer or other indications in the US, China or other jurisdictions, its potential to gain approvals from regulatory authorities on an expedited basis or at all, the safety profile of savolitinib or surufatinib, HUTCHMED’s ability to fund, implement and complete its further clinical development and commercialization plans for savolitinib or surufatinib and the timing of these events. In addition, as certain studies rely on the use of other drug products such as osimertinib as combination therapeutics with savolitinib and PD-1/PD-L1 antibodies as combination therapeutics with surufatinib, such risks and uncertainties include assumptions regarding the safety, efficacy, supply and continued regulatory approval of these therapeutics. 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 on 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.

Medical Information

This press release contains information about products that may not be available in all countries, or may be available under different trademarks, for different indications, in different dosages, or in different strengths. Nothing contained herein should be considered a solicitation, promotion or advertisement for any prescription drugs including the ones under development.

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References & Abbreviations¹ BID = Twice per day.² CI = Confidence interval.³ QD = Once per day.