RemeGenCo., 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 GRANTED MARKETING APPROVAL FOR DISITAMAB VEDOTIN FOR INJECTION (BRAND NAME: 爱地希®) FOR THE TREATMENT OF HER2-POSITIVE ADVANCED BREAST CANCER WITH LIVER METASTASIS IN CHINA

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 for injection (brand name: 爱地希®) has officially been approved for marketing in China by the National Medical Products Administration (the "**NMPA**") for the treatment of HER2-positive advanced breast cancer patients with liver metastasis.

The approval of this indication is based on the Phase III clinical study RC48-C006, with detailed data presented at the San Antonio Breast Cancer Symposium (SABCS) in December 2024. The results demonstrated that, compared with lapatinib in combination with capecitabine, the disitamab vedotin group significantly prolonged progression-free survival ("**PFS**") and reduced the risk of disease progression or death by 44% (median PFS: 9.9 months vs 4.9 months; hazard ratio ("**HR**") = 0.56, P = 0.0143). While overall survival ("**OS**") data were immature, a favourable trend has been noticeably observed in the disitamab vedotin group, with median OS as Not Evaluable (NE) vs 25.9 months (HR = 0.56, 95% CI: 0.25-1.29). The disitamab vedotin group also demonstrated a favourable overall safety profile, with no new safety signals identified.

Breast cancer is the second most common type of cancer globally, as evidenced by the fact that 2.3 million new cases diagnosed and 670,000 related deaths were reported worldwide in 2022, with an increasing trend observed year by year. Approximately 20%-25% of breast cancer cases are HER2-positive, with HER2 being a key driver gene and prognostic indicator in breast cancer. HER2-positive breast cancer is characterised by high aggressiveness, higher malignancy, rapid disease progression and generally poor prognosis. Liver metastasis is one of the most common forms of metastasis in breast cancer. Previously, there was no unified standard treatment regimen for HER2-positive breast cancer patients with liver metastasis, and the search for novel treatment approaches and improved patient benefit period have remained key focuses in the field of breast cancer research.

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

Disitamab vedotin is the first original antibody-drug conjugate ("**ADC**") drug developed by the Company in China, targeting the HER2 protein on the surface of tumors, which can accurately identify and kill tumor cells. World-leading clinical data have been obtained in clinical trials of disitamab vedotin for the treatment of gastric cancer, uroepithelial carcinoma, and breast cancer, etc. It is the first ADC drug in China to receive dual recognition as a breakthrough therapy by the Food and Drug Administration (FDA) in the U.S. and the NMPA in China. Its new drug applications for the treatment of gastric cancer and uroepithelial carcinoma were reviewed under the priority review and approval process and were conditionally approved for marketing in China in June 2021 and December 2021, respectively, as urgently needed clinical drugs with outstanding clinical value.

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 (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, the People's Republic of China
May 9, 2025

As at the date of this announcement, the Board comprises Mr. Wang Weidong, Dr. Fang Jianmin, Mr. Wen Qingkai and Mr. Lin Jian as the executive directors, Dr. Wang Liqiang and Dr. Su Xiaodi as the non-executive directors, and Mr. Hao Xianjing, Mr. Chen Yunjin and Mr. Huang Guobin as the independent non-executive directors.

* *For identification purpose only*