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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 FDA CLEARANCE FOR THE CLINICAL TRIAL APPLICATION OF 6MW5311 FOR 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 June 13, 2026.

The Company has received the Study May Proceed Notification (《臨床研究繼續進行通知書》) issued by the U.S. Food and Drug Administration ("**FDA**"). The clinical trial application for 6MW5311 for Injection targeting indications of hematological malignancies, including acute myeloid leukemia ("**AML**"), chronic myelomonocytic leukemia ("**CMML**") and multiple myeloma ("**MM**"), has been officially cleared by the FDA. In addition, the clinical trial application for 6MW5311 has been accepted for review by the National Medical Products Administration ("**NMPA**"). 6MW5311 is the world's first novel TCE drug targeting LILRB4/CD3 that receives approval for clinical trials. Given that the clinical trials 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: 6MW5311 for Injection

Application Matter: Clinical trial application of new drug

Application No.: IND 180976

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

Approval Conclusion: The FDA has completed the safety assessment of the application and approved the commencement of the proposed clinical research plan for the product.

II. Other Relevant Information Regarding the Drug

6MW5311 is a bispecific antibody targeting LILRB4/CD3 developed based on the Company's T Cell Engager ("**TCE**") technology platform. It is developed for the intended indications of hematological malignancies (AML, CMML and MM).

AML is a group of malignant clonal diseases originating from myeloid stem cells, featuring high heterogeneity and a high mortality rate. There were approximately 172,400 new AML cases worldwide in 2022, and the figure is projected to rise to 221,400 by 2035, representing a compound annual growth rate ("**CAGR**") of 1.94%. In China, around 30,800 new AML cases were recorded in 2022, accounting for 17.9% of the global total. The number is expected to reach 36,700 by 2035, making up 16.6% of the global total, with a CAGR of 1.36%.

CMML is a clonal hematopoietic stem cell disease that presents overlapping characteristics of myelodysplastic syndromes ("**MDS**") and myeloproliferative neoplasms ("**MPN**"). It is primarily manifested by a marked increase in peripheral blood monocytes and carries an inherent risk of progression to AML (approximately 15% to 20% within 3 to 5 years). As a rare disease, CMML has an annual incidence of 3 to 4 cases per 100,000 population, and there is a lack of effective therapeutic drugs for this condition.

MM is a clonal malignant plasma cell neoplasm. It is characterized by the uncontrolled proliferation of monoclonal plasma cells in the bone marrow, which leads to excessive production of abnormal immunoglobulins and subsequent end-organ damage, presenting as hypercalcemia, renal impairment, anemia and bone lesions (namely, CRAB criteria). Globally, MM accounts for 1% to 2% of all cancers and around 10% of hematological malignancies. The median age at diagnosis is approximately 69 years, with a higher incidence among males and people of African descent. Over the past two decades, the widespread use of proteasome inhibitors, immunomodulatory drugs and monoclonal antibodies has greatly improved patient survival rates. Nevertheless, MM remains largely incurable, and most patients experience multiple disease relapses during treatment, therefore 6MW5311 boasts promising market prospects going forward.

6MW5311 adopts an asymmetric "2+1" molecular structure and targets both LILRB4 and CD3. It bridges tumor cells and T cells to form immunological synapses, thereby activating T cells and enabling potent tumor cell killing. With a uniquely designed steric hindrance structure, this molecule markedly reduces the binding activity of CD3 antibodies to T cells in the absence of tumor cells. It specifically activates T cells only when tumor cells are present, which enhances anti-tumor efficacy while greatly improving safety profiles. In vitro studies have demonstrated that 6MW5311 exerts potent cytotoxic activity against multiple tumor cell lines and patient-derived samples. In vivo pharmacodynamic studies show that 6MW5311 delivers significant tumor inhibition in AML tumor models with high and low LILRB4 expression, and can even achieve complete tumor regression in models with high LILRB4 expression. Furthermore, 6MW5311 has exhibited favorable safety profile in safety evaluation studies using cynomolgus monkeys.

As a key technology that directly mobilizes T cells to efficiently eliminate tumor cells, TCE has demonstrated remarkable clinical value for various lymphoma indications, with multiple products already launched commercially. Currently, treatments for AML and CMML mainly include chemotherapy, hematopoietic stem cell transplantation and targeted drugs for specific mutations, while no TCE-based products have yet been approved for these two diseases. As the world's first novel TCE drug targeting LILRB4/CD3 to receive clinical trial approval, 6MW5311 enjoys broad prospects for clinical development and great market potential.

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 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 6MW5311 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, June 13, 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.