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® IN PATIENTS WITH RELAPSED OR REFRACTORY MANTLE CELL LYMPHOMA

JW (Cayman) Therapeutics Co. Ltd (the "**Company**" or "**JW Therapeutics**"), an independent and innovative biotechnology company focused on developing, manufacturing and commercializing cell immunotherapy products, announced that the National Medical Products Administration of China (the "**NMPA**") accepted the supplemental Biological License Application (the "**sBLA**") for its anti-CD19 autologous chimeric antigen receptor T ("**CAR-T**") cell immunotherapy product Carteyva® (relmacabtagene autoleucel injection) for the treatment of adult patients with relapsed or refractory ("**r/r**") mantle cell lymphoma ("**MCL**"). This is the third marketing application on Carteyva® submitted by JW Therapeutics, and is expected to be the first cell therapy product approved in China for the treatment of patients with r/r MCL. Carteyva® was granted, by NMPA, Breakthrough Therapy Designation in March 2022, as well as Priority Review in December 2023.

MCL is a rare and heterogeneous B cell non-Hodgkin lymphoma which is currently incurable with existing therapies[1]. MCL, associated with a poor prognosis, mainly occurs in elderly men who were not diagnosed until advanced stage[2]. Significant progress has been made in the last decade as the treatment paradigm has shifted from traditional chemoimmunotherapy toward targeted therapies such as bruton tyrosine kinase inhibitors ("**BTKi**"). Despite the use of BTKi in r/r MCL has improved their survival outcomes, many patients will ultimately relapse with shortened remission durations (6 to 10 months)[3].

1 The consensus of the diagnosis and treatment of mantle cell lymphoma in China (2016 version). Chin J Hematol.2016, 37(9):735–741

2 Herrmann A, Hoster E, Zwingers T, et al. Improvement of Overall Survival in Advanced Stage Mantle Cell Lymphoma[J]. Journal of Clinical Oncology, 2009, 27(4):511–518

3 Burkart M, Karmali R. Relapsed/Refractory Mantle Cell Lymphoma: Beyond BTK Inhibitors. J Pers Med. 2022 Mar 1;12(3):376

Notwithstanding the above, there are still unmet medical needs for a safe, effective novel approach to overcome the limitations of current treatments of r/r MCL.

The sBLA was supported by the clinical results from a single-arm, multi-center, pivotal study on Carteyva® in adult participants with r/r MCL in China. In the Study, participants with r/r MCL who had been treated with a CD20-targeting antibody, anthracycline or bendamustine, or BTKis were included. After being treated with lymphodepleting chemotherapy, participants received relma-cel (100×10^6 CAR-T cells). As of October 25, 2023, a total of 59 participants received relma-cel infusion. Of 56 efficacy evaluable participants, relma-cel demonstrated remarkable clinical responses achieving high rates of objective response rate ("**ORR**") and complete response rate ("**CRR**") (3 months best ORR 81.36%, 3 months best CRR 66.10%) and the incidence of severe (grade ≥ 3) cytokine release syndrome was 6.8%, the incidence of severe (grade ≥ 3) neurotoxicity was 6.8%.

Mark J. Gilbert, MD, chief medical officer of JW Therapeutics, noted: "We are delighted to have a product that can deliver meaningful efficacy in this disease, nearly 70% of participants with r/r MCL have achieved complete remission after treatment with relma-cel, and the overall safety data demonstrated that the treatment was generally well tolerate. Carteyva® is expected to become the first commercial CAR-T cell product for the treatment of r/r MCL in China."

About Relmacabtagene Autoleucel Injection (trade name: Carteyva®)

Relmacabtagene autoleucel injection (abbreviated as relma-cel, trade name: 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 former subsidiary of Bristol Myers Squibb). Being the first product of JW Therapeutics, relma-cel has been approved by the NMPA in September 2021 for the treatment of adult patients with r/r large B-cell lymphoma after two or more lines of systemic therapy, 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 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 4, 2024

As of the date of this announcement, the Board 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 purposes only*