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**RemeGen Co., Ltd.\***

**榮昌生物製藥（煙台）股份有限公司**

*(A joint stock company incorporated in the People's Republic of China with limited liability)*

**(Stock Code: 9995)**

**VOLUNTARY ANNOUNCEMENT  
NATIONAL MEDICAL PRODUCTS ADMINISTRATION (NMPA)  
ACCEPTS NEW DRUG APPLICATION FOR DISITAMAB VEDOTIN  
(BRAND NAME: 爱地希®) FOR THE TREATMENT OF  
HER2 EXPRESSING LOCALLY ADVANCED OR  
METASTATIC UROTHELIAL CARCINOMA**

This announcement is made by RemeGen Co., Ltd.\* 榮昌生物製藥（煙台）股份有限公司 (the “**Company**”) on a voluntary basis.

The board of directors of the Company (the “**Board**”) is pleased to announce that the National Medical Products Administration (NMPA) has accepted the new drug application (NDA) for disitamab vedotin (RC48, brand name: 爱地希®), the anti-HER2 antibody-drug conjugate (ADC) independently developed in-house by the Company, for the treatment of HER2 expressing locally advanced or metastatic urothelial carcinoma.

This is the second NDA in China for disitamab vedotin (RC48, brand name: 爱地希®) after it successfully received conditional marketing approval by the NMPA for the treatment of locally advanced or metastatic gastric cancer (gastro esophageal junction (GEJ) carcinoma) in China on June 9, 2021.

It is also the first domestically developed ADC to submit NDA in China for the treatment of HER2 expressing locally advanced or metastatic urothelial carcinoma.

## **ABOUT DISITAMAB VEDOTIN (RC48, BRAND NAME: 爱地希®)**

Disitamab vedotin (RC48, brand name: 爱地希®) is an anti-HER2 ADC targeting prevalent cancers with significant unmet medical needs, and it is the first domestically developed ADC in China to receive marketing approval. It was granted conditional marketing approval by the NMPA to treat locally advanced or metastatic gastric cancer (GEJ carcinoma) in China on June 9, 2021.

We are implementing a differentiated development and commercial strategy for disitamab vedotin, targeting prevalent HER2 expressing indications that are currently underserved, including (i) gastric cancer (GC); (ii) urothelial carcinoma (UC); (iii) breast cancer (BC); and (iv) other cancer indications expressed by HER2. The clinical needs in these therapeutic areas are underserved and can expand a broad addressable patient population for disitamab vedotin.

**Warning under Rule 18A.05 of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited:** There is no assurance that the disitamab vedotin will ultimately be successfully marketed by the Company. Shareholders of the Company and potential investors are advised to exercise caution when dealing in the shares of the Company.

By order of the Board  
**RemeGen Co., Ltd.**  
**Mr. Wang Weidong**  
*Chairman and executive director*

Yantai, The People's Republic of China  
July 14, 2021

*As at the date of this announcement, the Board of the Company comprises Mr. Wang Weidong, Dr. Fang Jianmin, Dr. He Ruyi and Mr. Lin Jian as the executive directors, Dr. Wang Liqiang and Dr. Su Xiaodi as the non-executive directors, and Ms. Yu Shanshan, Mr. Hao Xianjing and Dr. Ma Lan as the independent non-executive directors.*

\* *For identification purposes only*