

Press Release

HUTCHMED Initiates Phase II/III Trial of the Combination of Surufatinib and Camrelizumab for Treatment-Naïve Pancreatic Ductal Adenocarcinoma in Collaboration with Hengrui

- Almost half a million people diagnosed each year across the globe -

- Collaboration based on synergistic potential of inhibiting angiogenesis and tumor-associated macrophages with HUTCHMED's surufatinib and anti-PD-1 antibody with Hengrui's camrelizumab, promoting the immune response against tumor cells -

Hong Kong, Shanghai & Florham Park, NJ - Tuesday, May 14, 2024: HUTCHMED (China) Limited ("[HUTCHMED](#)") (Nasdaq/AIM:HCM; HKEX:13) today announces the initiation of a Phase II/III trial to evaluate the efficacy of a combination of the HUTCHMED drug candidate surufatinib, the Jiangsu Hengrui Pharmaceuticals Co., Ltd ("Hengrui Pharma") PD-1 antibody camrelizumab, nab-paclitaxel and gemcitabine as a first-line treatment for patients with metastatic pancreatic ductal adenocarcinoma ("PDAC") in China. PDAC is an exocrine tumor and the most common form of pancreatic cancer. The first patient received the first dose on May 8, 2024.

PDAC is a highly aggressive form of cancer, representing over 90% of pancreatic cancer cases. Globally, an estimated 511,000 people were diagnosed with pancreatic cancer, leading to approximately 467,000 deaths in 2022, with an average five-year survival rate of less than 10%. In China, an estimated 119,000 people were diagnosed with pancreatic cancer, causing approximately 106,000 deaths in 2022.^[1] Treatments such as chemotherapy, surgery and radiation are commonly employed, but have not shown significant improvement in patient outcomes. Under 20% of metastatic pancreatic cancer patients survive more than a year.^[2]

The trial is a multicenter, randomized, open-label, active-controlled, Phase II/III trial to evaluate the efficacy and safety of surufatinib combined with camrelizumab, nab-paclitaxel, and gemcitabine versus nab-paclitaxel plus gemcitabine as a treatment for adults with metastatic pancreatic cancer who have not been previously treated with a systemic anti-tumor therapy. After an initial safety run-in stage, the Phase II/III stage of the study may enroll a further 500 patients, with a primary endpoint of overall survival (OS). Other endpoints include objective response rate (ORR), progression free survival (PFS), disease control rate (DCR), safety, quality of life, duration of response and time to response. Additional details may be found at clinicaltrials.gov, using identifier [NCT06361888](#).

Dr Weiguo Su, Chief Executive Officer and Chief Scientific Officer of HUTCHMED, said, "Emerging data including those from an investigator-initiated study presented at the ASCO Gastrointestinal Cancers Symposium, demonstrated that combinations of surufatinib, camrelizumab and chemotherapy have promising efficacy in comparison with existing chemotherapy-based treatments in metastatic PDAC.^[3] We hope that this partnership will enable us to bring new, potentially life-changing treatment options to patients."

About Surufatinib

Surufatinib is a novel, oral angio-immuno kinase inhibitor that selectively inhibits the tyrosine kinase activity associated with vascular endothelial growth factor receptors (VEGFRs) and fibroblast growth factor receptor (FGFR), which both inhibit angiogenesis, and colony stimulating factor-1 receptor (CSF-1R), which regulates tumor-associated macrophages, promoting the body's immune response against tumor cells. Its unique dual mechanism of action may be very suitable for possible combinations with other immunotherapies, where there may be synergistic anti-tumor effects.

Surufatinib is marketed in China by HUTCHMED under the brand name SULANDA[®], and was first included in the China National Reimbursement Drug List (NRDL) in January 2022 for the treatment of non-pancreatic and pancreatic neuroendocrine tumors (NETs).

About Camrelizumab

Camrelizumab (SHR-1210) is a humanized monoclonal antibody targeting the programmed death-1 (PD-1) receptor. Blockade of the PD-1/PD-L1 signaling pathway is a therapeutic strategy showing success in a wide variety of solid and hematological cancers. Currently, more than 10 clinical trials are underway worldwide in a broad range of tumors and treatment settings.

Camrelizumab, under the brand name AiRuiKa[®], is currently approved for nine indications in China, including hepatocellular carcinoma ("HCC") (second-line and first-line), relapsed/refractory classic Hodgkin's lymphoma (third-line), esophageal squamous cell carcinoma (second-line) and nasopharyngeal carcinoma (third-line or further) and in combination with chemotherapy for the treatment of non-small cell lung cancer (non-squamous and squamous), esophageal squamous cell carcinoma, and nasopharyngeal carcinoma in the first-line setting. All indications have been included in China's national medical insurance catalog, making it the leading domestic PD-1 product in terms of approved indications and tumor types covered. The U.S. Food and Drug Administration ("FDA") granted Orphan Drug Designation to camrelizumab for advanced HCC in April 2021, and accepted a New Drug Application (NDA) for camrelizumab and rivoceranib as a first-line therapy for unresectable HCC, with FDA Prescription Drug User Fee Act (PDUFA) dates in May 2024.

About Hengrui Pharma

Hengrui Pharma is a leading global pharmaceutical company headquartered in China with a focus on research, development, manufacturing, and commercialization of innovative and high-quality healthcare products. Innovation is the core development strategy. Hengrui Pharma ranked 24th among top 1,000 global pharmaceutical companies in 2021. Hengrui Pharma has been on the Pharma Exec's annual listing of the top 50 global pharmaceutical companies for the fifth consecutive year.

About HUTCHMED

HUTCHMED (Nasdaq/AIM:HCM; HKEX:13) is an innovative, commercial-stage, biopharmaceutical company. It is committed to the discovery, global development and commercialization of targeted therapies and immunotherapies for the treatment of cancer and immunological diseases. It has approximately 5,000 personnel across all its companies, at the center of which is a team of about 1,800 in oncology/immunology. Since inception, HUTCHMED has focused on bringing cancer drug candidates from in-house discovery to patients around the world. Its first three medicines are marketed in China, the first of which is also marketed in the U.S. 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 surufatinib for the treatment of patients with PDAC and the further development of surufatinib 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 an NDA submission of surufatinib for the treatment of patients with PDAC or other indications in China or other jurisdictions, its potential to gain approvals from regulatory authorities on an expedited basis or at all, the efficacy and safety profile of surufatinib, HUTCHMED's ability to fund, implement and complete its further clinical development and commercialization plans for surufatinib and the timing of these events. In addition, as certain studies rely on the use of other drug products such as camrelizumab as combination therapeutics with surufatinib, 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.

Medical Information

This press release 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] [The Global Cancer Observatory, World Fact Sheets](#). Accessed April 9, 2024.

[2] Sarantis P *et al.* Pancreatic ductal adenocarcinoma: Treatment hurdles, tumor microenvironment and immunotherapy. *World J Gastrointest Oncol.* 2020;12(2):173-181. DOI: [10.4251/wjgo.v12.i2.173](https://doi.org/10.4251/wjgo.v12.i2.173)

[3] Jia R *et al.* Updated results of a phase 1b/2 study of surufatinib plus camrelizumab, nab-paclitaxel and S-1 (NASC) as first-line therapy for metastatic pancreatic adenocarcinoma (mPDAC). *JCO* 42, 671-671(2024). DOI: [10.1200/JCO.2024.42.3_suppl.671](https://doi.org/10.1200/JCO.2024.42.3_suppl.671)

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