Everest Medicines Limited
雲頂新耀有限公司
(incorporated in the Cayman Islands with limited liability)
(Stock Code: 1952)

VOLUNTARY ANNOUNCEMENT BUSINESS UPDATE ON APPROVAL OF CLINICAL TRIAL APPLICATION BY CHINA NATIONAL MEDICAL PRODUCTS ADMINISTRATION FOR PHASE 3 REGISTRATION TRIAL OF SACITUZUMAB GOVITECAN-HZIY FOR METASTATIC UROTHELIAL CANCER

This announcement is made by Everest Medicines Limited (the "**Company**") on a voluntary basis to inform the shareholders and potential investors of the Company about the latest business update.

The board of directors of the Company (the "**Board**") is pleased to announce that the Center for Drug Evaluation (CDE) of the National Medical Products Administration (NMPA) of the People's Republic of China has approved a Clinical Trial Application ("**CTA**") for sacituzumab govitecan-hziy for the treatment of patients with metastatic urothelial cancer ("**mUC**").

With this CTA, the Company plans to enroll patients in China as part of the Phase 3, global, multicenter, open-label randomized controlled TROPiCS-04 trial. The trial will evaluate sacituzumab govitecan-hziy compared with standard of care chemotherapeutic options in subjects with metastatic or locally advanced unresectable urothelial cancer who have progressed after prior therapy with a platinum-based regimen and anti-programmed cell death protein 1 (PD-1)/programmed death-ligand 1 (PD-L1) therapy. Subjects will be randomized to receive either sacituzumab govitecan-hziy or Treatment of Physician's Choice (TPC), including paclitaxel, docetaxel, and vinflunine.

Positive results from the pivotal Phase 2 TROPHY U-01 study of sacituzumab govitecan-hziy in 113 mUC patients, presented at the ESMO 2020 annual conference, confirmed earlier study results showing sacituzumab govitecan-hziy has significant activity and is safe in patients with heavily pretreated mUC who progressed on both platinum-based chemotherapy and checkpoint inhibitors (CPI). Results from the study showed that sacituzumab govitecan-hziy achieved a 27% overall response rate (ORR) and a median duration of response (DOR) of 5.9 months in heavily pre-treated patients with mUC. Sacituzumab govitecan-hziy has received Fast Track Designation from the U.S. Food and Drug Administration (FDA) in this indication.

INFORMATION ABOUT UROTHELIAL CANCER

Urothelial cancer is a type of cancer that begins in urothelial cells that line the urethra, bladder, ureters, renal pelvis, and some other organs that make up the urinary system. According to Frost & Sullivan, in 2019, the incidence of urothelial cancer reached 76.4 thousand in China.

INFORMATION ABOUT SACITUZUMAB GOVITECAN-HZIY

Sacituzumab govitecan-hziy is a first-in-class, antibody-drug conjugate (ADC) directed at TROP-2, a membrane antigen that is over-expressed in many common epithelial cancers. Under a licensing agreement with Gilead Sciences, Inc., the Company has exclusive rights to develop, register, and commercialize sacituzumab govitecan-hziy for all cancer indications in Greater China, South Korea, and certain Southeast Asian countries.

Cautionary statement: We cannot guarantee that we will be able to develop, or ultimately market, sacituzumab govitecan-hziy successfully. Shareholders and potential investors of the Company are advised to exercise due care when dealing in the shares of the Company.

By Order of the Board
Everest Medicines Limited
Wei Fu
Chairman and Executive Director

Hong Kong, January 6, 2021

As at the date of this announcement, the board of directors of the Company comprises Mr. Wei Fu as Chairman and Executive Director, Dr. Kerry Levan Blanchard, Mr. Ian Ying Woo and Mr. Xiaofan Zhang as Executive Directors, Mr. Yubo Gong and Ms. Lan Kang as Non-executive Directors, and Mr. Bo Tan, Mr. Yifan Li and Mr. Shidong Jiang as Independent Non-executive Directors.