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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)

**INSIDE INFORMATION ANNOUNCEMENT
RESEARCH AND DEVELOPMENT UPDATE
NMPA APPROVAL OF RELMACABTAGENE AUTOLEUCEL
INJECTION IN CHINA**

This announcement is made by JW (Cayman) Therapeutics Co. Ltd (the “**Company**” or “**JW Therapeutics**”, together with its subsidiaries, the “**Group**”) pursuant to Rule 13.09 of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited (“**Listing Rules**”) and the Inside Information Provisions (as defined in the Listing Rules) under Part XIVA of the Securities and Futures Ordinance (Chapter 571, Laws of Hong Kong).

The board (the “**Board**”) of directors (the “**Directors**”) of the Company is pleased to announce that, the National Medical Products Administration (the “**NMPA**”) of China has approved the New Drug Application (“**NDA**”) for the Company’s anti-CD19 autologous chimeric antigen receptor T (“**CAR-T**”) cell immunotherapy product relmacabtagene autoleucel injection (“**relma-cel**”), R&D code: JWCAR029) for the treatment of adult patients with relapsed or refractory large B-cell lymphoma (“**r/r LBCL**”) after two or more lines of systemic therapy. Relma-cel is the first CAR-T product approved as a Category 1 biologics product in China, and sixth approved CAR-T product globally.

Relma-cel, JW Therapeutics’ first CAR-T product, was independently developed based on a CAR-T cell process platform of Juno Therapeutics (a Bristol Myers Squibb company) to meet the needs of the Chinese market. Currently, it is the only approved CAR-T product in China that has been simultaneously included in the National Significant New Drug Development Program, granted priority review (for relma-cel as a treatment of r/r LBCL) and breakthrough therapy designations (for relma-cel as a treatment of follicular lymphoma). To date, over 100 patients have been dosed with relma-cel in clinical studies, making relma-cel the most studied anti-CD19 CAR-T product in China.

This approval is based on the results of a single-arm, multi-center, pivotal study (“**RELIANCE study**”) to evaluate the efficacy and safety of relma-cel in patients with r/r LBCL in China. RELIANCE study results show that relma-cel demonstrated high rates of durable disease response and low rates of CAR-T associated toxicities, and may provide a best-in-class CAR-T therapy profile.

About Relma-cel

Relma-cel is an autologous anti-CD19 CAR-T cell immunotherapy product that was independently developed by JW Therapeutics based on a CAR-T cell process platform of Juno Therapeutics (a Bristol Myers Squibb company). The first product of JW Therapeutics, relma-cel was approved by the NMPA in September 2021 for the treatment of adult patients with r/r LBCL 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”, granted priority review and breakthrough therapy designations.

About RELIANCE Study (NCT04089215)

RELIANCE study was a single-arm, multi-center, pivotal study to evaluate the efficacy and safety of relma-cel in patients with r/r LBCL in China. At the time it was conducted, this study was the largest clinical study of CAR-T cell therapy in China under the Investigational New Drug (“**IND**”) pathway.

RELIANCE study enrolled 59 patients with r/r LBCL who had failed at least two lines of therapy, including a CD20 agent and anthracycline, and patients continued to be monitored for up to 2 years and beyond for long term outcomes. As of the June 17, 2020 data cut-off, the Best Overall Response Rate was 75.9% with a Best Complete Response Rate of 51.7% in 58 evaluable patients; of 59 treated patients, 5.1% and 3.4% of the patients experienced cytokine release syndrome (“**CRS**”) and neurological toxicity (“**NT**”) of Grade 3 or above, respectively. Rates for any severity grade CRS and NT were 47.5% and 20.3%, respectively.

About JW Therapeutics

JW Therapeutics is an innovative biotechnology company focusing on developing, manufacturing and commercializing cell immunotherapy products. Co-founded by Juno Therapeutics (a Bristol Myers Squibb company) and WuXi AppTec in 2016, JW Therapeutics is committed to becoming an innovation leader in cell immunotherapy. The Company has built a top world-class platform for technology and product development in cell immunotherapy, as well as a promising product pipeline covering both hematologic malignancies and solid tumors, to bring the hope of a cure for Chinese and global patients, and to lead 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, September 3, 2021

As at the date of this announcement, the Board of Directors of the Company comprises Dr. Yiping James Li as Chairman and executive Director, Mr. Hans Edgar Bishop, Dr. Krishnan Viswanadhan, Ms. Xing Gao, Dr. Ann Li Lee, Mr. Jinyin Wang, Dr. Cheng Liu as non-executive Directors, and Mr. Yanling Cao, Mr. Chi Shing Li, Mr. Yiu Leung Andy Cheung, Mr. Kin Cheong Kelvin Ho as independent non-executive Directors.

* *For identification purpose only*