

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
FDA GRANTS TELITACICEPT FAST TRACK
DESIGNATION FOR TREATMENT OF pSS**

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 U.S. Food and Drug Administration (FDA) has granted telitacicept (RC18, Brand Name: 泰愛®) a fast track designation (FTD) for the treatment of patients with primary Sjögren’s Syndrome (pSS). At the end of 2023, FDA approved the investigational new drug (IND) application for a Phase III trial of telitacicept for the treatment of patients with pSS.

Fast track designation is an FDA policy for expedited review of clinically urgent products designed to streamline the development and accelerate the review of innovative drugs with potential to treat serious or life-threatening diseases and that potentially address an unmet medical need. A drug candidate that receives the designation is eligible for more frequent communication and interaction with the FDA, potentially leading to accelerated approval.

Previously, the results of a randomized, double-blind and placebo-controlled Phase II clinical trial of telitacicept for the treatment of patients with pSS in China were published in RHEUMATOLOGY, a leading international journal. The conclusion of the study suggested that telitacicept demonstrated a favorable clinical benefit in the treatment of patients with pSS. Compared with placebo, the telitacicept treatment group significantly improved ESSDAI scores and MFI-20 scores and reduced immunoglobulin levels in patients with pSS at weeks 12 and 24, was safely tolerated without serious adverse events, and there were no deaths in any of the groups during the trial period.

ABOUT TELITACICEPT (RC18, BRAND NAME: 泰愛®)

Telitacicept (RC18, Brand Name: 泰愛®) is a proprietary novel fusion protein for the treatment of autoimmune diseases formulated using the extracellular domain of the human transmembrane activator and calcium modulator and cyclophilin ligand interactor (TACI) receptor and the fragment crystallisable (Fc) domain of human immunoglobulin G (IgG). Telitacicept targets two cell-signaling molecules critical for B-lymphocyte development: B-cell lymphocyte stimulator (BLyS) and a proliferation-inducing ligand (APRIL), which allows it to effectively reduce B-cell mediated autoimmune responses that are implicated in several autoimmune diseases.

It was granted full marketing approval by China's National Medical Products Administration (NMPA) in November 2023 to treat systemic lupus erythematosus (SLE). We are currently conducting several Phase II or III clinical studies for telitacicept to treat other indications within the autoimmune disease area, in an attempt to address the significant unmet or underserved medical needs in this therapeutic area.

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 (RC18, Brand Name: 泰愛®) (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
April 2, 2024

As at the date of this announcement, the Board comprises Mr. Wang Weidong, Dr. Fang Jianmin, Dr. He Ruyi and Mr. Lin Jian as the executive directors; Dr. Wang Liqiang and Dr. Su Xiaodi as the non-executive directors; and Mr. Hao Xianjing, Dr. Ma Lan and Mr. Chen Yunjin as the independent non-executive directors.

* *For identification purpose only*