



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 Highlights Pivotal Phase II Data for Fanregratinib in Intrahepatic Cholangiocarcinoma Presented at ESMO Gastrointestinal Cancers Congress 2026

- *Registration-enabling study demonstrated high clinically meaningful objective responses, achieving rapid and durable disease control —*
- *Fanregratinib holds promise as a new treatment option for pretreated advanced ICC patients harboring FGFR2-fusions/rearrangements —*

HUTCHMED (China) Limited ("[HUTCHMED](#)") today announces results from the pivotal Phase II registration study of fanregratinib (HMPL-453) in patients with intrahepatic cholangiocarcinoma ("ICC") will be presented at the European Society for Medical Oncology (ESMO) Gastrointestinal Cancers Congress taking place from July 1 to 4, 2026 in Munich, Germany.

Supported by data from the study, a New Drug Application (NDA) for fanregratinib for the treatment of adult patients with advanced, metastatic or unresectable ICC with fibroblast growth factor receptor ("FGFR") 2 fusion/rearrangement who have previously received systemic therapy has been accepted for review and granted priority review by the China National Medical Products Administration (NMPA) in December 2025.

"The clinical reality for this patient population with advanced FGFR2–fusion/rearrangement ICC is highly challenging, as the entire cohort had progressed on prior chemotherapy, and a significant majority had prior immunotherapy exposure," said **Professor Jianming Xu of the Chinese PLA General Hospital** and leading Principal Investigator of the study. "The results from this registration-enabling trial represent an important milestone in the targeted treatment landscape for FGFR2-altered ICC. The objective response rate and survival metrics achieved by fanregratinib clearly support its therapeutic value as a potent, selective oral treatment option. We are encouraged by these findings and hope to see this innovation translate into clinical practice to address a critical need in gastrointestinal oncology."

This pivotal study is a single-arm, multi-center, open-label, Phase II registration clinical trial conducted across 53 sites in China to evaluate the efficacy, safety and pharmacokinetic of fanregratinib in treating advanced ICC patients with FGFR2 fusion/rearrangement ([NCT04353375](#)). All patients had received at least one line of systemic therapy, of which all had received chemotherapy and 72% had received immunotherapy. The study has met its primary endpoint, demonstrating an Independent Review Committee (IRC)-assessed objective response rate (ORR) of 42.5% (95% CI: 30.0%–53.6%). Key secondary endpoints showed consistent clinical activity and a rapid onset of action, with a median time to response of 1.4 months. Median duration of response (DoR) was 6.9 months (95% CI: 5.6–8.5) and disease control rate (DCR) reached 83.9% (95% CI: 74.5%–90.9%). Furthermore, the median progression-free survival (PFS) was 6.9 months (95% CI: 4.1–8.2), while the median overall survival (OS) was 16.6 months (95% CI: 12.4–16.6).

Fanregratinib exhibited a manageable safety profile consistent with the known mechanism of selective FGFR inhibitors. Drug-related adverse events of Grade 3 or greater were reported in 48.3% of patients, with the most common being

elevations in liver enzymes and palmar-plantar erythrodysesthesia syndrome (PPES). Treatment discontinuation due to drug-related adverse events was limited to 2.2% of patients, and no treatment-related deaths were recorded.

Details of the presentation are as follows:

Title:	Fanregratinib in fibroblast growth factor receptor 2 (FGFR2)- fusions/rearrangements intrahepatic cholangiocarcinoma (ICC): Pivotal part of a phase II trial
Lead Author:	Jianming Xu, Chinese PLA General Hospital, Beijing, China
Session:	Rapid oral session on innovation
Presentation Number:	343RO
Date & Time:	Saturday, July 4, 2026, 9:00 am CEST
Location:	Room 13a

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.hutch-med.com or follow us on [LinkedIn](#).

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 but not limited to its expectations regarding the therapeutic potential of fanregratinib, the further clinical development 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. 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 combination therapies, 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 markets 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 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.

By Order of the Board

Edith Shih

Non-executive Director and Company Secretary

Hong Kong, June 25, 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