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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 Clinical Data to be Presented at 2023 ESMO Asia and ESMO Immuno-Oncology Congresses

HUTCHMED (China) Limited ("[HUTCHMED](#)") today highlights that new clinical data from several ongoing studies with HUTCHMED investigational drug candidates fruquintinib, surufatinib and HMPL-295, which will be presented at the upcoming European Society for Medical Oncology ("ESMO") Asia Congress, taking place on December 1-3, 2023 in Singapore, and the ESMO Immuno-Oncology Congress, taking place on December 6-8, 2023 in Geneva, Switzerland.

HMPL-295:

Title:	A first in human, open-label, dose-escalation study of ERK1/2 inhibitor HMPL-295 in patients with advanced solid tumors
Lead Author:	Rujiao Liu, Department of Medical Oncology, Fudan University Shanghai Cancer Center, Shanghai, China
Type:	Oral presentation
Abstract # & Link:	77MQ
Session & Location:	ESMO Asia – Developmental and precision medicine (ID 29), Hall 402
Date & Time:	Friday, December 1, 2023, 11:50 am Singapore time

This presentation will report data from a multi-center, open-label clinical trial to evaluate safety, tolerability, pharmacokinetics and preliminary efficacy profile of HMPL-295, and to determine the maximum tolerated dose ("MTD") and recommended Phase II dose in patients with advanced malignant solid tumors. The continuous-administration MTD was determined to be 50 mg QD, and intermittent administration studies are ongoing.

HMPL-295 is an investigational, selective, oral inhibitor of extracellular signal-regulated kinase 1 & 2 (ERK1/2), which is a downstream component of the RAS-MAPK pathway signaling cascade. The investigational compound has the potential to address intrinsic or acquired resistance from upstream mechanisms such as RAS, RAF and MEK. HMPL-295 is one of several investigational compounds discovered by HUTCHMED that target the RAS-MAPK pathway.

Fruquintinib:

Title: Fruquintinib plus sintilimab in advanced cervical cancer patients: Results from a multicenter, single-arm Phase II study

Lead Author: Xiaotian Han, Oncologic Gynecology Department, Fudan University Shanghai Cancer Center, Shanghai, China

Type: Oral presentation

Abstract # & Link: [289MO](#)

Session & Location: ESMO Asia – Gynaecological cancers (ID 28), Hall 401

Date & Time: Friday, December 1, 2023, 11:25 am Singapore time

Title: Fruquintinib plus sintilimab in patients with advanced non-small cell lung cancer (“NSCLC”) with PD-L1 positive expression: A multicenter, single-arm phase II study

Lead Author: Shun Lu, Shanghai Lung Cancer Center, Shanghai Chest Hospital, School of Medicine, Shanghai Jiaotong University, Shanghai, China

Abstract # & Link: [496P](#)

Session & Location: ESMO Asia – Poster Display (ID78), Exhibition area

Date & Time: Saturday, December 2, 2023, 5:50 pm Singapore time

These presentations will report results from the cervical cancer and NSCLC patient cohorts of the basket clinical trial in China of fruquintinib plus sintilimab. This trial is an open-label, multi-center, non-randomized, Phase II study to assess the safety and efficacy of fruquintinib in combination with sintilimab in patients with advanced cervical cancer, endometrial cancer (“EMC”), gastric cancer (GC), hepatocellular carcinoma (HCC), NSCLC or renal cell carcinoma (“RCC”). Data from the EMC and RCC cohorts of this trial led to the initiation of registration enabling programs. This combination treatment showed promising antitumor activity in advanced cervical cancer and NSCLC patients, particularly for patients with PD-L1 positive status. This combination treatment also showed manageable toxicity profiles consistent with that seen in other cohorts.

Fruquintinib is a selective oral inhibitor of vascular endothelial growth factor receptors (“VEGFR”) -1, -2 and -3. VEGFR inhibitors play a pivotal role in blocking tumor angiogenesis. Fruquintinib was designed to have enhanced selectivity that limits off-target kinase activity, allowing for high drug exposure, sustained target inhibition, and flexibility for the potential use as part of combination therapy. Fruquintinib has demonstrated a manageable safety profile and is being investigated in combination with other anti-cancer therapies including the approved PD-1 inhibitor, sintilimab.

