

Hong Kong Exchanges and Clearing Limited and The Stock Exchange of Hong Kong Limited take no responsibility for the contents of this announcement, make no representation as to its accuracy or completeness and expressly disclaim any liability whatsoever for any loss howsoever arising from or in reliance upon the whole or any part of the contents of this announcement.



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

Approval of the New Drug Application for Disitamab Vedotin for the Indication of HER2-Low Breast Cancer with Liver Metastases

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 Company has received the Drug Registration Certificate approved and issued by the National Medical Products Administration of the People's Republic of China (“**China's NMPA**”). The New Drug Application for the new indication of Disitamab Vedotin (Code: RC48, Trade Name: 爱地希[®], Approval No.: National Medicine Approval S20210017, Certificate No.: 2026S00808) for the treatment of HER2-low expressing breast cancer with liver metastases has been approved. This is the fourth approved indication for Disitamab Vedotin in China.

Specifically, the new indication is for the treatment of adult patients with unresectable or metastatic, HER2-low (IHC 1+ or IHC 2+/ISH-) breast cancer with liver metastases, who have received at least one prior systemic therapy in the metastatic setting, or whose disease recurred during or within 12 months of completing adjuvant chemotherapy. The approval is based on data from the randomized, open-label, parallel-controlled, multi-center Phase III clinical trial (RC48-C012) conducted in China. This study confirmed the favorable efficacy and safety of Disitamab Vedotin for this specific patient population.

Breast cancer is the most common malignant tumor in women globally. According to GLOBOCAN 2022 data, there are approximately 2.3 million new cases and 670,000 deaths worldwide annually. In China, there are approximately 357,000 new cases and 75,000 deaths each year. Liver metastasis, a particularly severe form, occurs in approximately 17.8% to 35% of metastatic breast cancer patients and is associated with a poor prognosis, with a 5-year survival rate of about 20%. HER2 is a key driver gene and prognostic indicator for breast cancer. Approximately 45% to 55% of breast cancer cases are HER2-low. The 3-year survival rate of breast cancer patients with low HER2 expression is about 20%, and approximately one-third of such patients experience recurrence and metastasis, with a significantly poorer prognosis for visceral metastasis compared with non-visceral metastasis. For a long time, treatment options for these patients have been limited following standard endocrine therapy or chemotherapy.

Disitamab Vedotin is China's first original ADC independently developed by the Company. It precisely targets the HER2 protein on tumor cells, and has achieved world-leading clinical data in clinical trials for the treatment of gastric cancer, urothelial carcinoma, breast cancer and other tumors. It is the first ADC in China to receive Breakthrough Therapy designations from both the U.S. Food and Drug Administration and China's NMPA. With this latest approval, Disitamab Vedotin is now approved in China for four indications: HER2-overexpressing locally advanced or metastatic gastric cancer; HER2-overexpressing locally advanced or metastatic urothelial carcinoma; HER2-positive advanced breast cancer with liver metastases; and HER2-low expressing breast cancer with liver metastases.

The approval of this new indication has further enhanced the market competitiveness of Disitamab Vedotin. Due to the characteristics of the pharmaceutical industry, the commercialization of the drugs after marketing approval is subject to various factors including policy environment, market demand and competitive landscape, which entail certain uncertainties. The Company will fulfill its information disclosure obligations in a timely manner in accordance with subsequent developments. 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
March 23, 2026

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 purposes only