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HUTCHMED (China) Limited

和黃醫藥(中國)有限公司

 $(Incorporated\ in\ the\ Cayman\ Islands\ with\ limited\ liability)$

(Stock Code: 13)

VOLUNTARY ANNOUNCEMENT

HUTCHMED Highlights Data to be Presented at AACR Annual Meeting 2025

HUTCHMED (China) Limited ("<u>HUTCHMED</u>") today announces that new and updated data from several studies of compounds discovered by HUTCHMED including savolitinib, fruquintinib and surufatinib, which will be presented at the upcoming American Association of Cancer Research (AACR) Annual Meeting 2025, taking place on April 25-30, 2025 in Chicago, Illinois.

Details of the presentations are as follows:

Presenter / Lead author	Presentation details
Xianwen Yang, HUTCHMED,	4450
Shanghai, China	Poster Session (PO.ET03.04) Tuesday, April 29, 2025
Jonathan W. Riess, University of California, UC Davis Comprehensive	LB416 Late-Breaking Poster Session
Cancer Center, CA, US	(LBPO.CL04) Wednesday, April 30, 2025
Kowser Miah, AstraZeneca, Waltham, MA, US	4353 Poster Session (PO.ET07.01)
	Xianwen Yang, HUTCHMED, Shanghai, China Jonathan W. Riess, University of California, UC Davis Comprehensive Cancer Center, CA, US Kowser Miah, AstraZeneca, Waltham,

INVESTIGATOR-INITIATED STUDIES		
A multi-cohort study of treatment regimens for metastatic colorectal cancer (mCRC): Subgroup analysis of sequential therapy between fruquintinib and regorafenib	Wangxia Lv, Cancer Hospital of the University of Chinese Academy of Sciences/ Zhejiang Cancer Hospital, Hangzhou, China	CT085 Poster Session (PO.CT02.03) Monday, April 28, 2025
Phase Ib/II study of fruquintinib (F) combined with capecitabine (C) as maintenance therapy (MT) for RAS/BRAF wild-type metastatic colorectal cancer (mCRC) after first-line treatment with cetuximab combined with chemotherapy	Lin Yang/ Kai Ou, Chinese Academy of Medical Sciences and Peking Union Medical College, Beijing, China	CT222 Poster Session (PO.CT02.02) Tuesday, April 29, 2025
Tyrosine kinase inhibitor (TKI) plus PD-1 blockade in TKI-responsive MSS/pMMR metastatic colorectal adenocarcinoma (mCRC): Results of a multicenter, phase II trial (TRAP)	Jingdong Zhang/ Qian Dong, Liaoning Cancer Hospital & Institute, Cancer Hospital of Dalian University of Technology, Shenyang, China	6002 Poster Session (PO.CL08.03) Tuesday, April 29, 2025



Abstract title	Presenter / Lead author	Presentation details
Efficacy and mechanism of radiotherapy combined with fruquintinib and tislelizumab in mCRC	Xianglin Yuan, Tongji Hospital, Tongji Medical College, Huazhong University of Science and Technology, Wuhan, China	1828 Poster Session (PO.ET08.02) Monday, April 28, 2025
Prediction of surufatinib treatment outcome in advanced grade 3 neuroendocrine tumors (NET G3) patients	Jing Hao, Qilu Hospital of Shandong University, Jinan, China	CT084 Poster Session (PO.CT02.03) Monday, April 28, 2025
Surufatinib and sintilimab in combination with capecitabine for previously treated metastatic small bowel adenocarcinoma or appendiceal carcinoma: A single-arm, single-center, phase Ib/II trial	Yanhong Deng/ Xiaoyu Xie, The Sixth Affiliated Hospital of Sun Yat-sen University, Guangzhou, China	CT033 Poster Session (PO.CT01.03) Monday, April 28, 2025
GPR34-driven damage-response macrophages underlie therapeutic resistance to surufatinib	Song Gao, Tianjin Medical University Cancer Institute and Hospital, Tianjin, China	6818 Poster Session (PO.ET07.02) Wednesday, April 30, 2025
Efficacy and mechanism of surufatinib combination with PD-1 monoclonal antibody and chemotherapy for the treatment of pancreatic cancer with liver metastasis in animal models	Guanghai Dai/ Ru Jia, The Fifth Medical Center, Chinese PLA General Hospital, Beijing, China	6824 Poster Session (PO.ET07.02) Wednesday, April 30, 2025
Efficacy and mechanistic insights of Shengyang Qushi Decoction in managing surufatinib-associated diarrhea	Huangying Tan, China-Japan Friendship Hospital, Beijing, China	1043 Poster Session (PO.PR02.03) Sunday, April 27, 2025

About Lung Cancer

Lung cancer is the leading cause of cancer death, accounting for about one-fifth of all cancer deaths.¹ More than a third of the world's lung cancer patients are in China. Lung cancer is broadly split into non-small cell lung cancer ("NSCLC") and small cell lung cancer, with NSCLC accounting for about 80% of cases.² Approximately 10-15% of NSCLC patients in the US and Europe and 30-40% of patients in Asia have an epidermal growth factor receptor ("EGFR") mutation ("EGFRm").³,4,5,6 Approximately 2-3% of NSCLC patients have tumors with MET exon 14 skipping alterations, a targetable mutation in the MET gene.¹

About Savolitinib and MET Aberrations in Lung Cancer

Savolitinib is an oral, potent, and highly selective MET tyrosine kinase inhibitor ("TKI") being jointly developed by AstraZeneca and HUTCHMED and commercialized by AstraZeneca. MET is a tyrosine kinase receptor that has an essential role in normal cell development.⁸ 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.^{8,9} 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 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 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 Savolitinib in combination with TAGRISSO® (osimertinib)

Among patients who experience disease progression following treatment with a third-generation EGFR TKI, approximately 15-50% present with MET aberration, depending on the sample type, detection method and assay cut-off used. TAGRISSO® is a third-generation, irreversible EGFR-TKI with proven clinical activity in NSCLC, including against central nervous system metastases. Treatment with savolitinib in combination with TAGRISSO® has been studied extensively in these patients in the TATTON (NCT02143466) and SAVANNAH (NCT03778229) studies. The encouraging results led to the initiation of several



Phase III trials in this setting including the SACHI trial in China (NCT05015608) and the global SAFFRON trial (NCT05261399), as well as the SANOVO trial in China (NCT05009836).

