

Press Release

HUTCHMED Highlights Presentation of Results from the Phase IIIb Trial of Savolitinib at the 2023 World Conference of Lung Cancer

Hong Kong, Shanghai & Florham Park, NJ — Tuesday, September 12, 2023: HUTCHMED (China) Limited (“[HUTCHMED](#)”) (Nasdaq/AIM: HCM, HKEX: 13) today announces that results from the confirmatory Phase IIIb clinical trial of savolitinib in patients with mesenchymal epithelial transition factor (“MET”) exon 14 skipping alteration non-small cell lung cancer (“NSCLC”), were presented during the IASLC 2023 World Conference on Lung Cancer hosted by the International Association for the Study of Lung Cancer (“WCLC”), which took place from September 9 to 12, 2023 in Singapore.

Title: **A Phase 3b Study of 1L Savolitinib in Patients with Locally Advanced or Metastatic NSCLC Harboring MET Exon 14 Mutation**
Lead Author: Shun Lu, MD, head of Shanghai Lung Cancer Center, Shanghai Chest Hospital, Shanghai Jiaotong University
Type: Oral presentation
Abstract Number: OA21.03
Session: OA21. MET Matters in NSCLC
Date & Time: Tuesday, September 12, 2023, 2:32-2:42 pm Singapore time
Location: Room 406, Suntec Singapore Convention & Exhibition Centre
Abstract Link: <https://cattendee.abstractsonline.com/meeting/10925/presentation/995>

Here we reported initial efficacy and safety data from the first-line cohort of a confirmatory Phase IIIb trial conducted in China of savolitinib as a monotherapy in patients with NSCLC MET exon 14 skipping alterations ([NCT04923945](#)). At data cut-off date of April 30, 2023, among the 84 patients in the tumor response evaluable set (TRES), objective response rate (ORR) was 60.7% (95% Confidence Interval (“CI”): 49.5% to 71.2%) and disease control rate (DCR) was 95.2% (95% CI: 88.3% to 98.7%), as assessed by an independent review committee. At median follow-up of 11.1 months, median progression free survival (mPFS) was 13.8 months (95% CI: 9.7 months to not reached). Median duration of response (DoR) and overall survival (OS) have not been reached. No new safety signals were observed.

The other cohort of this confirmatory trial was fully enrolled in H1 2023 and included patients who received prior treatments. The trial follows the June 2021 approval of savolitinib as a monotherapy in this indication from China’s National Medical Products Administration (NMPA), which was based on positive results from a Phase II trial ([NCT02897479](#)). This confirmatory trial enrolled a more representative proportion of the different NSCLC subtypes, which may confer different prognostic outcomes.

More than a third of the world’s lung cancer patients are in China and, among those with NSCLC globally, approximately 2-3% have tumors with MET exon 14 skipping alterations. Savolitinib was launched and is marketed under the brand name ORPATHYS® by our partner, AstraZeneca for this patient population, representing the first selective MET inhibitor approved in China.

Title: **Computational Pathology-Based Assessment of cMET IHC Expression for Patient Selection in the Treatment of MET Overexpressing NSCLC**
Lead Author: Simon Christ, AstraZeneca
Type: E-Poster
Abstract Number: EP06.05-09
Session: EP06.05 Pathology and Biomarkers - Pathology
Abstract Link: <https://cattendee.abstractsonline.com/meeting/10925/presentation/1348>

A Quantitative Continuous Scoring (QCS) algorithm is being developed as an automated methodology to identify patients who are most likely to respond to treatment. This e-poster showcased the application of this method based on information collected in the Phase II SAVANNAH study. The global Phase III study SAFFRON will serve as an additional independent validation cohort.

About Savolitinib (ORPATHYS® in China)

Savolitinib is an oral, potent and highly selective MET tyrosine kinase inhibitor 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), gene amplification or protein overexpression.

Savolitinib is [marketed](#) in China under the brand name ORPATHYS® for the treatment of patients with non-small cell lung cancer 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. Starting on March 1, 2023, ORPATHYS® was [included](#) in the National Reimbursement Drug List (NRDL) for the treatment of locally advanced or metastatic NSCLC adult patients with MET exon 14-skipping alterations who have progressed after or unable to tolerate platinum-based chemotherapy.

In 2011, 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.

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 approximately 5,000 personnel across all its companies, at the center of which is a team of about 1,800 in oncology/immunology. Since inception it has focused on bringing cancer drug candidates from in-house discovery to patients around the world, with its first three oncology drugs now approved and marketed in China. 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, 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. Forward-looking statements involve risks and uncertainties. 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 a combination therapy, 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 market of savolitinib for a targeted indication; the sufficiency of funding; and the impact of COVID-19 on general economic, regulatory and political conditions. 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, 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.

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