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Hutchmed (China) Limited
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Press Release

HUTCHMED Announces NDA Acceptance in China with Priority Review Status for Fanregratinib in Second-Line Intrahepatic Cholangiocarcinoma

- NDA supported by results from a Phase II registration trial in China -

- Second most common form of liver cancer after hepatocellular carcinoma, with generally poorer long-term survival in comparison -

Hong Kong, Shanghai & Florham Park, NJ - Monday, December 29, 2025: HUTCHMED (China) Limited ("HUTCHMED") (Nasdaq/AIM:HCM; HKEX:13) today announces that the New Drug Application ("NDA") for fanregratinib (HMPL-453) for the treatment of adult patients with advanced, metastatic or unresectable intrahepatic cholangiocarcinoma ("ICC") with fibroblast growth factor receptor ("FGFR") 2 fusion/rearrangement who have previously received systemic therapy has been accepted and granted priority review by the China National Medical Products Administration ("NMPA").

Fanregratinib (HMPL 453) is a novel, selective, oral inhibitor targeting FGFR 1/2/3. ICC is a highly aggressive malignancy arising from the intrahepatic biliary epithelium. It accounts for 8.2-15.0% of primary liver cancers, and consequently it is the second most common type after hepatocellular carcinoma. In recent years, the incidence of ICC has continued to rise, with a 5-year overall survival rate of approximately 9%.[1] Approximately 10-15% of ICC patients globally have tumors harboring FGFR2 fusions or rearrangements.[2],[3]

This NDA is supported by data from a single-arm, multi-center, open-label, Phase II registration study in China. The study has met its primary endpoint of objective response rate (ORR). Results from the secondary endpoints including progression-free survival (PFS), disease control rate (DCR), duration of response (DoR) and overall survival (OS) also support the primary endpoint findings. Full results will be submitted for presentation at an upcoming scientific conference. Additional details may be found at clinicaltrials.gov using identifier NCT04353375.

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 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.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, including its expectations regarding the review of a NDA for fanregratinib for the treatment of ICC with the NMPA and the timing of such review, therapeutic potential of fanregratinib for the treatment of patients with ICC and the further development of fanregratinib 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 fanregratinib for the treatment of patients with ICC or other indications in China or other jurisdictions, its potential to gain approvals from regulatory authorities on an expedited basis or at all, the safety profile of fanregratinib, HUTCHMED's ability to fund, implement and complete its further clinical development and commercialization plans for fanregratinib and the timing of these events. 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.

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[1] Expert consensus on precision detection of intrahepatic cholangiocarcinoma (2024 edition). *Chin J Clin Med*. 2025;32(1):1-18.

[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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