This combination represents a promising chemo-free oral treatment strategy to address mechanisms of resistance in this advanced setting. Positive data from the SACHI randomized Phase III trial has led to the <u>filing of a second New Drug Application ("NDA") in China</u>. Strong data from the SAVANNAH single-arm Phase II study was recently <u>presented at the European Lung Cancer Congress</u> (ELCC) in March 2025 demonstrated high, clinically meaningful and durable objective response rate (ORR), with consistent safety results. The SAFFRON randomized Phase III trial is progressing. Following AstraZeneca's consultation with the US Food and Drug Administration ("FDA"), we look forward to completing the SAFFRON trial as soon as possible to support potential US and other global registration filings.

SACHI: The SACHI China Phase III trial met the primary endpoint of progression free survival (PFS) during its interim analysis towards the end of 2024 and a NDA was accepted and granted Breakthrough Therapy Designation and Priority Review status in China in December 2024. SACHI evaluated the combination of savolitinib and TAGRISSO* for the treatment of patients with EGFRm, MET-amplified locally advanced or metastatic NSCLC after progression on EGFR TKI compared to platinum-based doublet chemotherapy. Results will be presented at an upcoming scientific conference.

SAFFRON: In 2023, savolitinib and TAGRISSO® received Fast Track Designation from the US FDA in this setting. The global SAFFRON Phase III trial is currently ongoing to 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 progression on treatment with TAGRISSO®. Patients are being prospectively selected using the high MET level cut-off identified in SAVANNAH.

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 or follow us on LinkedIn.

Forward-Looking Statements

This announcement 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 fruquintinib, savolitinib and surufatinib, the further clinical development for fruquintinib, savolitinib and surufatinib, its expectations as to whether any studies on fruquintinib, savolitinib and surufatinib 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 fruquintinib, savolitinib and surufatinib, 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 fruquintinib, savolitinib and surufatinib for a targeted indication, and the sufficiency of funding. In addition, as certain studies rely on the use of osimertinib, capecitabine, sintilimab or tislelizumab, 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

Medical Information

This announcement 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.



- ⁵ Zhang Y, et al. The prevalence of EGFR mutation in patients with non-small cell lung cancer: a systematic review and meta-analysis. *Oncotarget*. 2016;7(48). DOI: 10.18632/oncotarget.12587.
- ⁶ Szumera-Ciećkiewicz A, *et al.* EGFR Mutation Testing on Cytological and Histological Samples in 11. Non-Small Cell Lung Cancer: a Polish, Single Institution Study and Systematic Review of European Incidence. *Int J Clin Exp Pathol.* 2013:6;2800-12. PMID: 24294366.
- Vuong HG, et al. Clinicopathological implications of MET exon 14 mutations in non-small cell lung cancer A systematic review and meta-analysis. Lung Cancer. 2018; 123: 76-82. DOI: 10.1016/j.lungcan.2018.07.006.
- ⁸ Uchikawa E, et al. Structural basis of the activation of c-MET receptor. Nat Commun. 2021;12(4074). DOI: 10.1038/s41467-021-24367-3.
- ⁹ Wang Q, et al. MET inhibitors for targeted therapy of EGFR TKI-resistant lung cancer. *Journal of Hematology & Oncology.* 2019;63. DOI: <u>10.1186/s13045-</u>019-0759-9.

By Order of the Board

Edith Shih

Non-executive Director and Company Secretary

Hong Kong, April 24, 2025

As at the date of this announcement, the Directors of the Company are:

Chairman and Non-executive Director:

Dr Dan ELDAR

Executive Directors:

Dr Weiguo SU

(Chief Executive Officer and
Chief Scientific Officer)

Mr CHENG Chig Fung, Johnny
(Chief Financial Officer)

Non-executive Directors:

Ms Edith SHIH Ms Ling YANG

Independent Non-executive Directors:

Mr Paul Rutherford CARTER
(Senior Independent Director)
Dr Renu BHATIA
Dr Chaohong HU
Mr Graeme Allan JACK
Professor MOK Shu Kam, Tony
Mr WONG Tak Wai

World Health Organization. International Agency for Research on Cancer. All cancers fact sheet. Available at: https://gco.iarc.who.int/media/globocan/factsheets/cancers/39-all-cancers-fact-sheet.pdf. Accessed November 2022.

² American Cancer Society. What is Lung Cancer? Available at: https://www.cancer.org/cancer/types/lung-cancer/about/what-is.html. Accessed November 2022.

³ Knight SB, et al. Progress and prospects of early detection in lung cancer. Open Biol. 2017;7(9): 170070. DOI: 10.1098/RSOB.170070.

⁴ Keedy VL, et al. American Society of Clinical Oncology Provisional Clinical Opinion: Epidermal Growth Factor Receptor (EGFR) Mutation Testing for Patients with Advanced Non-Small-Cell Lung Cancer Considering First-Line EGFR Tyrosine Kinase Inhibitor Therapy. J Clin Oncol. 2011:29;2121-27. DOI: 10.1200/JCO.2010.31.8923.