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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

Telitacicept (Brand Name: 泰爱®) Meets Primary Endpoint in Phase III Clinical Trial for Primary Sjögren's Syndrome 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 its global first-in-class BLyS/APRIL dual-target fusion protein drug, Telitacicept (brand name: 泰爱®), met the primary endpoint in its Phase III clinical trial for the treatment of primary Sjögren's syndrome (pSS) in China, as per the pre-specified study protocol. The Company will promptly submit a Biologics License Application (BLA) to the Center for Drug Evaluation (CDE) of the National Medical Products Administration (NMPA) of the PRC and plans to present the detailed data at major international academic conferences in due course. Telitacicept is the world's first BLyS/APRIL dual-target fusion protein drug to complete a Phase III study in the Sjögren's syndrome treatment field.

This multi-center, randomized, double-blind, placebo-controlled Phase III clinical study aimed to evaluate the efficacy and safety of Telitacicept in the treatment of patients with primary Sjögren's syndrome. The primary endpoint was the change from baseline in the ESSDAI score (the gold standard for measuring Sjögren's syndrome disease activity) at Week 24. The clinical results demonstrated that Telitacicept sustainably and effectively improved the clinical symptoms of patients with Sjögren's syndrome, while showing favorable efficacy and safety profile.

Sjögren's syndrome is a chronic inflammatory autoimmune disease characterized primarily by lymphocyte infiltration and damage to exocrine glands. Beyond persistent dry mouth and dry eyes caused by salivary and lacrimal gland dysfunction, it can also affect multiple organ systems. The prevalence rate of Sjögren's syndrome in China is 0.3% to 0.7%, showing an upward trend, with significant unmet clinical needs.

The study indicates that the overactivation of autoreactive B cells is a crucial pathological basis for Sjögren's syndrome. Telitacicept, a novel dual-target fusion protein independently developed by the Company, simultaneously inhibits the overexpression of B-cell Lymphocyte Stimulator (BLyS) and A Proliferation-Inducing Ligand (APRIL). It effectively blocks the abnormal differentiation and maturation of B cells and has demonstrated favorable efficacy and safety in both clinical and real-world studies.

In China, Telitacicept has been recommended by multiple authoritative guidelines, including the Chinese Clinical Practice Guideline for Off-Label Use of Drugs in Sjögren's Syndrome, the Chinese Expert Consensus on B-Cell Targeted Therapy for Rheumatic Immune Diseases, and the Multidisciplinary Expert Consensus on the Diagnosis and Treatment of Primary Sjögren's Syndrome. Internationally, Telitacicept's Sjögren's syndrome indication has been granted fast track designation by the U.S. Food and Drug Administration and the approval to initiate a global multi-center Phase III clinical trial.

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
August 14, 2025

As at the date of this announcement, the Board comprises Mr. Wang Weidong, Dr. Fang Jianmin, Mr. Lin Jian and Mr. Wen Qingkai 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*