

*Hong Kong Exchanges and Clearing Limited and The Stock Exchange of Hong Kong Limited take no responsibility for the contents of this announcement, make no representation as to its accuracy or completeness and expressly disclaim any liability whatsoever for any loss howsoever arising from or in reliance upon the whole or any part of the contents of this announcement.*



**EVEREST MEDICINES**

**云 頂 新 耀**

**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  
CHINA NMPA ACCEPTING BIOLOGICS LICENSE  
APPLICATION FOR SACITUZUMAB GOVITECAN-HZIY IN  
METASTATIC TRIPLE-NEGATIVE BREAST 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 China National Medical Products Administration (“**NMPA**”) has accepted for review its Biologics License Application for sacituzumab govitecan-hziy (“**SG**”), an investigational therapy for the treatment of adult patients with unresectable locally advanced or metastatic triple-negative breast cancer (“**TNBC**”) who have received two or more prior systemic therapies, at least one of them for metastatic disease.

Under the trade name Trodelvy<sup>®</sup>, the U.S. Food and Drug Administration previously granted accelerated approval to SG in April 2020 and full approval in April 2021 for adult patients with unresectable locally advanced or metastatic TNBC who have received two or more prior systemic therapies, at least one of them for metastatic disease.

The Ministry of Food and Drug Safety in South Korea has also recently granted Fast Track Designation and Orphan Drug Designation to SG for the treatment of metastatic TNBC. In addition, the Company announced in January 2021 that it submitted a New Drug Application to the Health Sciences Authority of Singapore for SG for the treatment of patients with metastatic TNBC who have received at least two prior therapies for metastatic disease. That application is currently under review.

## INFORMATION ABOUT TRIPLE-NEGATIVE BREAST CANCER

TNBC is a highly aggressive disease and accounts for approximately 15% of all breast cancer types worldwide. The median age of breast cancer diagnoses tends to be younger in Asian than western countries, and the percentage of the TNBC molecular subtype has been increasing in the past 10 years. TNBC cells lack sufficient estrogen, progesterone or HER2 receptor expression to benefit from the use of hormonal or HER2-directed therapy. Overall survival among patients with this form of breast cancer has not changed in the past 20 years, which highlights the need for advances in therapeutic options for these patients.

## INFORMATION ABOUT SACITUZUMAB GOVITECAN-HZIY

SG is a first-in-class antibody and topoisomerase inhibitor conjugate directed at TROP-2, a protein frequently expressed in multiple types of epithelial cancers. SG is approved in the United States under the trade name Trodelvy<sup>®</sup>. The U.S. approval was supported by data from the Phase 3 ASCENT study, which demonstrated a statistically significant and clinically meaningful 57% reduction in the risk of disease worsening or death (progression-free survival or PFS), extending median PFS to 4.8 months from 1.7 months with chemotherapy (HR: 0.43; 95% CI: 0.35–0.54; p<0.0001). SG also extended median overall survival (OS) to 11.8 months vs. 6.9 months (HR: 0.51; 95% CI: 0.41–0.62; p<0.0001), representing a 49% reduction in the risk of death.

The most frequent Grade  $\geq 3$  adverse reactions for SG compared to single-agent chemotherapy in the study were neutropenia (52% vs. 34%), diarrhea (11% vs. 1%), leukopenia (11% vs. 6%) and anemia (9% vs. 6%). Adverse reactions leading to treatment discontinuation occurred in 5% of patients receiving SG. The Trodelvy U.S. Prescribing Information has a BOXED WARNING for severe or life-threatening neutropenia and severe diarrhea.

Under a licensing agreement with Gilead Sciences, Inc., the Company has exclusive rights to develop, register, and commercialize SG for all cancer indications in Greater China, South Korea, and certain Southeast Asian countries. In October 2020, SG was included in the updated 2020 China Guidelines for the Standardized Diagnosis and Treatment of Advanced Breast Cancer, compiled by the Breast Cancer Expert Committee of the National Cancer Control Center, the Breast Cancer Professional Committee of the Chinese Anti-Cancer Association, and the Cancer Drug Clinical Research Professional Committee of the Chinese Anti-Cancer Association.

**Cautionary statement:** We cannot guarantee that we will be able to develop, or ultimately market, SG 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, 17 May 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.*