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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-Expressing Urothelial Carcinoma

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.:2026S01078) in combination with Toripalimab for the treatment of HER2-expressing (IHC 1+/2+/3+) locally advanced or metastatic urothelial carcinoma has been approved. This is the fifth approved indication for Disitamab Vedotin in China.

The approval is based on data from a randomized, controlled, multi-center Phase III clinical trial (RC48-C016) conducted in China, with Professor Guo Jun from Peking University Cancer Hospital as the lead principal investigator. A total of 484 subjects were enrolled across 74 clinical trial centers in China. The study is the world's first Phase III trial to demonstrate, in a head-to-head comparison, that the combination of a HER2-targeting ADC and immunotherapy is significantly superior to platinum-based chemotherapy as first-line treatment for HER2-expressing advanced urothelial carcinoma. The results were presented at the Presidential Symposium of the European Society for Medical Oncology (ESMO) Annual Congress in October 2025 and were simultaneously published in The New England Journal of Medicine (NEJM).

As of March 31, 2025, the study met its dual primary endpoints of progression-free survival (PFS) and overall survival (OS), with statistically significant differences and substantial clinical benefits. Specifically, the median PFS was 13.1 months, double that of the platinum-based chemotherapy group, representing a 64% reduction in the risk of disease progression or death. The median OS was 31.5 months, also nearly double that of the chemotherapy group, representing a 46% reduction in the risk of death. The objective response rate (ORR) was 76.1% (65.5% in the HER2 IHC 1+ subgroup), and the disease control rate (DCR) was 91.4%. The median duration of response was 14.6 months, significantly longer than that of chemotherapy. The study covered the full spectrum of HER2 expression (IHC 1+/2+/3+), and the benefits in PFS and OS were consistently observed regardless of cisplatin eligibility or HER2 expression level. The safety profile was also improved, with an overall incidence of grade ≥3 treatment-related adverse events of 55.1%.

Urothelial carcinoma (UC) is one of the most common malignant tumor globally, with the highest incidence and mortality among male genitourinary tumors. Approximately 90% of UC cases originate in the bladder, with the remainder arising in the renal pelvis or ureter. According to a Frost & Sullivan report, the global number of new UC cases is expected to reach 662,000 by 2030, of which approximately 106,000 are expected in China, representing a higher incidence than the global average. UC has a high rate of recurrence and metastasis, with approximately 20% of patients already having metastases or unresectable disease at initial diagnosis, representing a significant unmet medical need. Currently, platinum-based chemotherapy is the standard first-line treatment for advanced or metastatic UC, but more than half of patients are intolerant to platinum-based regimens.

Disitamab Vedotin is China's first original antibody-drug conjugate (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. FDA and China's NMPA. With this latest approval, Disitamab Vedotin is now approved in China for five 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; HER2-low expressing breast cancer with liver metastases; and in combination with Toripalimab for the treatment of HER2-expressing locally advanced or metastatic urothelial carcinoma.

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
April 10, 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*