Mabwell (Shanghai) Bioscience Co., Ltd.
邁威(上海)生物科技股份有限公司
(A joint stock company incorporated in the People's Republic of China with limited liability)
(Stock Code: 2493)

VOLUNTARY ANNOUNCEMENT REGARDING THE RECEIPT OF U.S. FDA CLEARANCE FOR THE CLINICAL TRIAL APPLICATION OF 9MW5211 INJECTION

This announcement is made by Mabwell (Shanghai) Bioscience Co., Ltd. (邁威(上海)生物科技股份有限公司) (the "**Company**") on a voluntary basis. Reference is also made to the overseas regulatory announcement of the Company dated May 9, 2026.

The Board of the Company (the "**Board**") is pleased to announce that the Company has received a Study May Proceed Notification (《臨床研究繼續進行通知書》) from the U.S. Food and Drug Administration ("**FDA**"), pursuant to which the clinical trial application for 9MW5211 injection for the treatment of inflammatory bowel disease ("**IBD**") has been formally cleared by the FDA. In addition, the clinical trial applications for multiple indications, including IBD and multiple sclerosis ("**MS**"), have been accepted for review by the National Medical Products Administration ("**NMPA**") of the People's Republic of China, and the Company is also actively advancing clinical trial applications for other indications. Given that the research and development of pharmaceutical products involves lengthy cycles and multiple regulatory approval stages and is therefore subject to various uncertainties, investors are advised to exercise prudence in making investment decisions and to pay due attention to investment risks.

I. Basic Information of the Drug

Drug Name: 9MW5211 Injection
Application Matter: Clinical Trial Application for a New Drug
Application Number: IND 180525
Applicant: Mabwell (Shanghai) Bioscience Co., Ltd.

Approval Conclusion: The FDA has completed its safety evaluation of the present application and has granted clearance for the proposed clinical study plan to be conducted with the investigational product, namely, "a randomized, placebo-controlled, single-ascending-dose first-in-human study designed to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics, and immunogenicity of 9MW5211 in healthy subjects."

II. Other Relevant Information Regarding the Drug

9MW5211 is a highly specific, depleting and innovative antibody independently developed by the Company, designed to precisely intervene in the key pathological mechanisms mediated by abnormal immune cells in autoimmune diseases. The abnormal activation and tissue infiltration of immune cells act as the core driving factors in the occurrence and development of various autoimmune diseases. The target molecule of 9MW5211 is specifically expressed on the surface of pathogenic immune cells and serves as a vital biological marker of their abnormal activation. By selectively recognizing and depleting this population of pathogenic cells, 9MW5211 can effectively block the immune cascade, thereby delaying disease progression and ameliorating clinical symptoms.

Through multiple rounds of molecular engineering optimization, 9MW5211 has demonstrated excellent target selectivity. While achieving efficient blockade, it significantly mitigates the risk of non-specific binding, ensuring deep depletion of pathogenic cells highly expressing the target protein. Such a unique mechanism of action is expected to not only bring deeper disease remission but also potentially support an extended dosing interval, thereby enhancing patient compliance and quality of life.

Preclinical study results have demonstrated that 9MW5211 exhibits significant therapeutic potential in various mouse models of autoimmune diseases, suggesting its future clinical application may cover multiple major indications. As of the date of disclosure of this announcement, the clinical trial application for 9MW5211 for the treatment of IBD has been cleared by the FDA, and the clinical trial applications for multiple indications, including IBD and MS, have been accepted for review by the National Medical Products Administration (NMPA) of China. The Company is also actively advancing clinical trial applications for other indications. Concurrently, safety evaluations conducted in cynomolgus monkey models have shown a favourable safety profile. As the first clinical-stage drug candidate globally targeting this molecule, 9MW5211 holds the potential to usher in a new chapter in precision therapy for autoimmune diseases.

IBD is a chronic, relapsing, immune-mediated disorder of the gastrointestinal tract, which primarily includes ulcerative colitis and Crohn's disease. The number of IBD cases globally has been steadily increasing. Epidemiological studies indicate that the number of newly diagnosed IBD patients worldwide rose from 5.90 million in 2019 to 7.00 million in 2023, representing a compound annual growth rate (CAGR) of 4.4%. The number of newly diagnosed IBD patients globally is projected to reach 11.50 million by 2032, with a CAGR of 5.6% from 2023 to 2032.

MS is a chronic autoimmune disease characterized by inflammatory damage to the protective myelin sheaths surrounding the nerves of the brain and spinal cord. The number of MS patients globally increased from 2.80 million cases in 2020 to 3.00 million cases in 2024, and is projected to reach approximately 3.50 million cases by 2035. In China, the number of MS patients increased from 32,800 cases in 2020 to 33,900 cases in 2024, and is expected to reach 35,500 cases by 2035.

III. Risk Warning

Given that pharmaceutical products are characterised by high technology, high risks and high added value, the process from clinical trials, regulatory approval to commercial production involves lengthy cycles and multiple stages, and is therefore subject to various uncertainties. Investors are advised to exercise prudence in making investment decisions and to pay due attention to investment risks.

The Company will actively advance the aforementioned research and development projects and will strictly adhere to relevant regulations to fulfill its information disclosure obligations regarding the subsequent progress of the projects in a timely manner.

Cautionary statement required by Rule 18A.05 of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited: The Company cannot guarantee that 9MW5211 will ultimately be successfully developed and marketed. Shareholders of the Company and potential investors are advised to excercise caution when dealing in the shares of the Company.

By Order of the Board
Mabwell (Shanghai) Bioscience Co., Ltd.
Dr. Liu Datao
Chairman of the Board and Executive Director

Shanghai, the PRC, May 9, 2026

As at the date of this announcement, the directors of the Company are: (i) Mr. Tang Chunshan, Dr. Liu Datao (Chairman of the Board), Dr. Wu Hai, Mr. Hu Huiguo, Dr. Gui Xun as executive directors; (ii) Mr. Wu Yufeng as non-executive director; and (iii) Mr Qin Zhengyu, Dr. Xu Qing, Dr. Zhao Qian and Ms. Wang Fang as independent non-executive directors.