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 Announces NMPA Approval for ATLED® (Fanregratinib) for the Treatment of Patients with FGFR2-Fusion/Rearrangement Intrahepatic Cholangiocarcinoma

—Novel, highly potent oral selective FGFR 1/2/3 inhibitor approved for patients with advanced FGFR2-altered intrahepatic cholangiocarcinoma in China —

HUTCHMED (China) Limited ("HUTCHMED") today announces that the New Drug Application (NDA) for fanregratinib (HMPL-453), a novel, selective, oral inhibitor targeting FGFR 1/2/3, has been granted conditional approval by the China National Medical Products Administration ("NMPA") for the treatment of adult patients with advanced, metastatic or unresectable intrahepatic cholangiocarcinoma ("ICC") with fibroblast growth factor receptor ("FGFR") 2 fusion or rearrangement who have previously received systemic therapy. Fanregratinib will be marketed in China under the brand name ATLED®.

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]

The approval is supported by data from the Phase II registration cohort of the single-arm, multi-center, open-label, pivotal Phase II/IIIb clinical trial of ATLED® in China (NCT04353375). The results were recently presented at the European Society for Medical Oncology (ESMO) Gastrointestinal Cancers Congress 2026. The study met its primary endpoint, demonstrating an Independent Review Committee (IRC)-assessed objective response rate (ORR) of 42.5% (95% CI: 30.0%–53.6%) in pretreated advanced ICC patients harboring FGFR2-fusions/rearrangements, representing a strong, clinically meaningful response.

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).

"As a major and devastating subtype of primary liver cancer, intrahepatic cholangiocarcinoma carries an immense disease burden with historically limited targeted options. We are thrilled by the NMPA approval of ATLED®, which directly addresses this critical therapeutic gap in China," said Mr Johnny Cheng, Acting Chief Executive Officer and Chief Financial Officer of HUTCHMED. "This approval unlocks an important new treatment alternative for a substantial population of pretreated advanced ICC patients. We are fully prepared to leverage our established commercial infrastructure to bring this precision medicine to patients as rapidly as possible."

The Phase IIIb portion of the trial will serve as the confirmatory study to further validate the clinical benefits and safety of ATLED® in this setting. Enrollment for this confirmatory cohort was initiated in January 2026.

About ATLED®

ATLED® (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 four 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 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. 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 other jurisdictions and to gain commercial acceptance after obtaining regulatory approval; the potential market of fanregratinib for a targeted indication; and 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 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.

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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.

By Order of the Board

Edith Shih
Non-executive Director and Company Secretary

Hong Kong, August 28, 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