Title: Efficacy and safety of fruquintinib + best supportive care (BSC) vs placebo + BSC in refractory metastatic colorectal cancer: Asian vs non-Asian outcomes in FRESCO-2

Lead Author: Daisuke Kotani, National Cancer Center Hospital East Kashiwa, Japan

Abstract # & Link: [93P](#)

Session & Location: ESMO Asia – Poster Display (ID78), Exhibition area

Date & Time: Saturday, December 2, 2023, 5:50 pm Singapore time

This presentation will report efficacy and safety data according to race for Asian and non-Asian patient subgroups from the FRESCO-2 study. FRESCO-2 is a global Phase III multi-regional clinical trial (MRCT) conducted in the U.S., Europe, Japan and Australia investigating fruquintinib plus best supportive care (“BSC”) vs. placebo plus BSC in patients with previously treated metastatic colorectal cancer. There was a clinically meaningful improvement in overall survival (OS) and progression-free survival (PFS) in both Asian and non-Asian patients. The safety and efficacy subgroup analysis results were consistent with the overall FRESCO-2 population and with the established monotherapy profile of fruquintinib.

Investigator-initiated studies presentations:

Abstract title	Presenter / Lead author	Presentation details
ESMO Asia Congress 2023		
Tyrosine kinase Inhibitor (TKI) plus PD-1 blockade in TKI-responsive MSS/pMMR metastatic colorectal adenocarcinoma: updated results of TRAP study	Jingdong Zhang, Qian Dong, Medical Oncology Department of Gastrointestinal Cancer, Liaoning Cancer Hospital & Institute, Shenyang, China	96P Poster presentation (Gastrointestinal tumours, colorectal) Saturday, December 2, 2023
Efficacy and safety of fruquintinib with Nab-Paclitaxel in Advanced G/GEJ cancer after exposure to immune checkpoint inhibitors: A single-center prospective clinical trial	Lin Yang, Xiaoting Ma, Department of Medical Oncology, Chinese Academy of Medical Sciences and Peking Union Medical College – National Cancer Center, Beijing, China	186P Poster presentation (Gastrointestinal tumours, non- colorectal) Saturday, December 2, 2023
ESMO Immuno-Oncology Congress 2023		
A single-center, Phase II study of surufatinib combined with toripalimab, pemetrexed, and platinum in patients with advanced non-squamous non-small cell lung cancer (nsq-NSCLC)	Li Zhang, Wenfeng Fang, Department of Medical Oncology, Sun Yat-sen University Cancer Center, Guangzhou, China	74P Poster Display Thursday, December 7, 2023
Surufatinib plus toripalimab combined with etoposide and cisplatin in patients with advanced naïve small cell lung cancer (SCLC) – Updated results of a phase Ib/II trial	Li Zhang, Wenfeng Fang, Department of Medical Oncology, Sun Yat-sen University Cancer Center, Guangzhou, China	124P Poster Display Thursday, December 7, 2023

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 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 it has focused on bringing cancer 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 marketed in the U.S. 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 U.S. 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 fruquintinib, surufatinib and HMPL-295, the further clinical development for fruquintinib, surufatinib and HMPL-295, its expectations as to whether any studies on fruquintinib, surufatinib and HMPL-295 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 the timing and outcome of clinical studies and the sufficiency of clinical data to support approval of fruquintinib, surufatinib and HMPL-295 for the treatment of patients with colorectal cancer or other indications in jurisdictions such as China, the U.S., the E.U. or Japan, its potential to gain approvals from regulatory authorities on an expedited basis or at all; the efficacy and safety profile of fruquintinib, surufatinib and HMPL-295; assumptions regarding changes to clinical protocols or regulatory requirements; unexpected adverse events or safety issues; the ability of fruquintinib, surufatinib and HMPL-295, 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 fruquintinib, surufatinib and HMPL-295 for a targeted indication; the sufficiency of funding; and the impact of COVID-19 or other infectious diseases on general economic, regulatory and political conditions. In addition, as certain studies rely on the use of nab-paclitaxel, sintilimab, toripalimab, pemetrexed, platinum, etoposide or cisplatin as combination therapeutics, such risks and uncertainties include assumptions regarding their safety, efficacy, supply and continued regulatory approval. 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 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, December 1, 2023

As at the date of this announcement, the Directors of the Company are:

Executive Directors:

Mr TO Chi Keung, Simon
(Chairman)

Dr Weiguo SU
*(Chief Executive Officer and
Chief Scientific Officer)*

Mr CHENG Chig Fung, Johnny
(Chief Financial Officer)

Non-executive Directors:

Dr Dan ELDAR
Ms Edith SHIH
Ms Ling YANG

Independent Non-executive Directors:

Mr Paul Rutherford CARTER
(Senior Independent Director)
Mr Graeme Allan JACK
Professor MOK Shu Kam, Tony