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 HAS ACCEPTED THE APPLICATION FOR IND FOR THE TREATMENT OF PERIOPERATIVE MUSCLE-INVASIVE BLADDER CANCER WITH THE COMBINATION OF DISITAMAB VEDOTIN AND TORIPALIMAB INJECTION

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 formally accepted the application for investigational new drug (IND) for the treatment of perioperative muscle-invasive bladder cancer (MIBC) with the combination of Disitamab Vedotin (RC48, Brand Name: 爱地希®) and Toripalimab Injection (Brand Name: 拓益®) on December 10, 2021.

This is a single-arm, open-label, multi-center Phase II clinical study to evaluate the efficacy and safety of the combination of Disitamab Vedotin and Toripalimab Injection in patients with MIBC scheduled for surgical radical surgery.

Bladder cancer is one of the most common malignant tumors of urinary system, which is originated from urothelial carcinoma of bladder. Systemic perioperative treatment is very important to improve the prognosis of patients with MIBC. There is a huge clinical need to be met in this field. The Company is dedicated to bringing new treatment options to Chinese patients with MIBC as soon as possible.

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 (including gastro esophageal junction (GEJ) carcinoma) by the NMPA on June 9, 2021. On July 14 of the same year, the NMPA formally accepted the application for IND for the treatment of HER2-expressing locally advanced or metastatic urothelial cancer.

The Food and Drug Administration ("**FDA**") has granted Disitamab Vedotin breakthrough therapy and fast-track eligibility for locally advanced or metastatic urothelial cancer. Disitamab Vedotin has also been qualified for breakthrough therapy by the NMPA for prior use of pertuzumab and paclitaxel for the treatment of patients with HER2-expressing locally advanced or metastatic urothelial cancer and HER2-positive breast cancer with liver metastases.

The Company is implementing a differentiated development and commercial strategy for Disitamab Vedotin, targeting HER2-expressing indications that are currently underserved, including (i) gastric cancer (GC), (ii) urothelial carcinoma (UC) and (iii) breast cancer (BC), and (iv) other HER2-expressing cancer indications.

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 (RC48, Brand Name: 爱地希®) (for other new indications) 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
December 10, 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*