Press Release

HUTCHMED Highlights Clinical Data to be Presented at the 2025 ASCO Annual Meeting

Hong Kong, Shanghai & Florham Park, NJ — Friday, May 23, 2025: HUTCHMED (China) Limited ("HUTCHMED") (Nasdaq/AIM:HCM; HKEX:13) today announces that new data from several studies of compounds discovered by HUTCHMED including savolitinib, ranosidenib, fruquintinib and surufatinib, will be presented at the American Society of Clinical Oncology ("ASCO") Annual Meeting taking place on May 30 – June 3, 2025 in Chicago, USA.

Results from the SACHI China Phase III study of savolitinib in combination with osimertinib in 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 EGFR inhibitor therapy will be presented at a late breaking oral presentation. SACHI had met the pre-defined primary endpoint of progression-free survival (PFS) in a planned interim analysis. SACHI data supports the New Drug Application (NDA) for this oral-only treatment, which has been accepted and granted priority review in China.

Further data with additional analysis stratified by brain metastasis status from a high MET overexpression and/or amplification treatment subset of the SAVANNAH Phase II study of the savolitinib and osimertinib combination in NSCLC patients harboring EGFR mutation and MET amplification or overexpression after progressing on osimertinib were reported. The savolitinib and osimertinib combination demonstrated better efficacy outcomes compared to savolitinib plus placebo. The combination showed promising central nervous system ("CNS") activity, with reduced CNS progression and fewer new CNS lesions.

Results will be presented from the dose-escalation stage of the Phase I study of ranosidenib (HMPL-306), a novel, small-molecule, highly selective oral dual-inhibitor of both Isocitrate dehydrogenase ("IDH") 1 and IDH2 enzymes, being studied in patients with locally advanced or metastatic solid tumors with IDH mutations. Results show that the compound was well tolerated, showing target inhibition and durable responses in patients. Efficacy signals were observed especially in the efficacy evaluated group of lower-grade glioma patients (N=14), with an objective response rate ("ORR") of 7.1% and a disease control rate ("DCR") of 100%.

Results will also be presented from the sub-group analyses of the FRUSICA-1 open-label, single-arm, pivotal Phase II study to evaluate the efficacy and safety of fruquintinib plus sintilimab in previously treated advanced endometrial cancer (EMC) patients with pMMR (proficient mismatch repair) status. Efficacy findings for patients with serous carcinoma (N=27) were clinically meaningful and characterized by responses similar to those observed in full trial population (N=98), with an Independent Review Committee ("IRC")-assessed ORR of 37.0% and a DCR of 88.9%. The analysis of whether the response was affected by prior neoadjuvant/adjuvant chemotherapy ("NACT/ACT") showed durable and clinically meaningful responses regardless of whether the patient had received NACT/ACT. Results were comparable for patients with and without prior NACT/ACT, with an IRC-assessed ORR of 34.0% versus 31.4% and DCR of 85.1% versus 82.4%, respectively.

Results from two subgroup analyses of a Phase IV study of fruquintinib involving 2,798 colorectal cancer patients in China will be presented. In the subgroup analysis evaluating the safety of fruquintinib as monotherapy and in combination therapy, fruquintinib demonstrated a manageable safety profile in both groups. Treatment-emergent adverse events (TEAE) of Grade 3 or above occurred in 23.94% in the fruquintinib monotherapy group and 26.06% in the combination therapy group with other anti-cancer treatments. The most common treatment related adverse events (TRAE) of any grade in both groups were palmar-plantar erythrodysesthesia (PPES) and hypertension. The combination therapy group exhibited a longer treatment duration, potentially indicating improved patient outcomes. In the subgroup analysis by age, the safety of fruquintinib was assessed in younger (age <50) and late-elderly (age ≥75) patients. The safety profile was comparable across both age groups, with younger patients receiving more intensive treatment. Combination therapy with fruquintinib also showed a longer duration than monotherapy in both age subgroups, which may suggest improved survival potential.

Details of the presentations, including links to available abstracts, are as follows:

