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 PRELIMINARY CLINICAL DATA ON RELMA-CEL INJECTION IN ADULTS WITH ACTIVE SYSTEMIC LUPUS ERYTHEMATOSUS IN CHINA AT THE EULAR 2024 CONGRESS

JW (Cayman) Therapeutics Co. Ltd (the "**Company**" or "**JW Therapeutics**", together with its subsidiaries, the "**Group**"), an independent and innovative biotechnology company focused on developing, manufacturing and commercializing cell immunotherapy products, presented the preliminary clinical data on relmacabtagene autoleucel ("**relma-cel**") injection in adults with active systemic lupus erythematosus ("**SLE**") in China at the 2024 European Alliance of Associations for Rheumatology Congress ("**EULAR 2024**").

Updates on safety and efficacy of relma-cel in adults with SLE in China (abstract number: 3246; Poster number: POS0054)

SLE is a chronic autoimmune disease causing widespread inflammation and tissue damage in the affected organs. There are about one million SLE patients in China, ranking the first worldwide in total numbers and the second in incidence rate. Current conventional therapies include corticosteroids, antimalarial drugs, non-steroidal anti-inflammatory drugs (NSAIDs), cytotoxic drugs and immunosuppressive/modulatory agents. However, conventional treatments are poorly tolerated over time, which affects the clinical efficacy, thus leading to poor disease control with organ damage and further affecting prognosis and long-term survival, especially in patients with moderately to severely active SLE who require high doses of corticosteroids and immunosuppressants.

This is a single-arm, open-label, multi-center dose escalation study (NCT05765006) in China. Participants will receive an intravenous infusion of CAR-T cells at doses of 25×10^6(25M), 50×10^6(50M), 75×10^6(75M), or 100×10^6(100M), to evaluate the safety and efficacy of relma-cel in SLE patients.

As of April 8, 2024, a total of 12 patients enrolled and received the single infusion of relma-cel. Safety, pharmacokinetics and pharmacodynamics ("**PK/PD**") and efficacy assessments were conducted across low, medium, and high dosage groups, with the longest follow-up duration of more than 9 months. At EULAR 2024, we presented data from patients in the low-dose group with relatively longer follow-up period, up to the data cutoff date of December 18, 2023.

Three patients with active SLE received single intravenous infusion of relma-cel at the dose level of 25M and completed at least 4-months follow-up. All the three patients were female with multiorgan involvement and previously exposed to high-dose steroids and several immunosuppressive treatments. Two had a medical history of more than ten years, and two patients received biological agents. After relma-cel administration, clinical signs and symptoms of SLE patients continued to be improved: SELENA-SLEDAI (Systemic Lupus Erythematosus Disease Activity Index) ("**SRI-4**") score dramatically decreased from 8~14 to 0/1, and all the three patients achieved SRI-4 while two patients reached the more stringent lupus low disease activity status (LLDAS). As of the data cut-off, all the three patients no longer used corticosteroids nor immunosuppressants. PK/PD data once again confirmed the proliferation of relma-cel in vivo and complete depletion of peripheral blood B cells. In addition, relma-cel demonstrated manageable safety profile. Cytokine release syndrome ("**CRS**") occurred in two patients (one had Grade 1 and another had Grade 3). No neurotoxicity (NT) occurred. Cytopenia occurred in two patients. Infection, macrophage activation syndrome (MAS), and effusion were observed in one single patient. The patients completely recovered around Day 60 with appropriate treatments.

The above three patients are still under study follow-up. Over the follow-up time exceeding 6 months, all three patients demonstrated ongoing improvements in both disease activity and clinical symptoms. Our preliminary data showed that relma-cel, even at a dosage significantly lower than that of hematological tumors, can effectively induce profound and lasting remissions in patients with moderate to severe SLE, while maintaining a favorable safety profile. These encouraging results bolster JW Therapeutics' potentials for further clinical development in SLE and other autoimmune diseases.

Up to date, the investigator-initiated trial ("**IIT**") is actively ongoing to accumulate data from a larger cohort with longer follow-up periods. To summarize the efficacy data for nine patients at different dose levels (three cases in the 25M dosage group, three cases in the 50M dosage group, and three cases in the 75M dosage group), 100% patients achieved an SRI-4 response at 3-month after relma-cel infusion. Notably, for those four patients (three cases from the 25M group and one from the 50M group) followed up for at least six months, still maintained a 100% SRI-4 response rate. Among all patients who received relma-cel infusion (three cases in the 25M group, three cases in the 50M group, and six cases in the 75M group), eleven patients (91.67%) stopped using traditional corticosteroids and immunosuppressants. This has not only alleviated the medication burden on patients but also minimized potential side effects. Additionally, significant improvements in organ damage have been observed in most patients, with remarkable reductions in SLE disease activity and anti-double-stranded DNA (dsDNA) antibody levels, as well as a notable decrease in the 24-hour urinary protein levels post-infusion. And 100% patients achieved rapid complete peripheral B-cell depletion after the infusion, with a median time of four days to onset. Across all dosage groups, CAR-T cells rapidly expanded, reaching peak levels around Day 8, and a clear dose-response relationship was observed. Patients in the higher dosage groups exhibited higher peak pharmacokinetic (PK) values, and longer-lasting duration of B-cell depletion.

Patients in all dosage groups showed good safety and tolerability, with only one case of Grade 3 CRS and no instances of Grade 3 or above neurotoxicity. Additionally, only two patients experienced Grade 3 infections, and all adverse events resolved following appropriate treatment.

The preliminary data from this IIT indicated that relma-cel could achieve deep and durable disease remission in patients with moderate to severe SLE, with a favorable safety profile. Based on the available/published clinical trial data, this study stands out among all clinical studies of CAR-T therapy in SLE due to its largest number of patients enrolled and the longest follow-up period, offering us robust efficacy, PK/PD, and safety data. As the pioneering commercial CAR-T therapy to receive the first Investigational New Drug (IND) approval for SLE treatment, relma-cel shows promising prospects for swift progression to the Biologics License Application (BLA) stage. We anticipate further communications with regulatory authorities to hasten the commercialization of this groundbreaking treatment and offer a transformative therapeutic option to those living with SLE.

Dr. Mark J. Gilbert, Chief Medical Officer of JW therapeutics, said, "Despite the recent emergence of novel biologics and therapies for SLE, many SLE patients still do not respond to available treatments, and there is currently no reliable treatment strategy to achieve drug-free remissions or even to cure the disease. The short-term follow-up data from this study have preliminarily shown that low-dose relma-cel injection has a favorable safety profile in SLE patients, and is able to bring about deep remission, especially enabling patients to achieve low disease activity or even drug-free remission, which makes its application in the treatment of SLE a promising prospect."

About Relmacabtagene Autoleucel Injection

Relmacabtagene autoleucel injection (abbreviated as relma-cel, 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, relma-cel has been approved by the China National Medical Products Administration for two indications, including the treatment of adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, and 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), 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, and is committed to becoming an innovation leader in cell immunotherapy. Founded in 2016, JW Therapeutics has built a world-class 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 worldwide, and 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 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*
Yiping James Li
Chairman

Shanghai, PRC, May 30, 2024

As at the date of this announcement, the Board of Directors of the Company comprises Dr. Yiping James Li as Chairman and executive Director, Ms. Xing Gao, Dr. Sungwon Song and Dr. Cheng Liu as non-executive Directors, and Mr. Yiu Leung Andy Cheung, Mr. Kin Cheong Kelvin Ho, Dr. Debra Yu, Dr. Krishnan Viswanadhan and Dr. Ann Li Lee as independent non-executive Directors.

* *For identification purpose only*