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JW (Cayman) Therapeutics Co. Ltd

藥明巨諾（開曼）有限公司*

(Incorporated in the Cayman Islands with limited liability)

(Stock Code: 2126)

**VOLUNTARY ANNOUNCEMENT
RESEARCH AND DEVELOPMENT UPDATE
DATA SUBMITTED FROM PHASE I STUDY OF RELMA-CEL IN
CHINESE ADULT PATIENTS WITH ACTIVE SYSTEMIC LUPUS
ERYTHEMATOSUS TO NMPA**

JW (Cayman) Therapeutics Co. Ltd (the “**Company**” or “**JW Therapeutics**”, together with its subsidiaries, the “**Group**”), an independent and innovative biotechnology company focusing on developing, manufacturing and commercializing cell immunotherapy products, announced that the Company has submitted the Phase I study data of Relmacabtagene autoleucel injection (“**Relma-cel**”) in adult patients with active systemic lupus erythematosus (“**SLE**”) in China to the National Medical Products Administration of China (“**NMPA**”). NMPA accepted both data and meeting application.

Updates on the Safety and Efficacy of Relma-cel in Adults with Active SLE in China

SLE is a chronic autoimmune disease that can cause damage to multiple organs and tissues throughout the body. It is estimated that in China there are approximately one million SLE patients, ranking first in the world in total number and second in incidence. Traditional treatments for SLE include corticosteroids, antimalarial drugs, nonsteroidal anti-inflammatory drugs, cytotoxic drugs, and immunosuppressants/modulators. However, these traditional therapies are associated with various side effects and poor long-term tolerability, leading to poor patient compliance and disease control, further compromising mid- to long-term prognosis and quality of life. This population, particularly those with moderately to severely active SLE who require high-dose steroids and immunosuppressants, faces a significant unmet treatment need.

This updated data comes from a Phase I, single-arm, open-label, multicenter, dose-finding study conducted in China. The starting dose was 50×10^6 CAR+ T cells. Using a Bayesian Optimal Interval (BOIN) design, three dose levels (50×10^6 CAR+ T cells, 75×10^6 CAR+ T cells, and 100×10^6 CAR+ T cells) were explored to evaluate the safety of Relma-cel injection in patients with SLE and ultimately determine the recommended dose for the Phase II study.

As of July 2025, a total of 12 subjects had been enrolled and completed Relma-cel injection infusions. Preliminary safety, efficacy, and pharmacokinetics and pharmacodynamics (PK/PD) were explored in the low, medium, and high dose groups.

A total of 12 patients were infused in this study. All were female, with a median age of 27 years (range: 20 to 41 years) and a median disease history of 9.5 years (range: 4 to 20 years). The highest SELENA-SLEDAI score was 16, the lowest was 4, and the median was 10, all representing moderately to severely active SLE. Eleven patients (91.7%) had abnormal antinuclear antibody (ANA), 33.3% had elevated anti-double stranded DNA (dsDNA) antibodies, and 16.7% had urine protein greater than 2000 mg/24 hours. All 12 patients (100%) had renal involvement, with other common organ system involvement including skin (50%), hematology (50%), and joints (16.7%). Prior to enrollment in this study, all patients had received combined therapy with steroids, multiple immunosuppressants, and/or biologics, but their disease remained recurrent, necessitating new and effective treatments.

As of July 2025, Phase I results from this study showed that among the 12 patients evaluable for 6-month efficacy, 12 (100%) achieved SRI-4 remission, 6 (50%) achieved lupus low disease activity state (LLDAS) remission, and 12 (100%) achieved drug-free status. Scores on the Disease Activity Index (SLEDAI-2K), SELENA-SLEDAI, SLE-DAS, and PGA scales all showed a downward trend, demonstrating preliminary and significant efficacy.