Abstract title	Presenter / Lead author	Presentation details
SPONSORED STUDIES		
Savolitinib (Savo) combined with osimertinib (osi) versus chemotherapy (chemo) in EGFR-mutant (EGFRm) and *MET*-amplification (*MET*amp) advanced NSCLC after disease progression (PD) on EGFR tyrosine kinase inhibitor (TKI): Results from a randomized phase 3 SACHI study	Shun Lu, Shanghai Chest Hospital, Shanghai Jiao Tong University School of Medicine, Shanghai, China	LBA8505 Oral Abstract Session: Lung Cancer - Non-Small Cell Metastatic Sunday, June 1, 2025 9:48 AM CDT
Efficacy and CNS results from a randomized subset of the phase 2 SAVANNAH study comparing savolitinib (savo) + osimertinib (osi) combination with savo + placebo (PBO)	Benjamin Philip Levy, Sidney Kimmel Comprehensive Cancer Center, Johns Hopkins University School of Medicine, Baltimore, MD	8513 Rapid Oral Session: Lung Cancer - Non-Small Cell Metastatic Monday, June 2, 2025 8:06 AM CDT
Phase I study of HMPL-306, an inhibitor of mutant IDH1/IDH2 (mIDH1/2), in western patients (pts) with advanced mIDH solid tumor, including glioma	Jordi Rodon Ahnert, The University of Texas MD Anderson Cancer Center, Houston, TX	2013 Rapid Oral Session: Central Nervous System Tumors Saturday, May 31, 2025 3:06 PM CDT
Analysis of serous carcinoma subgroup in FRUSICA-1: Fruquintinib plus sintilimab in treated advanced endometrial cancer (EMC) patients (pts) with pMMR status	Xiaohua Wu, Fudan University Shanghai Cancer Center, Shanghai, China	5596 Poster Session: Gynecologic Cancer
The Impact of Prior Neoadjuvant/Adjuvant Chemotherapy (NACT/ACT) on Fruquintinib Plus Sintilimab Outcomes in Advanced Endometrial Cancer (EMC) Patients with pMMR Status: A Subgroup Analysis of FRUSICA-1	Jing Wang, Hunan Cancer Hospital, Changsha, China	5611 Poster Session: Gynecologic Cancer
Safety of fruquintinib in young and late-elderly Chinese patients with colorectal cancer in real-world clinical practice: Age subgroup analysis of a fruquintinib Phase IV study	Yi Wang, Ningbo No.2 Hospital, Ningbo, China	e15512 Publication Only: Gastrointestinal Cancer - Colorectal and Anal
Safety of fruquintinib monotherapy and combination therapy in Chinese Patients with colorectal cancer in real-world clinical practice: A subgroup analysis from Phase IV study	Zhiqiang Wang, Sun Yat-Sen University Cancer Center, Guangzhou, China	e15515 Publication Only: Gastrointestinal Cancer - Colorectal and Anal
The appropriate therapeutic sequence with angiogenesis inhibitor and chemotherapy in patients with advanced gastric or gastroesophageal junction adenocarcinoma: Exploratory analysis from the Phase III FRUTIGA study	Jin Li, Shanghai East Hospital, Tongji University, Shanghai, China	e16011 Publication Only: Gastrointestinal Cancer - Gastroesophageal, Pancreatic, and Hepatobiliary
Subgroup analysis of efficacy and safety of fruquintinib plus paclitaxel versus paclitaxel in gastroesophageal junction adenocarcinoma patients from FRUTIGA: A randomized Phase III clinical trial in second-line treatment of gastric/gastroesophageal junction	Tianshu Liu, Zhongshan Hospital, Fudan University, Shanghai, Shanghai, China	e16012 Publication Only: Gastrointestinal Cancer - Gastroesophageal, Pancreatic, and Hepatobiliary
INVESTIGATOR-INITIATED STUDIES		
Fruquintinib in combination with camrelizumab and paclitaxel liposome and nedaplatin as first-line treatment for advanced esophageal squamous cell carcinoma (ESCC): a single-arm, Phase II study	Yanhong Gu, The First Affiliated Hospital of Nanjing Medical University, Nanjing, China	4042 Poster Session: Gastrointestinal Cancer - Gastroesophageal, Pancreatic, and Hepatobiliary
Updated results of fruquintinib combined with PD-1 inhibitors and chemotherapy in the first-line treatment of HER2-negative advanced gastric or gastroesophageal junction adenocarcinoma (FDZL-FIX): a single-arm, open-label Phase II study	Chenchen Wang, Fudan University Shanghai Cancer Center, Shanghai, China	4046 Poster Session: Gastrointestinal Cancer - Gastroesophageal, Pancreatic, and Hepatobiliary
Open-label, single-arm, single-center Phase Ib/II clinical study of fruquintinib combined with trastuzumab and XELOX in the first-line treatment of advanced HER2-positive metastatic gastric or gastroesophageal junction adenocarcinoma	Huifang Lv, The Affiliated Cancer Hospital of Zhengzhou University, Henan Cancer Hospital, Zhengzhou, China	TPS4203 Poster Session: Gastrointestinal Cancer - Gastroesophageal, Pancreatic, and Hepatobiliary

