

Press Release

HUTCHMED Highlights Clinical Data to be Presented at ESMO Congress 2023

Hong Kong, Shanghai & Florham Park, NJ - Monday, October 16, 2023: HUTCHMED (China) Limited ("[HUTCHMED](#)") (Nasdaq/AIM: HCM; HKEX13) today announces that new and updated clinical data from several ongoing studies of fruquintinib, in combination with chemotherapies and/or immunotherapies, will be presented at the upcoming European Society for Medical Oncology ("ESMO") Congress 2023, taking place on October 20-24, 2023 in Madrid, Spain.

Details of the presentations are as follows:

Abstract title	Presenter / Lead author	Presentation details
SPONSORED STUDY Fruquintinib plus Sintilimab in patients with either treatment naïve or previously treated advanced gastric or gastroesophageal junction adenocarcinoma: results from a multicenter, single-arm phase Ib/II study	Xiaoli Wei, Harbin Medical University Cancer Hospital, Harbin, China	1519P Poster presentation (Oesophagogastric cancer) Monday, October 23, 2023
INVESTIGATOR-INITIATED STUDIES		
First report of the safety/tolerability and preliminary antitumor activity of fruquintinib plus capecitabine versus capecitabine as maintenance treatment for metastatic colorectal cancer: an open-label, randomized phase Ib/II study	Wenhua Li, Department of Gastrointestinal Medical Oncology, Fudan University Shanghai Cancer Center, Shanghai, China	639P Poster presentation (Colorectal cancer) Sunday, October 22, 2023
Updated results from the multicenter phase II study of fruquintinib plus mFOLFOX6/FOLFIRI as first-line therapy in advanced metastatic colorectal cancer (mCRC)	Fuxiang Zhou, Department of Radiation and Medical Oncology, Zhongnan Hospital of Wuhan University, Wuhan, China	612P Poster presentation (Colorectal cancer) Sunday, October 22, 2023
A phase II study to evaluate the efficacy and safety of fruquintinib combined with tislelizumab and Hepatic artery infusion chemotherapy (HAIC) for advanced colorectal cancer liver metastases (CRLM)	Lu Wang, Liver surgery department, Fudan University Shanghai Cancer Center, Shanghai, China	637P Poster presentation (Colorectal cancer) Sunday, October 22, 2023
Fruquintinib combined with sintilimab and chemotherapy as the first-line treatment in advanced naïve EGFR- and ALK-negative non-squamous non-small cell lung cancer (nsq-NSCLC): Updated results of a phase II trial	Pei Ma, Department of Oncology, The First Affiliated Hospital of Nanjing Medical University, Nanjing, Jiangsu, China	1494P Poster presentation (NSCLC, metastatic) Monday, October 23, 2023

About Fruquintinib

Fruquintinib is a selective oral inhibitor of 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 high drug exposure, sustained target inhibition, and flexibility for the potential use as part of combination therapy. Fruquintinib has been shown to be generally well tolerated in patients to date and is being investigated in combinations with other anti-cancer therapies.

Fruquintinib was approved for marketing by the China National Medical Products Administration (NMPA) in September 2018 and commercially launched in China in November 2018 under the brand name ELUNATE[®]. A marketing submission to the U.S. Food and Drug Administration ("FDA") was granted Priority Review and assigned a Prescription Drug User Fee Act (PDUFA) goal date of November 30, 2023. In addition, a submission to the European Medicines Agency ("EMA") was validated and accepted for review in June 2023, and a submission to the Japan Pharmaceuticals and Medical Devices Agency ("PMDA") took place in September 2023.

Takeda has the exclusive worldwide license to further develop, and commercialize, and manufacture fruquintinib outside of China. Fruquintinib is developed and marketed in China by HUTCHMED, in partnership with Eli Lilly and Company.

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 oncology drugs now approved and marketed in China. 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 but not limited to its expectations regarding the approval of a New Drug Application ("NDA") for fruquintinib for the treatment of CRC with the FDA, EMA and the PMDA and the timing of such approvals, 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 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 or other indications in jurisdictions such as China, the U.S., the E.U. or Japan, its potential to gain approvals from regulatory authorities on an expedited basis or at all; the efficacy and safety profile of fruquintinib; 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 different jurisdictions and to gain commercial acceptance after obtaining regulatory approval; the potential market of fruquintinib for a targeted indication; the sufficiency of funding; and the impact of COVID-19 or other infectious diseases on general economic, regulatory and political conditions. In addition, as certain studies rely on the use of capecitabine, mFOLFOX6/FOLFIRI, tislelizumab or 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 U.S. 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.

CONTACTS

Investor Enquiries

+852 2121 8200 / +1 973 306 4490 / ir@hutch-med.com

Media Enquiries

Ben Atwell / Alex Shaw, FTI Consulting

+44 20 3727 1030 / +44 7771 913 902 (Mbbile) / +44 7779 545 055 (Mbbile) / HUTCHMED@fticonsulting.com

Zhou Yi, Brunswick

+852 9783 6894 (Mbbile) / HUTCHMED@brunswickgroup.com

Nominated Advisor

Atholl Tweedie / Freddy Crossley / Daphne Zhang, Panmure Gordon +44 (20) 7886 2500

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