

Press Release

HUTCHMED Initiates Phase Ib/II Study of HMPL-453 in Combination with Chemotherapy or Toripalimab for Advanced Solid Tumors in China

Hong Kong, Shanghai & Florham Park, NJ — Friday, February 4, 2022: HUTCHMED (China) Limited (“[HUTCHMED](#)”) (Nasdaq/AIM: HCM; HKEX:13) today announces that it has initiated a Phase Ib/II study in China of HMPL-453, an investigational novel selective inhibitor targeting fibroblast growth factor receptors (“FGFR”) 1/2/3, in combination with chemotherapy or the anti-PD-1 therapy, toripalimab. The first patient received their first dose on January 22, 2022.

The clinical trial is a multi-center, two-stage, open-label study to evaluate the safety, tolerability, pharmacokinetics and preliminary efficacy profile of HMPL-453 combination therapy in patients with specific advanced or metastatic solid tumors.

The first stage of the study is a dose escalation phase to determine the dose limiting toxicity (DLT) and recommended Phase II dose (“RP2D”) of HMPL-453 in combination with chemotherapy (gemcitabine and cisplatin) or toripalimab. The second stage of the study is a dose expansion phase in solid tumor patients with either gastric cancer, intrahepatic cholangiocarcinoma, or urothelial carcinoma, harboring specific FGFR gene alterations. Each solid tumor cohort will be treated with a specific combination of HMPL-453 and a chemotherapy or anti-PD-1 therapy to further evaluate the preliminary efficacy, safety and tolerability at the RP2D.

A Phase II study of HMPL-453 monotherapy is also underway in patients with advanced intrahepatic cholangiocarcinoma (IHCC) in China (clinicaltrials.gov identifier [NCT04353375](#)).

About HMPL-453

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 (through tissue growth and repair), 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 HMPL-453 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. It has more than 4,600 personnel across all its companies, at the center of which is a team of about 1,500 in oncology/immunology. Since inception it has advanced 12 cancer drug candidates from in-house discovery into clinical studies 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 its expectations regarding the therapeutic potential of HMPL-453, the further clinical development for HMPL-453, its expectations as to whether any studies on HMPL-453 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 HMPL-453, 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 HMPL-453 for a targeted indication; the sufficiency of funding; and the impact of the COVID-19 pandemic on general economic, regulatory and political conditions. In addition, as certain studies rely on the use of gemcitabine, cisplatin, docetaxel and toripalimab as combination therapeutics with HMPL-453, such risks and uncertainties include assumptions regarding the safety, efficacy, supply and continued

regulatory approval of these therapeutics. 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.

CONTACTS

Investor Enquiries

Mark Lee, Senior Vice President	+852 2121 8200
Annie Cheng, Vice President	+1 (973) 567 3786

Media Enquiries

Americas – Brad Miles, Solebury Trout	+1 (917) 570 7340 (Mobile) bmiles@troutgroup.com
Europe – Ben Atwell / Alex Shaw, FTI Consulting	+44 20 3727 1030 / +44 7771 913 902 (Mobile) / +44 7779 545 055 (Mobile) HUTCHMED@fticonsulting.com
Asia – Zhou Yi, Brunswick	+852 9783 6894 (Mobile) HUTCHMED@brunswickgroup.com

Nominated Advisor

Atholl Tweedie / Freddy Crossley, Panmure Gordon (UK) Limited	+44 (20) 7886 2500
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