

Press Release

HUTCHMED Highlights FRUSICA-2 Registration Trial Data to be Presented at the 2025 ESMO Congress

— The fruquintinib and sintilimab combination demonstrated significant PFS improvements in advanced renal cell carcinoma patients after progression on first-line therapies —

Hong Kong, Shanghai & Florham Park, NJ — Monday, October 13, 2025: HUTCHMED (China) Limited ("[HUTCHMED](#)") (Nasdaq/AIM:HCM; HKEX:13) announces results from the FRUSICA-2 registration clinical trial of the fruquintinib and sintilimab combination for the treatment of patients with locally advanced or metastatic renal cell carcinoma. Results of the Phase III part of the study will be presented on Friday, October 17, 2025 during the European Society for Medical Oncology ("ESMO") Congress in Berlin, Germany.

FRUSICA-2 is a randomized, open-label, active-controlled registration study evaluating the efficacy and safety of fruquintinib in combination with sintilimab versus axitinib or everolimus monotherapy for the second-line treatment of advanced renal cell carcinoma ([NCT05522231](#)). A total of 234 patients were randomized into a group that received fruquintinib plus sintilimab combination therapy, or into a group that received axitinib or everolimus monotherapy. As of the progression free survival ("PFS") final analysis cutoff of February 17, 2025, the median follow-up was 16.6 months.

The median PFS as assessed by blinded independent central review (BICR) was 22.2 months with fruquintinib plus sintilimab, compared to 6.9 months with axitinib/everolimus (stratified hazard ratio [HR] 0.373; stratified log-rank $p < 0.0001$). The objective response rate (ORR) was 60.5% vs 24.3% (Odds Ratio 4.622, $p < 0.0001$), and the median duration of response (DoR) was 23.7 vs 11.3 months, respectively. Overall survival data were still evolving at the time of data cutoff with maturity of approximately 20%. Efficacy benefits were observed in all prognostic risk groups, as defined by the International mRCC Database Consortium (IMDC) criteria.

The safety profile of the fruquintinib and sintilimab combination was tolerable and consistent with the known profiles of each individual treatment. Treatment-emergent adverse events (TEAEs) of grade 3 or above occurred in 71.4% of patients in the fruquintinib plus sintilimab group compared to 58.8% for patients in the axitinib/everolimus group.

"The FRUSICA-2 trial results provide compelling evidence that fruquintinib and sintilimab may offer a valuable new treatment option for patients with advanced renal cell carcinoma," said **Professor Dingwei Ye of Fudan University Shanghai Cancer Center** and the co-leading Principal Investigator of the FRUSICA-2 study. "These findings show the combination's potential to address a critical unmet need for this patient population, delivering consistent benefits across varied patient profiles and prognostic risk groups."

"The FRUSICA-2 study suggests that fruquintinib and sintilimab could play a meaningful role in shaping second-line treatment strategies for advanced renal cell carcinoma," said **Professor Zhisong He of Peking University First Hospital** and the co-leading Principal Investigator of the FRUSICA-2 study. "These results point to the combination's potential to enhance clinical outcomes, providing a new option for managing this challenging disease."

Supported by data from FRUSICA-2, a New Drug Application (NDA) for the combination of fruquintinib and sintilimab in patients with locally advanced or metastatic renal cell carcinoma who have failed prior treatment has been accepted for review by the China National Medical Products Administration (NMPA).

About Kidney Cancer and Renal Cell Carcinoma

It is estimated that approximately 435,000 new patients were diagnosed with kidney cancer worldwide in 2022.¹ In China, an estimated 74,000 new patients were diagnosed with kidney cancer in 2022.² Approximately 90% of kidney tumors are renal cell carcinoma.

The safety and efficacy of fruquintinib for the investigational uses discussed above have not been established and there is no guarantee that it will receive health authority approval or become commercially available in any country for the uses being investigated.

About Fruquintinib

Fruquintinib is a selective oral inhibitor of all three vascular endothelial growth factor receptors ("VEGFR") -1, -2 and -3. VEGFR inhibitors play a pivotal role in inhibiting tumor angiogenesis. Fruquintinib was designed to limit off-target kinase activity and improve drug exposure to achieve sustained target inhibition.³

Fruquintinib is co-developed and co-commercialized in China by HUTCHMED and Eli Lilly and Company under the brand name ELUNATE®. It is approved for the treatment of patients with metastatic colorectal cancer who have previously received fluoropyrimidine, oxaliplatin and irinotecan-based chemotherapy, and those who have previously received or are not suitable to receive anti-VEGF therapy or anti-epidermal growth factor receptor (EGFR) therapy (RAS wild-type) in China. The combination of fruquintinib and sintilimab has received conditional approval in China for the treatment of patients with advanced pMMR endometrial cancer who have failed prior systemic therapy and are not candidates for curative surgery or radiation.

Takeda holds the exclusive worldwide license to further develop, commercialize, and manufacture fruquintinib outside mainland China, Hong Kong and Macau, marketing it under the brand name FRUZAQLA®.

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