

Press Release

**HUTCHMED Highlights SACHI Phase III Study Data Presented at the 2025 ASCO Annual Meeting**

*- The all-oral chemotherapy-free combination of savolitinib plus osimertinib demonstrated significant PFS benefit with a favorable safety profile in the SACHI Phase III China study -*

*- Webcast to be held at 8:30 am HKT on Tuesday, June 3 to discuss the data presented -*

**Hong Kong, Shanghai & Florham Park, NJ - Monday, June 2, 2025:** HUTCHMED (China) Limited ("[HUTCHMED](#)") (Nasdaq/AIM: HCM; HKEX: 13) announces primary results from the interim analysis of the SACHI Phase III study. These results were presented in a late-breaking oral presentation on Sunday, June 1, 2025, during the American Society of Clinical Oncology ("ASCO") Annual Meeting in Chicago, USA.

SACHI is a Phase III study of the savolitinib and osimertinib combination for the treatment of patients with locally advanced or metastatic epidermal growth factor receptor ("EGFR") mutation-positive non-small cell lung cancer ("NSCLC") with MET amplification after disease progression on first-line EGFR inhibitor therapy (clinicaltrials.gov identifier [NCT05015608](#)).

**Title:** Savolitinib combined with osimertinib versus chemotherapy in EGFR-mutant and MET-amplification advanced NSCLC after disease progression on EGFR tyrosine kinase inhibitor: Results from a randomized Phase III SACHI study

**Lead Author:** Shun Lu, Shanghai Chest Hospital, Shanghai Jiao Tong University School of Medicine, Shanghai, China

**Session:** Oral Abstract Session: Lung Cancer - Non-Small Cell Metastatic

**Abstract Number:** [LBA8505](#)

**Date & Time:** Sunday, June 1, 2025, 8:00 AM Central Daylight Time

**Location:** Arie Crown Theater

**Prof. Shun Lu, Chief of the Shanghai Lung Cancer Center at Shanghai Chest Hospital, School of Medicine, Shanghai Jiaotong University, and Principal Investigator of the SACHI study,** said, "The results from the SACHI Phase III study represent a significant advancement in the treatment of EGFR mutation-positive NSCLC with MET amplification. The savolitinib and osimertinib combination demonstrates promising efficacy in patients who have progressed on prior EGFR inhibitor therapy. These findings highlight the potential of this novel, chemotherapy-free combination to enable a continued oral regimen, offering a convenient and well-tolerated treatment option that addresses critical unmet needs for patients with this challenging disease."

**HUTCHMED will host a webcast to discuss the data presented at the ASCO Annual Meeting at 8:30 - 9:00 am HKT on Tuesday, June 3, 2025 (8:30 - 9:00 pm EDT on June 2, 2025).** The event will be held in English and can be accessed via [www.hutch-med.com/event](http://www.hutch-med.com/event). A replay will also be available on the website shortly after the event.

As of the interim analysis data cut-off of August 30, 2024, a total of 211 patients were randomized to receive the savolitinib and osimertinib combination or chemotherapy. In the intention to treat (ITT) population, the median progression-free survival ("PFS") assessed by investigator was 8.2 months with savolitinib plus osimertinib, compared to 4.5 months with chemotherapy (hazard ratio ["HR"] 0.34; 95% confidence interval ["CI"] 0.23-0.49;  $p < 0.0001$ ). The independent review committee ("IRC") assessed median PFS was 7.2 months vs 4.2 months, respectively (HR 0.40; 95% CI 0.28-0.59;  $p < 0.0001$ ).

The investigator-assessed objective response rate (ORR) was 58% in the savolitinib plus osimertinib group compared to 34% for patients in the chemotherapy group. The disease control rate (DCR) was 89% vs 67% and the median duration of response (DoR) was 8.4 months vs 3.2 months, respectively. Overall survival was not mature at the time of the interim analysis.

Efficacy outcomes in the third-generation EGFR tyrosine kinase inhibitor ("TKI")-treated patients were comparable with those in the intention-to-treat and third-generation EGFR-TKI-naïve populations. In the third generation EGFR-TKI-treated subgroup, the investigator-assessed and IRC-assessed median PFS were highly consistent, both at 6.9 vs 3.0 months (HR 0.32;  $p < 0.0001$ ).

The safety profile of the savolitinib and osimertinib combination was tolerable and no new safety signals were observed. Treatment-emergent adverse events of Grade 3 or above occurred in 57% of patients in the savolitinib plus osimertinib group compared to 57% for patients in the chemotherapy group, suggesting a favorable safety profile.

In January 2025, the Independent Data Monitoring Committee (IDMC) of SACHI has considered that the study has met the pre-defined primary endpoint of PFS in a planned interim analysis and as a result, enrollment into the study has concluded. Supported by data from SACHI, a New Drug Application (NDA) for the combination of savolitinib and osimertinib for the treatment of patients with locally advanced or metastatic EGFR mutation-positive NSCLC with MET amplification after disease progression on first-line EGFR inhibitor therapy has been accepted and granted priority review by the China National Medical Products Administration (NMPA).

## 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 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. 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, 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](http://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 US Private Securities Litigation Reform Act of 1995. These forward-looking statements reflect HUTCHMED's current expectations regarding future events, including but not limited to its expectations regarding the therapeutic potential of savolitinib, the further clinical development for savolitinib, its expectations as to whether any studies on 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. Such risks and uncertainties include, among other things, assumptions regarding enrollment rates and the 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 savolitinib, including as combination therapies, to meet the primary or secondary endpoint of a study, to obtain regulatory approval in different jurisdictions and to gain commercial acceptance after obtaining regulatory approval; the potential markets of savolitinib for a targeted indication, and the sufficiency of funding. In addition, as certain studies rely on the use of other drug products such as osimertinib as combination therapeutics, such risks and uncertainties include assumptions regarding their safety, efficacy, supply and continued regulatory approval. 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 US Securities and Exchange Commission, The Stock Exchange of Hong Kong Limited and on AIM. 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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