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 ADMINSTRATION(NMPA) HAS GRANTED DISITAMAB VEDOTIN (BRAND NAME: 爱地希®) BREAKTHROUGH THERAPY DESIGNATION FOR THE TREATMENT OF HER2 POSITIVE BREAST CANCER WITH LIVER METASTASIS PATIENTS PREVIOUSLY TREATED WITH TRASTUZUMAB AND TAXANE

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 Disitamab Vedotin (RC48, Brand Name: 爱地希®), the anti-HER2 antibody-drug conjugate (ADC) independently developed in-house by the Company, has been granted breakthrough therapy designation by the China National Medical Products Administration (NMPA) for the treatment of HER2 positive breast cancer with liver metastasis patients previously treated with trastuzumab and taxane. The Company is currently conducting Phase III clinical trial for this indication in China.

This is the second breakthrough therapy designation for Disitamab Vedotin after it was granted breakthrough therapy designation for the treatment of urothelial carcinoma by both NMPA and FDA in 2020.

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

Disitamab Vedotin (RC48, Brand Name: 爱地希®) is an anti-HER2 antibody drug conjugate 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 to treat locally advanced or metastatic gastric cancer (gastro esophageal junction (GEJ) carcinoma)in China earlier this month.

We are implementing a differentiated development and commercial strategy for disitamab vedotin, targeting prevalent HER2 expressing indications that are currently underserved, including both (i) HER2 expressing cancer (IHC 1+ or above) indications beyond breast cancer (BC), such as gastric cancer (GC) and urothelial carcinoma (UC), and (ii) HER2 low-expressing cancer (IHC 2+/FISH – or IHC 1+) indications, such as HER2 low expressing BC. These therapeutic areas represent a less crowded but underserved field for HER2 targeted therapies, and 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
June 28, 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*