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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
RECEIPT OF BREAKTHROUGH THERAPY DESIGNATION FOR
CARTEYVA® IN CHINA AS SECOND-LINE TREATMENT
IN RELAPSED OR REFRACTORY ADULT LARGE B-CELL
LYMPHOMA**

JW (Cayman) Therapeutics Co. Ltd (the “**Company**” or “**JW Therapeutics**”), an independent and innovative biotechnology company focusing on developing, manufacturing and commercializing cell immunotherapy products, announced that the Center for Drug Evaluation of the National Medical Products Administration of China (the “**NMPA**”) has granted Breakthrough Therapy Designation for Carteyva® (relmacabtagene autoleucel injection) as second-line treatment in adults with relapsed or refractory large B-cell lymphoma (“**r/r LBCL**”). Carteyva® is an anti-CD19 autologous chimeric antigen receptor T (“**CAR-T**”) cell immunotherapy product independently developed by JW Therapeutics.

The Breakthrough Therapy Designation was supported by the results from the clinical study aimed to assess the efficacy and safety of Carteyva® in Chinese adults with r/r LBCL who were not intended for autologous stem cell transplantation after failure of first-line therapy. This is the first clinical result obtained in Chinese patients.

Large B-cell lymphoma 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 haematopoietic stem cell transplantation (HDCT/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.

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 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 two or more lines of systemic therapy including bruton tyrosine kinase inhibitors (BTKi), 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 JWCAR029–216 Study (NCT06093841)

This is a phase II, open-label, single-arm, multicenter study which aims to assess the efficacy and safety of Cartheyva® in Chinese adults with r/r LBCL who were not intended for autologous stem cell transplantation after failure of first-line therapy. This is the first clinical study to evaluate such novel therapy in Chinese LBCL patients. The study will be conformance with the Chinese clinical practices and will truly reveal the efficacy and safety data in Chinese patients. The study is currently ongoing. Preliminary clinical data found Cartheyva® providing outstanding efficacy and good safety profile for r/r LBCL patients, with a best overall response rate of 84%.

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*
Yiping James Li
Chairman

Shanghai, PRC, January 10, 2025

As at the date of this announcement, the Board of Directors of the Company comprises Dr. Yiping James Li as Chairman and non-executive Director, Mr. Min Liu as executive Director, 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*