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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

Center for Drug Evaluation (CDE) of the China National Medical Products Administration Grants Breakthrough Therapy Designation to RC148 for the Treatment of Non-Small Cell Lung Cancer (NSCLC)

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's proprietary novel bispecific antibody, RC148, has been officially included in the Breakthrough Therapy Drug Category by the Center for Drug Evaluation (CDE) of the China National Medical Products Administration. The designated indication is: RC148 in combination with docetaxel for the treatment of driver gene-negative locally advanced or metastatic non-small cell lung cancer (NSCLC) that has failed prior PD-1/PD-L1 inhibitor and platinum-based chemotherapy (administered either in combination or sequentially).

The inclusion of RC148 in the Breakthrough Therapy Drug Category is based on a multicenter, open-label Phase I/II clinical study (RC148-C001) conducted in China. This clinical study evaluated the efficacy and safety of RC148 in combination with docetaxel for the treatment of NSCLC that had failed prior PD-1/PD-L1 inhibitor and platinum-based chemotherapy (administered either in combination or sequentially), with the primary endpoint being objective response rate (ORR), among others. The study results demonstrated that in patients with advanced NSCLC who had failed prior PD-1/PD-L1 inhibitor and platinum-based chemotherapy (administered either in combination or sequentially), RC148 in combination with docetaxel exhibited superior efficacy compared to similar drugs or standard treatments, with controllable safety and good tolerability, offering a potential new treatment option for this patient population.

Breakthrough therapy drugs are defined as innovative or improved drugs intended for the prevention or treatment of life-threatening or severely survival-impacting diseases for which there are no effective prevention or treatment methods, or for which sufficient evidence exists to demonstrate significant clinical advantages over existing therapies. For innovative drugs included in the Breakthrough Therapy Drug Category, the CDE will prioritize resource allocation, significantly shortening the time to market approval. This designation highlights the substantial clinical value and development potential of RC148 and will accelerate its clinical development process, benefiting patients more quickly.

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 RC148 will ultimately be successfully developed and 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
August 19, 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*