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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 – REGULAR APPROVAL FOR TORIPALIMAB FOR PATIENTS WITH LOCALLY ADVANCED OR METASTATIC UROTHELIAL CARCINOMA WHO FAILED PLATINUM-CONTAINING CHEMOTHERAPY BY THE NATIONAL MEDICAL PRODUCTS ADMINISTRATION

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, recently, the Company has received the Notice of Approval for Supplemental Drug Application* (《藥品補充申請批准通知書》) issued by the National Medical Products Administration (the "**NMPA**"). The approval in relation to the indication for toripalimab injection (trade name: TUOYI®, product code: JS001) as a monotherapy for the treatment of patients with locally advanced or metastatic urothelial carcinoma (the "**UC**") who failed platinum-containing chemotherapy, including those who progressed within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy has been converted from conditional approval to regular approval.

ABOUT JS001

Drug name: Toripalimab Injection
Application matter: Supplemental application
Acceptance Nos.: CYSB2600232, CYSB2600233
Notice number: 2026B07469, 2026B07470
Marketing Authorization Holder: Shanghai Junshi Biosciences Co., Ltd.*
Review conclusions: According to 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 requirements, upon review, the drug satisfied the relevant requirements for drug registration and the supplemental application is approved. It is agreed that the approval in relation to the indication for toripalimab "as a monotherapy for the treatment of patients with locally advanced or metastatic urothelial carcinoma who failed platinum-containing chemotherapy or progressed within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy" has been converted from conditional approval to regular approval.

UC is one of the ten most prevalent malignant tumors in the world, and in China, its incidence and mortality rates continue rising annually. It is a serious threat to the life and health of patients, and there are huge unmet clinical needs.

In April 2021, based on a multi-center, single-arm, open-label Phase II clinical trial (the POLARIS-03 study, NCT03113266), toripalimab obtained conditional marketing approval from the NMPA for the second-line and above treatment of advanced UC, becoming the first immunotherapeutic drug approved for non-selective population-based indications of advanced UC in China.

This regular approval is primarily based on results from the RC48-C016 study (NCT05302284). The study is a multi-center, randomized, open-label and active-controlled phase III clinical trial which was designed to compare the efficacy and safety of toripalimab in combination with disitamab vedotin versus gemcitabine in combination with cisplatin/carboplatin in patients who had not previously received systemic anti-tumor therapy with HER2 (human epidermal growth factor receptor 2)-expressing (defined as HER2 IHC 1+, 2+ or 3+) locally advanced or metastatic UC. The study was conducted in 74 clinical centers across China with Professor Guo Jun from Beijing Cancer Hospital and Professor Zhou Aiping from the Cancer Hospital of the Chinese Academy of Medical Sciences as the principal investigators.

In October 2025, the results of the RC48-C016 study were published on The New England Journal of Medicine (NEJM) and were simultaneously presented orally at the Presidential Symposium of the 2025 European Society for Medical Oncology (ESMO) Annual Meeting (abstract number: #LBA7). The results showed that the primary endpoints of progression-free survival ("**PFS**", based on independent imaging assessment) and overall survival ("**OS**") achieved "dual-endpoint positive results". Compared with traditional chemotherapy, toripalimab in combination with disitamab vedotin as first-line treatment for HER2-expressing advanced urothelial carcinoma doubled the median PFS (13.1 months vs. 6.5 months, hazard ratio HR=0.36, 95% CI: 0.28-0.46; $p<0.0001$), significantly prolonged the median OS (31.5 months vs. 16.9 months, HR=0.54, 95% CI: 0.41-0.73; $p<0.0001$), substantially improved the objective response rate (ORR) (76.1% vs. 50.2%), and extended the median duration of response by several times (14.6 months vs. 5.6 months). The combination treatment group substantially improved safety compared with traditional chemotherapy.

As of the date of this announcement, TUOYI® has obtained marketing approval for 13 indications in Chinese Mainland, of which 12 indications have been included in the National Reimbursement Drug List (NRDL), and it is the only anti-PD-1 monoclonal antibody in the NRDL for the treatment of renal cancer, triple-negative breast cancer and melanoma.

RISK WARNING

Due to the high-tech, high-risk and high value-added characteristics of pharmaceutical products, and the commercialisation of drugs being susceptible to certain uncertain factors, investors are advised to make cautious decisions and pay careful attention to investment risks. The Company will actively pursue the above research and development 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 of
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 purpose only*