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SHANGHAI JUNSHI BIOSCIENCES CO., LTD.*
上海君實生物醫藥科技股份有限公司
(a joint stock company incorporated in the People's Republic of China with limited liability)
(Stock code: 1877)

VOLUNTARY ANNOUNCEMENT – ACCEPTANCE OF THE SUPPLEMENTAL NEW DRUG APPLICATION OF TORIPALIMAB INJECTION (SUBCUTANEOUS INJECTION) FOR THE FIRST-LINE TREATMENT OF HER2-EXPRESSING UROTHELIAL CARCINOMA

This announcement is made by Shanghai Junshi Biosciences Co., Ltd.* (上海君實生物醫藥科技股份有限公司) (the "**Company**") on a voluntary basis. Reference is also made to the overseas regulatory announcement of the Company dated 28 October 2026.

The board (the "**Board**") of directors (the "**Directors**") of the Company is pleased to announce that the Company has received the Acceptance Notice (《受理通知書》) issued by the National Medical Products Administration, and the supplemental new drug application for the Company's product, toripalimab injection (subcutaneous injection) (code: JS001sc) in combination with disitamab vedotin for the treatment of HER2-expressing (HER2 expression is defined as HER2 immunohistochemistry results of 1+, 2+, or 3+) locally advanced or metastatic urothelial carcinoma (UC) has recently been accepted. The new drug application for toripalimab injection (subcutaneous administration), in respect of all 13 approved indications of toripalimab injection (trade name: TUOYI®, product code: JS001), have been accepted.

ABOUT JS001sc

Drug name: Toripalimab Injection (subcutaneous injection)
Application matter: Registration of Domestic Production of Pharmaceutical Product
Acceptance No.: CXSS2600173
Applicant: Shanghai Junshi Biosciences Co., Ltd.* (上海君實生物醫藥科技股份有限公司)
Specification: 180 mg (1 ml) in a single dose (pre-filled syringe)
Review conclusion: It is decided to be accepted upon review according to the requirements of Article 32 of the Administrative License Law of the People's Republic of China* (《中華人民共和國行政許可法》).

JS001sc is a subcutaneous injection formulation developed by the Company based on the marketed product, toripalimab injection. It is the first domestic anti-PD-1 monoclonal antibody in a subcutaneous formulation to enter the new drug application stage, and is expected to bring convenient administration to patients.

Immuno-oncology (I-O) therapies, represented by anti-PD-1 monoclonal antibodies, have become cornerstone therapies for the treatment of various malignant tumors. However, immuno-oncology drugs currently available in China are predominantly formulated for intravenous infusion, which not only requires prolonged infusion times but also causes significant inconvenience to patients during treatment. Consequently, there is an urgent clinical need to improve the convenience of immunotherapy.

In November 2025, a multi-center, open-label, randomized controlled Phase III clinical study to compare JS001sc and toripalimab injection in combination with chemotherapy for the first-line treatment of recurrent or metastatic non-squamous non-small cell lung cancer met the primary endpoint.

In March 2026, the Phase III clinical study of JS001sc in combination with chemotherapy as a first-line treatment for non-squamous non-small-cell lung cancer was successfully selected for an oral presentation at the European Lung Cancer Congress 2026 (ELCC 2026). The study results demonstrated that the drug exposure of toripalimab subcutaneous injection was non-inferior to that of the intravenous formulation of toripalimab, with comparable clinical efficacy and safety profiles, and is expected to provide patients with a new, more convenient immunotherapy option.

In March 2026, the new drug application of JS001sc for 12 indications for the treatment of tumors was accepted by the National Medical Products Administration, making it the first domestic anti-PD-1 monoclonal antibody in a subcutaneous formulation to enter the new drug application stage.

RISK WARNING

Due to the high-tech, high-risk, and high value-added characteristics of pharmaceutical products, there is uncertainty as to whether the new drug application will be approved and, even if the new drug application is approved, the commercialization of the drug is susceptible to various uncertain factors. Investors are advised to make cautious decisions and pay careful attention to investment risks. The Company will actively pursue the above R&D project and fulfill its information disclosure obligations in a timely manner for subsequent progress in strict compliance with relevant regulations.

By order of the Board
Shanghai Junshi Biosciences Co., Ltd.*
Mr. Xiong Jun
Chairman

Shanghai, the PRC, 28 October 2026

As at the date of this announcement, the Board of Directors of the Company comprises Mr. Xiong Jun, Dr. Li Ning, Dr. Zou Jianjun, Mr. Li Cong, Mr. Zhang Zhuobing, Dr. Wang Gang and Dr. Li Xin as executive Directors; Dr. Yao Sheng and Mr. Tang Yi as non-executive Directors; and Dr. Feng Xiaoyuan, Mr. Li Zhongxian, Ms. Lu Kun, Dr. Yang Jin and Mr. Chen Liang as independent non-executive Directors.

* *For identification purposes only*