



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 and Innovent Jointly Announce NMPA Approval for ELUNATE® (Fruquintinib) in Combination with TYVYT® (Sintilimab Injection) for the Treatment of Patients with Locally Advanced or Metastatic Renal Cell Carcinoma

*— Reduced risk of disease progression or death by 63%, with median PFS of 22.2 months in the
FRUSICA-2 registration study —*

HUTCHMED (China) Limited ("[HUTCHMED](#)") and Innovent Biologics, Inc. ("[Innovent](#)") today jointly announce that the New Drug Application (NDA) for the combination of ELUNATE® (fruquintinib) and TYVYT® (sintilimab injection) has been granted approval by the China National Medical Products Administration ("NMPA") for the treatment of patients with locally advanced or metastatic renal cell carcinoma who have failed prior vascular endothelial growth factor receptor-tyrosine kinase inhibitors (VEGFR-TKI) therapy and have not received programmed death receptor-1 ("PD-1") or programmed death-ligand 1 ("PD-L1") inhibitor therapy in the first-line setting.

The approval is supported by data from FRUSICA-2, 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 patients with locally advanced or metastatic renal cell carcinoma. The study met its primary endpoint of progression free survival ("PFS") as assessed by blinded independent central review ("BICR").

"The rapid advancements in targeted therapies, immunotherapies, and their combination regimens have led to a significant evolution in the treatment landscape for advanced renal cell carcinoma. Optimizing the selection of treatment for individual patients is a key focus of clinical interest," said **Professor Dingwei Ye of Fudan University Shanghai Cancer Center and co-lead Principal Investigator of the FRUSICA-2 study**. "The approval of the fruquintinib and sintilimab combination underscores its potential to address the pressing medical needs of patients with this challenging disease."

"The FRUSICA-2 trial results provided compelling evidence that the fruquintinib and sintilimab combination 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 co-lead Principal Investigator of the FRUSICA-2 study**. "We are optimistic about the clinical implications of this approval as we strive to provide effective treatment options for patients."

"This approval reaffirms our deep commitment to delivering innovative therapies to patients facing advanced renal cell carcinoma in China, where second-line treatment options remain limited," said **Mr Johnny Cheng, Acting Chief Executive Officer and Chief Financial Officer of HUTCHMED**. "We are excited to continue pushing the boundaries of our research — across monotherapies, combination strategies, and exciting new platforms such as our ATTC technology — to unlock even greater therapeutic potential across various tumor types, ultimately providing more impactful and transformative solutions to patients."

Dr Hui Zhou, Chief R&D Officer of Oncology of Innovent, stated: “The approval is a significant milestone for patients with advanced renal cell carcinoma in China. It further validates the potential of the sintilimab plus fruquintinib combination regimen, now approved for two difficult-to-treat cancers. We are also proud to achieve the 10th approved indication for sintilimab (TYVYT®), and remain committed to advancing clinical value optimization to benefit an even broader population of cancer patients.”

About The FRUSICA-2 Trial

Results from the Phase III part of the study were presented at the 2025 European Society for Medical Oncology (ESMO) Congress. As of the PFS final analysis cutoff of February 17, 2025, the median follow-up was 16.6 months. The median PFS as assessed by 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 months 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 consistent with the known profiles of each individual treatment. Additional details may be found at clinicaltrials.gov, using identifier [NCT05522231](https://clinicaltrials.gov/ct2/show/study/NCT05522231).

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.

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 have enhanced selectivity that limits off-target kinase activity, allowing for drug exposure that achieves sustained target inhibition and flexibility for potential use as part of a combination therapy.³

About Fruquintinib Approvals

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. It was included in China’s National Reimbursement Drug List (NRDL) in January 2020.

The combination of ELUNATE® (fruquintinib) and TYVYT® (sintilimab injection) has conditional approval in China for the treatment of patients with advanced mismatch repair proficient (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®. Fruquintinib received approval for the treatment of previously treated metastatic colorectal cancer in the US, Europe, Japan and many other countries around the world.

About Sintilimab

Sintilimab, marketed as TVYVY[®] (sintilimab injection) in China, is a PD-1 immunoglobulin G4 monoclonal antibody co-developed by Innovent and Eli Lilly and Company. Sintilimab is a type of immunoglobulin G4 monoclonal antibody, which binds to PD-1 molecules on the surface of T-cells, blocks the PD-1/PD-L1 pathway, and reactivates T-cells to kill cancer cells.⁴

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](#).

About Innovent

Innovent is a leading biopharmaceutical company with the mission to empower patients worldwide with affordable, high-quality biopharmaceuticals. Innovent discovers, develops, manufactures and commercializes innovative medicines that target some of the most intractable diseases. Its pioneering therapies treat cancer, cardiovascular and metabolic, autoimmune and eye diseases. Innovent has launched 18 products in the market, 4 assets in Phase III or pivotal clinical trials and 15 more molecules in early clinical stage. Innovent partners with over 30 global healthcare companies to improve drug availability and enhance the quality of patients' lives.

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 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. 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 fruquintinib, including as a combination therapy, to meet the primary or secondary endpoint of a study, to obtain regulatory approval in other jurisdictions and to gain commercial acceptance after obtaining regulatory approval; the potential market of fruquintinib for a targeted indication; and HUTCHMED and/or its partner's ability to fund, implement and complete its further clinical development and commercialization plans for fruquintinib, and the timing of these events. In addition, as certain studies rely on the use of other drug products such as sintilimab as combination therapeutics with fruquintinib, such risks and uncertainties include assumptions regarding the safety, efficacy, supply and continued regulatory approval of these therapeutics. 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 announcement, whether as a result of new information, future events or circumstances or otherwise.

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.

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- ¹ The Global Cancer Observatory, kidney cancer fact sheet. <https://gco.iarc.who.int/media/globocan/factsheets/cancers/29-kidney-fact-sheet.pdf>. Accessed February 19, 2025.
 - ² The Global Cancer Observatory, China fact sheet. <https://gco.iarc.who.int/media/globocan/factsheets/populations/160-china-fact-sheet.pdf>. Accessed February 19, 2025.
 - ³ Sun Q, et al. Discovery of fruquintinib, a potent and highly selective small molecule inhibitor of VEGFR 1, 2, 3 tyrosine kinases for cancer therapy. *Cancer Biol Ther*. 2014;15(12):1635-45. doi: 10.4161/15384047.2014.964087.
 - ⁴ Wang J, et al. Durable blockade of PD-1 signaling links preclinical efficacy of sintilimab to its clinical benefit. *mAbs* 2019;11(8): 1443-1451. doi: 10.1080/19420862.2019.1654303.

By Order of the Board

Edith Shih

Non-executive Director and Company Secretary

Hong Kong, May 21, 2026

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

*(Acting Chief Executive Officer and
Chief Financial Officer)*

Non-executive Directors:

Ms Edith SHIH

Ms Ling YANG

Independent Non-executive Directors:

Dr Renu BHATIA

(Senior and Lead Independent Non-executive Director)

Dr Chaohong HU

Professor TAN Shao Weng, Daniel

Mr WONG Tak Wai