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
PHASE III CLINICAL STUDY OF DISITAMAB VEDOTIN FOR INJECTION FOR THE TREATMENT OF HER2-POSITIVE ADVANCED BREAST CANCER PATIENTS WITH LIVER METASTASES MET PRIMARY STUDY ENDPOINT

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 randomized, open, parallel-controlled, multi-center Phase III clinical study of the Company's product, Disitamab Vedotin for Injection (brand name: 爱地希®), for the treatment of patients with HER2-positive advanced breast cancer with liver metastases, has achieved a positive result and met the primary study endpoint of the clinical trial. The project has been granted breakthrough therapy designation by the National Medical Products Administration (the "**NMPA**") in June 2021. The Company plans to submit a marketing application to the Centre for Drug Evaluation (CDE) of the NMPA in the near future.

According to the data of GLOBOCAN 2022, the number of new cases of the year in the world reached 2.3 million, and the number of deaths reached 660,000 in respect of breast cancer, which was the cancer with the highest incidence rate among women. In China, the incidence and mortality rate of breast cancer ranked 6th and 7th among malignant tumors, respectively. The number of new cases of the year reached 360,000, and the number of deaths reached 70,000. The incidence of HER-2 positive breast cancer with liver metastasis was 44.5%. Without active treatment, the median survival was only 4-8 months, but there was a lack of specific treatment options.

RC48-C006 (NCT03500380) is an open, parallel-controlled, multi-center Phase III clinical study conducted in China. It aims to evaluate the efficacy and safety of Disitamab Vedotin for Injection versus Lapatinib (brand name: Tykerb®) in combination with Capecitabine (brand name: Xeloda®) for the treatment of patients with HER2-positive advanced breast cancer. According to the final analysis of this study, Disitamab Vedotin for Injection significantly prolonged progression-free survival (PFS) in patients compared with Lapatinib in combination with Capecitabine. Safety data of Disitamab Vedotin for Injection are similar to the known risks, and no new safety signals have been identified.

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

Disitamab Vedotin (RC48, brand name: 爱地希®) is an anti-HER2 antibody-drug conjugate (ADC) targeting a number of cancers with significant unmet medical needs, and it is the first domestically developed ADC in China to receive marketing approval. The product was granted conditional marketing approval by the NMPA to treat locally advanced or metastatic gastric cancer (including gastroesophageal junction (GEJ) carcinoma) in China on June 9, 2021. NMPA conditionally approved the marketing application for Disitamab Vedotin for Injection for the treatment of HER2 expressing locally advanced or metastatic urothelial carcinoma on December 31, 2021.

Disitamab Vedotin has gained approval to conduct Phase III clinical trials and received the breakthrough therapy and fast track designations for the treatment of locally advanced or metastatic urothelial carcinoma following platinum-containing chemotherapy from the U.S. Food and Drug Administration (the "**FDA**"). It has also received breakthrough therapy designation for patients with HER2 expressing locally advanced or metastatic urothelial carcinoma and HER2-positive breast cancer with liver metastasis who were previously treated with pertuzumab (brand name: Perjeta®) and taxane from NMPA.

The Company is implementing a differentiated development and commercialisation strategy for Disitamab Vedotin, targeting HER2 expressing indications with unmeet medical needs currently, including (i) gastric cancer (GC); (ii) urothelial carcinoma (UC); (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 Disitamab Vedotin (RC48, brand name: 爱地希®) (for the treatment of other 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, PRC
June 13, 2024

As at the date of this announcement, the Board 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 Mr. Hao Xianjing, Dr. Ma Lan and Mr. Chen Yunjin as the independent non-executive directors.

* *For identification purpose only*