Preliminary safety results showed that among the 12 patients who received the infusion, 11 experienced cytokine release syndrome (CRS), all of which were Grade 1. One patient (at a dose of 75×10^6) developed Grade 2 immune effector cell associated neurotoxicity syndrome (ICANS), which resolved with symptomatic treatment. None of the 12 patients experienced dose-limiting toxicities (DLTs). The safety results of this study demonstrate that Relma-cel has a favorable safety profile in the treatment of moderately to severely active SLE.

Currently, this study is ongoing to accumulate data with long-term follow-up.

Based on the results of the previous Phase I trial and this Phase I clinical study, Relma-cel has a favorable overall safety profile, manageable adverse reactions, and significant efficacy in the treatment of moderately to severely active SLE in Chinese adults. As the first commercial CAR-T therapy to receive an Investigational Designation (IND) for the treatment of SLE, Relma-cel demonstrated a favorable safety profile and significant efficacy in a Phase I study for the treatment of moderately to severely active SLE, demonstrating

strong potential for rapid advancement to the Biologics License Application (BLA) stage. We have submitted the data and have received acceptance, and we look forward to further discussions with regulatory authorities regarding the Phase II pivotal study to accelerate the development of this innovative therapy and provide a groundbreaking treatment option for SLE patients.

About Relmacabtagene Autoleucel Injection

Relmacabtagene autoleucel injection (abbreviated as **relma-cel**, trade name for oncology indications: Carteyva[®]) is an autologous anti-CD19 CAR-T cell immunotherapy product independently developed by JW Therapeutics based on a CAR-T cell process platform of Juno Therapeutics (a Bristol Myers Squibb company). Being the first product of JW Therapeutics, Carteyva[®] has been approved by the NMPA for three indications, including the treatment of adult patients with relapsed or refractory large B-cell lymphoma (r/r LBCL) after two or more lines of systemic therapy; the treatment of adult patients with follicular lymphoma that is refractory or that relapses within 24 months of second-line or above systemic treatment (r/r FL), and the treatment of adult patients with relapsed or refractory mantle cell lymphoma (r/r MCL) after second-line or higher systemic therapy including Bruton tyrosine kinase inhibitor (BTKi) treatment making it the first CAR-T product approved as a Category 1 biologics product in China. Currently, it is the only CAR-T product in China that has been simultaneously included in the National Significant New Drug Development Program, priority review and breakthrough therapy designations.

About JW Therapeutics

JW Therapeutics (Stock Code: 2126) is an independent and innovative biotechnology company focusing on developing, manufacturing and commercializing cell immunotherapy products. Since its founding in 2016, JW Therapeutics has built an integrated platform for product development in cell immunotherapy, as well as a product pipeline covering hematologic malignancies, solid tumors and autoimmune diseases. JW Therapeutics is committed to bringing breakthrough and quality cell immunotherapy products and the hope of a cure to patients in China and beyond, and to leading the healthy and standardized development of China's cell immunotherapy industry. For more information, please visit www.jwtherapeutics.com.

Cautionary Statement required by Rule 18A.05 of the Rules Governing the Listing of Securities of The Stock Exchange of Hong Kong Limited: JW Therapeutics cannot guarantee that it will be able to develop, or ultimately market relma-cel or Carteyva® successfully. Shareholders and potential investors of JW Therapeutics are advised to exercise due care when dealing in the shares of JW Therapeutics.

By order of the Board
JW (Cayman) Therapeutics Co. Ltd
藥明巨諾（開曼）有限公司*
Min Liu
Chairman

Shanghai, PRC, October 21, 2025

As at the date of this announcement, the Board of Directors of the Company comprises Mr. Min Liu as Chairman and executive Director, Dr. Yiping James Li, Ms. Xing Gao, Dr. Sungwon Song and Dr. Cheng Liu as non-executive Directors, and Mr. Kin Cheong Kelvin Ho, Dr. Debra Yu and Mr. Peng Kuan Chan as independent non-executive Directors.

* *For identification purpose only*