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 – APPROVAL OF THE SUPPLEMENTAL NEW DRUG APPLICATION OF TORIPALIMAB 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 21 May 2026.

The board (the "**Board**") of directors (the "**Directors**") of the Company is pleased to announce that the Company has received the Drug Registration Certificate* (《藥品註冊證書》) issued by the National Medical Products Administration (the "**NMPA**"). The supplemental new drug application for the new indication of toripalimab (trade name: TUOYI® (拓益®), product code: JS001) in combination with disitamab vedotin, an antibody drug conjugate independently developed by RemeGen Co., Ltd.*, for the treatment for patients with HER2-expressing (which is defined as achieving score of 1+, 2+ or 3+ in HER2 immunohistochemistry test) locally advanced or metastatic urothelial carcinoma (UC). This is the 13th indication of toripalimab injection approved in Chinese Mainland. Relevant details are hereby announced:

ABOUT TORIPALIMAB

Drug name: Toripalimab Injection
Application matter: Registration of pharmaceutical product (domestic production)
Acceptance Nos.: CXSS2500079, CXSS2500080
Certificate Nos.: 2026S01727, 2026S01728
Marketing Authorization Holder: Shanghai Junshi Biosciences Co., Ltd.*
Review conclusion: In accordance with the Drug Administration Law of the People's Republic of China and relevant rules, this drug has met relevant requirements for drug registration upon review, and new indication has been approved. Specific indication is: This drug in combination with disitamab vedotin for patients with HER2-expressing (HER2 expression is defined as HER2 immunohistochemistry results of 1+, 2+, or 3+) locally advanced or metastatic UC.

UC is one of the ten most prevalent malignant tumors in the world, and in China, its incidence and mortality rates continue rising annually. According to the latest data from the National Cancer Center, in 2022, the number of new cases of UC in China reached 92,900, and the number of deaths reached over 40,000. UC is a serious threat to the life and health of patients, and there are huge unmet clinical needs.

In 2021, toripalimab injection was approved for the second-line and above treatment of advanced UC, becoming the first immunotherapy drug approved for non-selective population-based indications of advanced UC in China.

The approval of new indication is based on results from the RC48-C016 study (NCT05302284). The study is a multi-center, randomized, open-label and controlled phase III clinical trial which evaluated the efficacy and safety of toripalimab in combination with disitamab vedotin versus gemcitabine in combination with cisplatin/carboplatin in systemic-treatment-naive patients with HER2 (human epidermal growth factor receptor 2)-expressing (which is 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 Chinese Academy of Medical Sciences as the principal investigators.

In October 2025, the research results of RC48-C016 were posted on *The New England Journal of Medicine* (NEJM), with oral presentation made at the chairperson forum of the 2025 European Society for Medical Oncology (ESMO) annual meeting simultaneously (Abstract No.: #LBA7). The results showed that the primary endpoints of progression free survival ("**PFS**", based on independent radiographic review) and overall survival ("**OS**") both achieved positive results. Compared with traditional chemotherapy, toripalimab in combination with disitamab vedotin for the first-line treatment for HER2-expressing advanced UC was doubled in terms of median PFS (13.1 months vs. 6.5 months, hazard ratio HR=0.36, 95%CI: 0.28-0.46; p<0.0001), with median OS significantly extended (31.5 months vs. 16.9 months, HR=0.54, 95%CI: 0.41-0.73; p<0.0001) and objective response rate (ORR) greatly increased (76.1% vs. 50.2%). The medium duration of response was extended by several times (14.6 months vs. 5.6 months). The combined therapy group showed a significant improvement in safety compared to conventional chemotherapy.

Toripalimab injection is the first domestic PD-1 monoclonal antibody approved for marketing in China, and has won the "Chinese Patent Gold Award (中國專利金獎)", the top award in China's patent field. Over forty toripalimab clinical studies sponsored by the Company covering more than fifteen indications have been conducted globally, including in China, the United States, Europe, and Southeast Asia. Ongoing or completed pivotal clinical studies evaluating the safety and efficacy of toripalimab cover a broad range of tumor types. As of the date of this announcement, there are 13 approved indications for toripalimab in Chinese mainland. In December 2020, toripalimab injection was successfully negotiated into the National Reimbursement Drug List (the "**NRDL**") for the first time. At present, 12 approved indications have been included in the NRDL. Toripalimab is the only anti-PD-1 monoclonal antibody included in the NRDL for the treatment of renal carcinoma, triple negative breast cancer and melanoma. Three indications of toripalimab for the treatment of advanced nasopharyngeal carcinoma and esophageal squamous cell carcinoma were approved in Hong Kong SAR, China.

In terms of international layout, as of the date of this announcement, toripalimab has been approved for marketing in more than 40 countries and regions including the United States, the European Union, India, the United Kingdom, Australia and Singapore, and is also under review for marketing in various countries and regions worldwide.

RISK WARNING

Due to the high-tech, high-risk and high-value-added characteristics of pharmaceutical products, there are substantial risks and uncertainties in the process of drug research, development and commercialization. These many stages make it susceptible to uncertainties and therefore, investors are advised to make cautious decisions and pay careful attention to investment risks. The Company will actively pursue the above project and fulfill its information disclosure obligations in a timely manner for subsequent progress of the project in strict compliance with relevant regulations.

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

Shanghai, the PRC, 21 May 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. Yao Sheng, Dr. Wang Gang and Dr. Li Xin as executive Directors; Mr. Tang Yi as a non-executive Director; and Mr. Zhang Chun, Dr. Feng Xiaoyuan, Mr. Li Zhongxian, Ms. Lu Kun and Dr. Yang Jin as independent non-executive Directors.

* *For identification purposes only*