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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
NMPA ACCEPTANCE OF THE SUPPLEMENTAL BIOLOGICAL
LICENSE APPLICATION FOR CARTEYVA® AS SECOND-LINE
TREATMENT IN RELAPSED OR REFRACTORY LARGE B-CELL
LYMPHOMA INELIGIBLE FOR AUTOLOGOUS STEM CELL
TRANSPLANTATION**

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 National Medical Products Administration of China (“**NMPA**”) accepted the supplemental Biological License Application (“**sBLA**”) for its cell immunotherapy product Carteyva® (relmacabtagene autoleucel injection) as second-line treatment in relapsed or refractory large B-cell lymphoma (“**r/r LBCL**”). This is the fourth sBLA on Carteyva® submitted by JW Therapeutics. In January 2025, Carteyva® was granted Breakthrough Therapy Designation by NMPA.

Large B-cell lymphoma (“**LBCL**”) is a highly aggressive non-Hodgkin’s lymphoma and is the most common subtype of lymphoma in adults. LBCL is a potentially curable disease, but 30–40% of patients still experience refractory or relapse. Patients who fail first-line treatment have a poor outcome, and although conventional treatment options such as high-dose chemotherapy followed by autologous stem cell transplantation (“**ASCT**”) are the standard of care, approximately more than half of the patients are not suitable for ASCT due to a variety of reasons such as advanced age, comorbidities, and so on, and there is no standard of care with a very poor outcome. There are still urgent unmet medical needs to develop additional active therapeutic approaches for the treatment of r/r LBCL.

The sBLA was supported by the clinical results from a single-arm, multi-center, pivotal study on Cartheyva® in Chinese adult patients with r/r LBCL ineligible for ASCT after failure of first-line therapy. In the study, patients with r/r LBCL who were ineligible for ASCT had failed first-line systemic therapy with CD20-targeted antibodies and anthracyclines were included. After lymphodepleting chemotherapy, patients received Cartheyva® (100×10⁶ CAR+ T cells). As of January 21, 2025, a total of 49 patients received Cartheyva® infusion and had at least 3-month follow-up. Of 48 efficacy evaluable patients, Cartheyva® demonstrated remarkable clinical responses and good safety. The best objective response rate (ORR) was 81.3% and the best complete response rate (CRR) was 54.2%. The incidence of severe (≥Grade 3) cytokine release syndrome (CRS) was 4.1%, and no severe neurological toxicity (NT) was observed.

About Relmacabtagene Autoleucel Injection

Relmacabtagene autoleucel injection (abbreviated as relma-cel, trade name for oncology indications: Cartheyva®) 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, Cartheyva® has been approved by the NMPA for three indications, including the treatment of adult patients with 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, May 28, 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*