

## Press Release

### **HUTCHMED Initiates Phase I Trials of novel ERK inhibitor HMPL-295 in Patients with Advanced Solid Tumors in China**

**Hong Kong, Shanghai and Florham Park, NJ — Tuesday, July 6, 2021:** HUTCHMED (China) Limited ("[HUTCHMED](#)") (Nasdaq/AIM: HCM; HKEX: 13) has initiated a Phase I study of HMPL-295, its investigative and highly selective oral inhibitor of ERK, which is a downstream component of the RAS-MAPK<sup>1</sup> pathway signaling cascade. HMPL-295 has the potential to address intrinsic or acquired resistance from upstream mechanisms such as RAS, RAF and MEK. This is our first of multiple candidates in discovery addressing the RAS-MAPK pathway. The first patient was dosed on July 2, 2021.

The clinical trial is a multi-center, open-label study to evaluate safety, tolerability, pharmacokinetics and preliminary efficacy profile of HMPL-295, and to determine the maximum tolerated dose and recommended Phase II dose ("RP2D") in patients with advanced malignant solid tumors. Following the initial dose escalation stage, another 10 to 15 patients will be enrolled at the RP2D to further evaluate its safety and the preliminary efficacy of HMPL-295. An exploratory study on the pharmacokinetic biomarkers of HMPL-295 is also planned. Additional details may be found at [clinicaltrials.gov](https://clinicaltrials.gov), using identifier [NCT04908046](#).

We currently retain all rights to HMPL-295 worldwide.

#### **About ERK and the RAS-MAPK pathway**

The RAS-MAPK pathway is dysregulated in human diseases, particularly cancer, in which mutations or nongenetic events hyperactivate the pathway in more than 50% of cancers. Activating mutations in RAS genes occur in more than 30% of cancers. RAS and RAF predict worse clinical prognosis in a wide variety of tumor types, mediate resistance to targeted therapies, and decrease the response to the approved standards of care, namely, targeted therapy and immunotherapy. On the RAS-MAPK pathway, KRAS inhibitors are under clinical evaluation, and acquired resistance develops for RAF/MEK targeted therapies. ERK inhibition has the potential to overcome or avoid the intrinsic or acquired resistance from upstream mechanisms such as these.

#### **About HUTCHMED**

HUTCHMED (Nasdaq/AIM: HCM; HKEX: 13) (formerly Hutchison China MediTech) 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. A dedicated organization of over 1,300 personnel has advanced ten cancer drug candidates from in-house discovery into clinical studies around the world, with its first three oncology drugs now approved. For more information, please visit: [www.hutch-med.com](http://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-295, the further clinical development for HMPL-295, its expectations as to whether such studies 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, 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-295, including as a combination therapy, to meet the primary or secondary endpoint of a study, to obtain regulatory approval in different jurisdictions, to gain commercial acceptance after obtaining regulatory approval, the potential market of HMPL-295 for a targeted indication, the sufficiency of funding and the impact of the COVID-19 pandemic on general economic, regulatory and political conditions. 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, on AIM and The Stock Exchange of Hong Kong Limited. 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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<sup>1</sup> Mitogen-activated protein kinase, MAPK.

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