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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 APPROVAL OF SUPPLEMENTARY APPLICATION
FOR ADDITIONAL INDICATIONS OF MAIWEIJIAN (邁衛健®) 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 21, 2026.

Recently, Jiangsu T-mab BioPharma Co., Ltd. (“**T-mab BioPharma**”), a wholly-owned subsidiary of the Company, received the Approval Notice for Supplementary Drug Application 《藥品補先申請批准通知書》 issued and approved by the National Medical Products Administration (“**NMPA**”), pursuant to which the supplementary application for Denosumab Injection (Maiweijian (邁衛健®), 9MW0321) to add the indications of bone metastases from solid tumors and multiple myeloma (for the treatment of patients with bone metastases from solid tumors or patients with multiple myeloma, to delay or reduce the risk of skeletal-related events (pathological fracture, spinal cord compression, bone radiotherapy, or bone surgery) has been approved by the NMPA. As the production and commercialization of drugs following approval are subject to certain uncertainties, investors are advised to exercise caution in their decision-making and pay attention to investment risk prevention. Relevant information is hereby announced as follows:

I. Basic Information of the Drug

Drug Name: Denosumab Injection

Dosage Form: Injection

Specification: 120mg (1.7ml) per vial

Application Matter: Supplementary Application for Domestically Produced Drugs

Added Indications: Indications for bone metastases of solid tumors and multiple myeloma (for the treatment of patients with bone metastases from solid tumors or patients with multiple myeloma, to delay or reduce the risk of skeletal-related events including pathological fracture, spinal cord compression, bone radiotherapy and bone surgery)

Notice Number: 2026B02916

Applicant: Jiangsu T-mab BioPharma Co., Ltd.

Approval Conclusion: In accordance with the Drug Administration Law of the People's Republic of China and relevant provisions, upon review, this product complies with the relevant requirements for drug registration, and the supplementary application for revision of the package insert of this product is hereby approved.

II. Other Relevant Information Regarding the Drug

9MW0321 (Maiweijian (邁衛健®)) is a recombinant fully human anti-RANKL monoclonal antibody injection. Marketing authorisation application of Maiweijian (邁衛健®) was approved by the NMPA on March 29, 2024 for the treatment of unresectable giant cell tumor of bone or cases where surgical resection may cause severe dysfunction, including adult patients and skeletally mature adolescent patients (defined as having at least 1 mature long bone and a body weight of $\geq 45\text{kg}$). It is one of the first-tier approved biosimilars of Xgeva® in China.

In 2022 and 2024, the Company successively published the Phase I and Phase III clinical research findings of denosumab biosimilar in *International Immunopharmacology* and *JAMA Oncology*, one of top-tier international journals, respectively. Through “head-to-head” pharmacokinetic comparison and clinical efficacy comparison studies conducted in patients with solid tumor bone metastases, the similarities between 9MW0321 and the reference original drug in terms of pharmacokinetics, pharmacodynamics, clinical efficacy and safety have been fully and systematically verified.

In terms of overseas commercialisation, in August 2025, the product received registration approval from the Drug Regulatory Authority of Pakistan, marking the first biosimilar of Xgeva® approved in Pakistan, and the product has already been supplied in the country. In June 2025, T-mab BioPharma successfully passed the on-site GMP inspection conducted by the Instituto Nacional de Vigilancia de Medicamentos y Alimentos (INVIMA) for denosumab. As of this announcement disclosure date, the Company has signed formal cooperation agreements for 9MW0321 with 33 countries including Brazil, Colombia, Indonesia, Singapore, Pakistan, Thailand, Egypt, Peru, Saudi Arabia, Vietnam, and Malaysia. Registration applications have been submitted to 8 countries such as Jordan, Egypt, and Brazil, with applications for other countries in preparation. The Company will continue to leverage its existing commercial network and expansion capabilities in emerging markets to rapidly advance cooperation, registration, and launch of this product in overseas markets.

The original reference drug Xgeva® has been approved in more than 70 countries worldwide. In China, Xgeva was granted conditional approval in May 2019 for the treatment of unresectable giant cell tumor of bone or lesions where surgical resection may cause severe dysfunction, covering adult patients and skeletally mature adolescent patients (defined as having at least 1 mature long bone and a body weight of $\geq 45\text{kg}$), which was converted to regular approval in January 2024. It received conditional approval in November 2020 for the treatment of patients with bone metastases from solid tumors or multiple myeloma to delay or reduce the risk of skeletal-related events including pathological fracture, spinal cord compression, bone radiotherapy and bone surgery, and was switched to regular approval in April 2026. In 2025, the sales revenue of Xgeva® in China reached approximately USD306 million, representing a year-on-year increase of 36.4% compared with 2024 (source: periodic reports of BeiGene).

The core competitive advantages of Maiweijian (邁衛健®) are as follows: 1) As one of the first-tier biosimilars of Xgeva® marketed in China, it boasts prominent first-mover advantages; 2) It delivers satisfactory therapeutic efficacy and is recommended by multiple expert consensus or in clinical treatment guidelines. Furthermore, compared with bisphosphonates commonly used in clinical practice, denosumab has the following strengths: ① It features targeted action. It specifically binds to RANKL to block the RANKL/RANK/OPG signaling pathway, thereby preventing and treating skeletal-related events caused by bone metastasis; ② Its clinical efficacy is markedly superior to that of bisphosphonates, and it remains effective in patients with treatment failure after bisphosphonate therapy; ③ It enjoys favorable safety profiles as it is not eliminated via renal pathways, leading to a lower incidence of nephrotoxic adverse reactions in patients treated with denosumab.

III. Risk Warning

Given that pharmaceutical products are characterised by high technology, high risks and high added value, and that the production and commercialization of approved drugs are 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 project and will strictly adhere to relevant regulations to fulfill its information disclosure obligations regarding the subsequent progress of the project 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 9MW0321 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, May 21, 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.