

Press Release

HUTCHMED Announces that it has Completed Enrollment of a Phase II/III Trial of Fruquintinib in Combination with Sintilimab for Advanced Renal Cell Carcinoma in China

Hong Kong, Shanghai & Florham Park, NJ — Wednesday, December 13, 2023: HUTCHMED (China) Limited (Nasdaq/AIM:HCM, HKEX:13) ("[HUTCHMED](#)") today announces that it has completed enrollment of its Phase II/III trial of fruquintinib in combination with sintilimab as second-line treatment for locally advanced or metastatic renal cell carcinoma ("RCC") in China.

The study is a randomized, open-label, active-controlled study to evaluate the efficacy and safety of fruquintinib in combination with sintilimab versus axitinib or everolimus monotherapy for the second-line treatment of advanced RCC. The primary endpoint is progression free survival ("PFS") per RECIST 1.1 as assessed by blinded independent central review (BICR). The secondary endpoints include objective response rate ("ORR"), disease control rate ("DCR"), duration of response ("DoR"), time to response (TTR), overall survival ("OS"), safety, and quality of life. A total of 234 patients have been enrolled in the study. The leading principal investigators are Dr Dingwei Ye of Fudan University Shanghai Cancer Center and Dr Zhisong He of Peking University First Hospital. Additional details may be found at clinicaltrials.gov, using identifier [NCT05522231](#).

The first patient in China received the first dose on October 27, 2022 and HUTCHMED expects to announce topline results from the study around year end 2024. If favorable, the results would enable a New Drug Application submission to China's National Medical Products Administration ("NMPA").

About Kidney Cancer and RCC

It is estimated that approximately 430,000 new patients were diagnosed with kidney cancer worldwide in 2020.¹ In China, an estimated 74,000 new patients were diagnosed with kidney cancer in 2020.² Approximately 90% of kidney tumors are RCC.

The safety and efficacy of fruquintinib for the following investigational uses 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 and Second-line treatment of RCC

Fruquintinib is a selective oral inhibitor of vascular endothelial growth factor receptors ("VEGFR") -1, -2 and -3. VEGFR inhibitors play a pivotal role in blocking tumor angiogenesis. Fruquintinib was designed to have enhanced selectivity that limits off-target kinase activity, allowing for high drug exposure, sustained target inhibition, and flexibility for the potential use as part of combination therapy. Fruquintinib has demonstrated a manageable safety profile and is being investigated in combination with other anti-cancer therapies including the approved PD-1 inhibitor, sintilimab.

The U.S. Food and Drug Administration ("FDA") has approved five immune-oncology combination therapies for first-line treatment of advanced RCC, however, no immune-oncology combination therapies have been approved in China, indicating an unmet medical need in these settings.

As [presented](#) at the 2023 American Society of Clinical Oncology Annual Meeting (ASCO), a proof of concept study of fruquintinib plus sintilimab demonstrated promising efficacy and tolerable safety profile in this setting. At the data cutoff date of November 30, 2022, all 20 enrolled previously treated patients were efficacy evaluable, and median follow-up duration was 23.3 months. The confirmed ORR was 60.0% and DCR was 85.0%. Median DoR was 13.9 months and mPFS was 15.9 months. OS was not reached.

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 medicines marketed in China, the first of which is also marketed in the U.S. 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 submission of a NDA for fruquintinib for the treatment of RCC with the NMPA and the timing of such submission, the therapeutic potential of fruquintinib for the treatment of patients with RCC and the further clinical development of fruquintinib in this and other indications. Forward-looking statements involve risks and uncertainties. Such risks and uncertainties include, among other things, assumptions regarding the timing and outcome of clinical studies and the sufficiency of clinical data to support NDA approval of fruquintinib for the treatment of patients with CRC, RCC or other indications in China or other jurisdictions, its potential to gain approvals from regulatory authorities on an expedited basis or at all; the efficacy and safety profile of fruquintinib; HUTCHMED ability to fund, implement and complete its further clinical development and commercialization plans for fruquintinib; the timing of these events; actions of regulatory agencies, which may affect the initiation, timing and progress of clinical trials or the regulatory pathway for fruquintinib; and the impact of COVID-19 on general economic, regulatory and political conditions. 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. Such forward-looking statements include, without limitation, statements regarding the plan to develop, manufacture and commercialize fruquintinib; and HUTCHMED’s strategy, goals and anticipated milestones, business plans and focus. 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, on AIM and on The Stock Exchange of Hong Kong Limited. 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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References

- ¹ The Global Cancer Observatory, kidney cancer fact sheet. <https://gco.iarc.fr/today/data/factsheets/cancers/29-Kidney-fact-sheet.pdf>. Accessed September 28, 2022.
- ² The Global Cancer Observatory, China fact sheet. <https://gco.iarc.fr/today/data/factsheets/populations/160-china-fact-sheets.pdf>. Accessed September 30, 2022.