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 TELITACICEPT (BRAND NAME: 泰爱®) FOR THE TREATMENT OF GENERALIZED MYASTHENIA GRAVIS 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 Telitacicept (brand name: 泰爱®) has officially been approved for marketing in China by the National Medical Products Administration (the "**NMPA**") for the treatment of adult patients with anti-acetylcholine receptor ("**AChR**") antibody-positive generalized myasthenia gravis ("**gMG**").

According to the phase III data presented at the annual meeting of the American Academy of Neurology (AAN) on April 9, 2025, Telitacicept demonstrated a clinically meaningful efficacy and safety profile in patients with gMG. According to the data, after 24 weeks of treatment, 98.1% of patients in the Telitacicept group demonstrated a ≥ 3-point improvement in Myasthenia Gravis Activities of Daily Living ("**MG-ADL**") score, far exceeding that of the placebo group which was 12.0%. The MG-ADL score decreased by 5.74 points from baseline in the Telitacicept group, compared to a decrease of 0.91 point in the placebo group. 87.0% of the patients in the Telitacicept group demonstrated a ≥ 5-point improvement in Quantitative Myasthenia Gravis ("**QMG**") score, far exceeding that of the placebo group which was 16.0%. The QMG score decreased by 8.66 points from baseline in the Telitacicept, compared to a decrease of 2.27 points in the placebo group, thereby proving significant treatment differences. In terms of safety, the overall adverse event (AE) rate in the Telitacicept group was comparable to that in the placebo group, indicating a good overall safety profile.

Among the drugs for generalized myasthenia gravis that have completed phase III clinical studies, Telitacicept had the highest MG-ADL response rate data. The approval of Telitacicept in China will benefit more patients with Myasthenia Gravis in the country, thereby allowing more ambitious treatment goals to be achieved in terms of long-term disease management. Currently, the Company is advancing the global multi-center phase III trial of Telitacicept in patients with Myasthenia Gravis, aiming to validate the efficacy and safety of Telitacicept in a wider patient population.

Myasthenia Gravis is an autoimmune disease caused by neuromuscular junction transmission disorders. It is characterized by fluctuating muscle weakness and fatigue in symptoms, long treatment cycles and high recurrence rate. Approximately 80%-85% of patients with myasthenia gravis are AChR antibody positive, and more than 85% of patients develop to gMG within 24 months of onset. According to Frost & Sullivan report, there are about 1.2 million patients with Myasthenia Gravis worldwide, including approximately 220,000 patients in China. At present, there is a great unmet medical demand.

Telitacicept is constructed with the extracellular domain of the human transmembrane activator and calcium modulator and cyclophilin ligand interactor (TACI) receptor and the fragment crystallizable (Fc) domain of human immunoglobulin G(IgG), it simultaneously targets B-cell stimulator (also known as BLyS) and a proliferation-inducing ligand (APRIL), and directly attacks the production source of pathenogenic antibodies – B cells and plasma cells.

Aside from Myasthenia Gravis, Telitacicept for the treatment of two major indications, systemic lupus erythematosus (SLE) and rheumatoid arthritis (RA), have been approved in China.

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 Telitacicept (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 27, 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*