Abstract title	Presenter / Lead author	Presentation details
A multi-cohort real-world study of treatment for metastatic colorectal cancer (mCRC): Overall efficacy analysis and subgroup analysis of previous bevacizumab use or not	Wangxia Lv, The Cancer Hospital of the University of Chinese Academy of Sciences (Zhejiang Cancer Hospital), Hangzhou, China	e15530 Publication Only: Gastrointestinal Cancer - Colorectal and Anal
Real-world Observational Study of Fruquintinib in Combination with Irinotecan and Capecitabine as Second-line Treatment in Patients with Advanced Colorectal Cancer	Ling Xu, the First Hospital of China Medical University, Shenyang, China	e15539 Publication Only: Gastrointestinal Cancer - Colorectal and Anal
Preliminary results of fruquintinib in combination with FOLFIRI as second-line treatment for RAS-mutant metastatic colorectal cancer: a prospective single-center Phase II study	Ru Jia, Fifth Medical Center, Chinese PLA General Hospital, Beijing, China	e15541 Publication Only: Gastrointestinal Cancer - Colorectal and Anal
Evaluating the efficacy of fruquintinib versus regorafenib and trifluridine/tipiracil in treating advanced metastatic colorectal cancer: A match-adjusted indirect comparison	Shukui Qin, Gastrointestinal Cancer Center of Nanjing Tianyinshan Hospital, China Pharmaceutical University, Nanjing, China	e15550 Publication Only: Gastrointestinal Cancer - Colorectal and Anal
Fruquintinib plus sintilimab and SOX as conversion therapy for initially unresectable gastric/gastroesophageal junction adenocarcinoma (GC/GEJC): Updated response and surgical results from a single-arm, Phase II clinical trial	Fei Ma, Henan Cancer Hospital, Zhengzhou, China	e16016 Publication Only: Gastrointestinal Cancer - Gastroesophageal, Pancreatic, and Hepatobiliary
A Phase II study to evaluate the efficacy and safety of fruquintinib combined with envafolimab in patients with advanced or unresectable locally advanced osteosarcoma and soft tissue sarcoma	Chenliang Zhou, Shanghai Jiao Tong University Affiliated Sixth People's Hospital, Shanghai, China	e23506 Publication Only: Sarcoma
Efficacy and safety of surufatinib (Sur) plus paclitaxel (Pac) as second line (2L) treatment for advanced gastric cancer (aGC): Final results from a Phase II trial	Xiuying Xiao, Renji Hospital, Shanghai Jiao Tong University School of Medicine, Shanghai, China	4028 Poster Session: Gastrointestinal Cancer - Gastroesophageal, Pancreatic, and Hepatobiliary
Efficacy and safety of surufatinib (S) plus KN046 (K) and chemotherapy in first line (1L) advanced pancreatic cancer (PC): a single-arm, Phase Ib/II trial	Wenquan Wang, Zhongshan Hospital, Fudan University, Shanghai, China	4157 Poster Session: Gastrointestinal Cancer - Gastroesophageal, Pancreatic, and Hepatobiliary
First-Line Treatment with Surufatinib, Camrelizumab, Nab-paclitaxel, and S-1 in Locally Advanced or Metastatic Pancreatic Ductal Adenocarcinoma (PDAC): A Phase Ib/II Randomized Study	Ru Jia/ Guanghai Dai, the Fifth Medical Center of the PLA General Hospital, Beijing, China	4161 Poster Session: Gastrointestinal Cancer - Gastroesophageal, Pancreatic, and Hepatobiliary
A prospective, single-arm, Phase II trial exploring the use of pamiparib combined with surufatinib as neoadiuvant therapy for advanced, unresectable ovarian cancer (PASSION)	Bairong Xia, The First Affiliated Hospital of University of Science and Technology of China, Hefei, China	5589 Poster Session: Gynecologic Cancer
The efficacy and safety of Surufatinib monotherapy as a third-line treatment for advanced hepatocellular carcinoma: A single-arm, open-label, multi-center Phase II study	Fuxiang Zhou, Zhongnan Hospital of Wuhan University, Wuhan, China	e16209 Publication Only: Gastrointestinal Cancer - Gastroesophageal, Pancreatic, and Hepatobiliary
Surufatinib combined with gemcitabine and cisplatin and immune checkpoint inhibitor (ICI) for unresectable locally advanced or metastatic intrahepatic cholangiocarcinoma	Jingtao Zhang/ Xuetao Shi, Cancer Hospital of Shandong First Medical University, Jinan, China	e16222 Publication Only: Gastrointestinal Cancer - Gastroesophageal, Pancreatic, and Hepatobiliary
Updated results from a multicenter, single-arm Phase ll study of surufatinib plus sintilimab and lBl310 in patients with high-grade advanced neuroendocrine neoplasm (HG-NEN)	Ming Lu/ Lin Shen, Peking University Cancer Hospital, Beijing, China	e16342 Publication Only: Gastrointestinal Cancer - Gastroesophageal, Pancreatic, and Hepatobiliary
A prospective, single-arm, Phase II study of surufatinib in combination with gemcitabine and nab-paclitaxel for the neoadjuvant treatment of resectable and borderline resectable pancreatic cancer	Song Gao/ Jihui Hao, Tianjin Medical University Cancer Institute and Hospital, Tianjin, China	e16442 Publication Only: Gastrointestinal Cancer - Gastroesophageal, Pancreatic, and Hepatobiliary

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 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, ranosidenib, fruquintinib and surufatinib, the further clinical development for savolitinib, ranosidenib, fruquintinib and surufatinib, its expectations as to whether any studies on savolitinib, ranosidenib, fruquintinib 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 savolitinib, ranosidenib, fruquintinib 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 savolitinib, ranosidenib, fruquintinib and surufatinib for a targeted indication, and the sufficiency of funding. In addition, as certain studies rely on the use of other drug products 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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