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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 Surufatinib and Toripalimab Combination Clinical Data being Presented at the ESMO Immuno-Oncology 2021 Meeting**

HUTCHMED (China) Limited ("[HUTCHMED](#)") today announces that new analyses and updates on the ongoing studies of surufatinib combined with toripalimab, in multiple disease settings, presented at the European Society for Medical Oncology's (ESMO) Immuno-Oncology Congress 2021, taking place virtually on December 8-11, 2021.

Further details of the poster presentations are as follows:

**Title:** Surufatinib plus toripalimab in patients with advanced small cell lung cancer (SCLC) after failure of 1L systemic chemotherapy

**First Author:** Ying Cheng, MD, Jilin Cancer Hospital

**Abstract No. & Link:** [157P](#)

**Date & Time:** Thursday, December 9, 2021, 11:30am – 11:50am CET

**Title:** Surufatinib plus toripalimab for 2L treatment of advanced gastric or gastroesophageal junction (G/GEJ) adenocarcinoma, esophageal squamous cell carcinoma (ESCC) and neuroendocrine carcinoma (NEC): A multicenter, single-arm phase II study

**First Author:** Ming Lu, MD, Peking University Cancer Hospital & Institute

**Abstract No. & Link:** [155P](#)

**Date & Time:** Thursday, December 9, 2021, 10:50am – 11:10am CET

#### **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 (VEGFR) 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.

HUTCHMED currently retains all rights to surufatinib worldwide.

## About Surufatinib Development

*Extra-pancreatic Neuroendocrine Tumors (“epNETs”) in China:* On December 29, 2020, surufatinib was granted drug registration [approval](#) by the National Medical Products Administration of China (“NMPA”) for the treatment of epNET. Surufatinib is marketed in China under the brand name SULANDA®. The approval was based on results from the SANET-ep study, a Phase III trial (clinicaltrials.gov identifier: [NCT02588170](#)) in patients with advanced epNETs conducted in China. The study met the pre-defined primary endpoint of PFS at a preplanned interim analysis, and was [published](#) in *The Lancet Oncology*<sup>1</sup>. Median PFS was significantly longer for patients treated with surufatinib at 9.2 months, compared to 3.8 months for patients in the placebo group (HR 0.334; 95% CI: 0.223-0.499; p<0.0001). Surufatinib had an acceptable safety profile, with the most common treatment related adverse events of grade 3 or worse being hypertension (36% of surufatinib patients vs. 13% of placebo patients), proteinuria (19% vs. 0%) and anemia (5% vs. 3%).

*Pancreatic Neuroendocrine Tumors (“pNETs”) in China:* On June 16, 2021, surufatinib was granted drug registration [approval](#) by the NMPA for the treatment of pNET. The approval was based on results from the SANET-p study, a Phase III trial (clinicaltrials.gov identifier: [NCT02589821](#)) in patients with advanced pNET in China. The pre-defined primary endpoint of [PFS was met](#) at a preplanned interim analysis and was [published](#) in *The Lancet Oncology*<sup>2</sup>, demonstrating that surufatinib reduces the risk of disease progression or death by 51% in patients, with a median PFS of 10.9 months compared to 3.7 months on placebo (HR 0.491; 95% CI: 0.391-0.755; p=0.0011). The safety profile of surufatinib was manageable and consistent with observations in prior studies.

*Immunotherapy combinations:* HUTCHMED entered into collaboration agreements to evaluate the safety, tolerability and efficacy of surufatinib in combination with anti-PD-1 monoclonal antibodies, including with [toripalimab](#), [tislezumab](#) and [sintilimab](#), which are approved as monotherapies in China.

*NETs in the U.S. and Europe:* A U.S. Food and Drug Administration (“FDA”) New Drug Application (NDA) submission was [accepted in June 2021](#), followed by a Marketing Authorisation Application (MAA) submission to the European Medicines Agency (EMA) validated in July 2021. The basis to support these filings includes the completed SANET-ep and SANET-p studies, along with existing data from surufatinib in U.S. epNET and pNET patients (clinicaltrials.gov identifier: [NCT02549937](#)). In the U.S., surufatinib was granted [Fast Track Designations](#) for development in pNET and epNET in April 2020, and [Orphan Drug Designation](#) for pNET in November 2019.

HUTCHMED has initiated an [Expanded Access Protocol](#) (EAP) in the U.S. to ensure patients with NET with limited therapeutic options have access to this treatment. Regulatory clearance of this protocol has been granted by the FDA and this program is open for site activation (clinicaltrials.gov identifier: [NCT04814732](#)).

## About Toripalimab

Toripalimab is an anti-PD-1 monoclonal antibody developed by Junshi Biosciences. More than thirty company-sponsored toripalimab clinical studies covering more than fifteen indications have been conducted globally, including in China, the United States, Southeast Asia, and European countries. Ongoing or completed pivotal clinical trials evaluating the safety and efficacy of toripalimab cover a broad range of tumor types including cancers of the lung, nasopharynx, esophagus, stomach, bladder, breast, liver, kidney and skin.

In China, toripalimab was the first domestic anti-PD-1 monoclonal antibody approved for marketing (approved in China as TUOYI®). To date, four indications of toripalimab has been approved by the NMPA for the treatment of melanoma, nasopharyngeal carcinoma (“NPC”) and urothelial carcinoma. In the United States, the FDA has granted priority review for the toripalimab Biologics License Application (BLA) for the treatment of NPC, which currently has no FDA-approved immuno-oncology treatment options. Earlier, the FDA granted 2 Breakthrough Therapy designations, 1 Fast Track designation, 4 Orphan Drug designations for toripalimab.

## 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 4,500 personnel across all its companies, at the center of which is a team of over 1,400 in oncology/immunology. Since inception it has advanced eleven 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](http://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 its expectations regarding the therapeutic potential of surufatinib for patients, its expectations as to whether any studies on surufatinib 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 surufatinib, 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 surufatinib 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 toripalimab, tislelizumab or sintilimab 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.*

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- <sup>1</sup> Xu J, Shen L, Zhou Z, et al. Surufatinib in advanced extrapancreatic neuroendocrine tumours (SANET-ep): a randomised, double-blind, placebo-controlled, phase 3 study. *Lancet Oncol.* 2020;21(11):1500-1512. doi: [10.1016/S1470-2045\(20\)30496-4](https://doi.org/10.1016/S1470-2045(20)30496-4).
- <sup>2</sup> Xu J, Shen L, Bai C, et al. Surufatinib in advanced pancreatic neuroendocrine tumours (SANET-p): a randomised, double-blind, placebo-controlled, phase 3 study. *Lancet Oncol.* 2020; 21(11):1489-1499. doi: [10.1016/S1470-2045\(20\)30493-9](https://doi.org/10.1016/S1470-2045(20)30493-9).

By Order of the Board

### Edith Shih

*Non-executive Director and Company Secretary*

Hong Kong, December 10, 2021

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

#### Executive Directors:

Mr TO Chi Keung, Simon

*(Chairman)*

Mr Christian Lawrence HOGG

*(Chief Executive Officer)*

Mr CHENG Chig Fung, Johnny

*(Chief Financial Officer)*

Dr Weiguo SU

*(Chief Scientific Officer)*

#### Non-executive Directors:

Dr Dan ELDAR

Ms Edith SHIH

#### Independent Non-executive Directors:

Mr Paul Rutherford CARTER

*(Senior Independent Director)*

Dr Karen Jean FERRANTE

Mr Graeme Allan JACK

Professor MOK Shu Kam, Tony