

Hong Kong Exchanges and Clearing Limited and The Stock Exchange of Hong Kong Limited take no responsibility for the contents of this announcement, make no representation as to its accuracy or completeness, and expressly disclaim any liability whatsoever for any loss howsoever arising from or in reliance upon the whole or any part of the contents of this announcement.



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

ANNOUNCEMENT IN RELATION TO CLINICAL TRIAL APPLICATION FOR 9MW5211 INJECTION APPROVED BY NMPA

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 July 31, 2026.

The Company has received the Approval Notice for Clinical Trials of Drugs (《藥物臨床試驗批准通知書》) from the National Medical Products Administration (“**NMPA**”), pursuant to which the clinical trial application for 9MW5211 injection for the indication of primary biliary cholangitis (“**PBC**”) has been approved. Previously, its clinical trial application for the indication of inflammatory bowel disease (“**IBD**”) has been approved by the NMPA and cleared by FDA, respectively, and its clinical trial applications for the indications of multiple sclerosis (“**MS**”), Type 1 diabetes mellitus (“**T1DM**”) and vitiligo have been approved by the NMPA. 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. The relevant particulars are hereby announced as follows:

I. BASIC INFORMATION OF THE DRUG

Drug Name: 9MW5211 Injection

Application Matter: Registration clinical trial of domestically-produced drugs

Applicant: Mabwell (Shanghai) Bioscience Co., Ltd.

Clinical Trial Approval Notice No.: 2026LP02330

Approval Conclusion: In accordance with the Drug Administration Law of the People's Republic of China (《中華人民共和國藥品管理法》) and relevant provisions, upon review, the clinical trial application for 9MW5211 Injection accepted on May 26, 2026 complies with the applicable requirements for drug registration, and approval is granted to conduct clinical trials of the product.

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 applications for 9MW5211 for the indications of vitiligo, PBC, T1DM, MS and IBD have been approved by the NMPA, and the clinical trial application for the indication of IBD has been cleared by FDA. 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.

PBC is a chronic autoimmune intrahepatic cholestatic liver disease. Its most prevalent clinical manifestations are fatigue and pruritus. The disease has a global distribution and affects all races and ethnicities, with an estimated global annual incidence of 1.76 per 100,000 population and a prevalence of 14.6 per 100,000 population. In 2023, the National Health Commission of the People's Republic of China included PBC in the Second Batch of Rare Disease Catalogue. Patients with PBC in the decompensated stage develop manifestations of decompensated cirrhosis. Approximately 40% of patients exhibit an inadequate response to ursodeoxycholic acid, the current first-line therapeutic agent. Treatment options for PBC remain limited, leaving substantial unmet clinical needs in this therapeutic area.

Vitiligo is characterized by the selective loss of melanocytes, which results in hypopigmentation in the affected areas of the skin and manifests as depigmentation of the skin, mucous membranes or hair. The prevalence of vitiligo worldwide ranges from 0.5% to 2.0%, while its overall prevalence in China is approximately 0.56%. Current treatments for vitiligo include topical medications, systemic medications, phototherapy, transplantation, camouflage and depigmentation. Although these treatment options may promote repigmentation of skin lesions to a certain extent, substantial unmet clinical needs remain. With an increasingly in-depth understanding of the pathogenesis of vitiligo, future treatments are expected to place greater emphasis on achieving more effective and durable therapeutic outcomes through targeted inhibition of melanocyte damage and autoimmune responses.

T1DM is a chronic autoimmune disorder primarily characterized by the body's immune system mistakenly attacking and destroying insulin-producing beta cells in the pancreas. This results in absolute insulin deficiency and subsequent persistent elevation of blood glucose levels. At present, insulin replacement therapy remains the cornerstone of the treatment landscape for T1DM, yet its therapeutic goals and implementation approaches have undergone marked evolution. Conventional T1DM treatment primarily centers on hyperglycaemia control; by contrast, the prevailing treatment trend places greater emphasis on achieving individualized glycaemic control approximating physiological levels while avoiding hypoglycaemia and diabetic ketoacidosis (“**DKA**”). Additional objectives include improving patients' quality of life, mitigating the risk of chronic complications and extending healthy life expectancy. For patients with T1DM, especially newly diagnosed individuals, the Chinese Guidelines for the Prevention and Treatment of Diabetes (2024 Edition) highlight the importance of preserving residual beta-cell function, reducing the incidence of T1DM-related complications, and lowering disability and mortality rates. According to the 2025 IDF Diabetes Atlas released by the International Diabetes Federation (“**IDF**”), there are 9.15 million patients with T1DM worldwide. Of these patients, 1.81 million are children and adolescents under 20 years of age, accounting for 19.8%, 6.28 million are aged between 20 and 59 years, representing 68.6%, and 1.06 million are aged 60 years or above, making up 11.8%. In China, the prevalence of T1DM stands at 599,000 patients, including 117,000 children and adolescents under 20 years old.

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.

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.

III. RISK WARNING

Given that pharmaceutical products are characterised by high technology, high risks and high added value, the process from clinical trials and 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 project and will strictly adhere to relevant regulations to fulfil its information disclosure obligations with respect to the subsequent progress of the project in a timely manner. All information concerning the Company shall be subject to the announcements published on the designated disclosure media of the Company and the website of the Shanghai Stock Exchange.

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 exercise 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, July 31, 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. Hua Jun and Dr. Gui Xun as executive directors; and (ii) Mr. Qin Zhengyu, Mr. Zhou Rui, Ms. Li Fan and Ms. Wang Fang as independent non-executive directors.