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Hutchmed (China) Limited
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Press Release

HUTCHMED Announces that it has Completed Enrollment of a Phase II Registration Study of Fanregratinib (HMPL-453) for Intrahepatic Cholangiocarcinoma in China

Hong Kong, Shanghai & Florham Park, NJ - Thursday, March 6, 2025: HUTCHMED (China) Limited ("HUTCHMED") (Nasdaq/AIM:HCM; HKEX:13) today announces that it has completed enrollment of its a Phase II trial of fanregratinib (HMPL-453) for intrahepatic cholangiocarcinoma ("IHCC") patients with fibroblast growth factor receptor ("FGFR")2 fusion/rearrangement.

The study is a single-arm, multi-center, open-label, Phase II registration study to evaluate the efficacy, safety and pharmacokinetic of fanregratinib in treating advanced IHCC patients with FGFR2 fusion/rearrangement. Primary endpoint is objective response rate (ORR). Secondary endpoints include progression-free survival (PFS), disease control rate (DCR), duration of response (DoR) and overall survival (OS). A total of 87 patients were enrolled into the registration phase of the study. Additional details may be found at clinicaltrials.gov using identifier NCT04353375.

The first patient received the first dose in March 2023 and HUTCHMED expects to announce topline results from the study around the end of 2025. If favorable, the results could enable a New Drug Application submission to China's National Medical Products Administration (NMPA).

About Fanregratinib

Fanregratinib (HMPL 453) is a novel, highly selective and potent inhibitor targeting FGFR 1, 2 and 3. Aberrant FGFR signaling has been found to be a driving force in tumor growth, promotion of angiogenesis and resistance to anti-tumor therapies. Abnormal FGFR gene alterations are believed to be the drivers of tumor cell proliferation in several solid tumor settings.

HUTCHMED currently retain all rights to fanregratinib worldwide.

About IHCC with FGFR2 Fusion/Rearrangement

IHCC is one of the subtypes of primary bile duct cancer. In China, an estimated 61,900 newly diagnosed IHCC occurred in 2015 and the overall IHCC incidence increased by 9.2% per year between 2006 and 2015.[1] FGFR2 fusion has been reported to have a prevalence of 10-15% in IHCC patients.[2],[3]

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 in the US, Europe and Japan. For more information, please visit: www.hutchmed.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, includ-ing its expectations regarding the thera-peutic potential of fanregratinib, the further clinical develop-ment for fanregratinib, its expectations as to whether any studies on fanregratinib 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 fanregratinib, 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 fanregratinib for a targeted indication and the sufficiency of funding. 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.

CONTACTS

Investor Enquiries	+852 2121 8200 / ir@hutch-med.com
Media Enquiries	
FTI Consulting -	+44 20 3727 1030 / HUTCHMED@fticonsulting.com
Ben Atwell / Alex Shaw	+44 7771 913 902 (Mobile) / +44 7779 545 055 (Mobile)
Brunswick - Zhou Yi	+852 9783 6894 (Mobile) / HUTCHMED@brunswickgroup.com
Panmure Liberum	*Nominated Advisor and Joint Broker*
Atholl Tweedie / Freddy Crossley / Rupert Dearden	+44 20 7886 2500
HSBC	*Joint Broker*
Simon Alexander / Alina Vaskina / Arnav Kapoor	+44 20 7991 8888
Cavendish	*Joint Broker*
Geoff Nash / Nigel Birks	+44 20 7220 0500

[1] An L, Zheng R, Zhang S, et al. Hepatocellular carcinoma and intrahepatic cholangiocarcinoma incidence between 2006 and 2015 in China: estimates based on data from 188 population-based cancer registries. *Hepatobiliary Surg Nutr.* 2023 Feb 28;12(1):45-55.

[2] Arai Y, Totoki Y, Hosoda F, et al. Fibroblast growth factor receptor 2 tyrosine kinase fusions define a unique molecular subtype of cholangiocarcinoma. *Hepatology.* 2014;59:1427-34.

[3] Nakamura H, Arai Y, Totoki Y, et al. Genomic spectra of biliary tract cancer. *Nat Genet.* 2015;47:1003-10.

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