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 FOR TORIPALIMAB AS 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 8 August 2025.

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. The supplemental new drug application ("**NDA**") for toripalimab (trade name: TUOYI®, product code: JS001) in combination with disitamab vedotin, an antibody-drug conjugate ("**ADC**") developed by RemeGen Co., Ltd.* (榮昌生物製藥(煙台)股份有限公司) as 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 been accepted. The relevant information is now announced as follows:

ABOUT TORIPALIMAB

Drug name: Toripalimab Injection
Application matter: Registration of Domestic Production of Pharmaceutical Product
Acceptance Nos.: CXSS2500079, CXSS2500080
Applicant: Shanghai Junshi Biosciences Co., Ltd.* (上海君實生物醫藥科技股份有限公司)
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》).

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 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. Over the past 5 years, the emergence of PD-(L)1 monoclonal antibodies and novel ADCs has been continuously reshaping the treatment landscape for advanced UC. Compared with conventional chemotherapy, novel therapies have demonstrated significant improvements in terms of survival benefit and tolerability, leading to more diverse and precise treatment options for patients.

The supplemental NDA 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 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 May 2025, the primary endpoints of progression-free survival ("**PFS**", based on independent radiographic review) and overall survival ("**OS**") of the RC48-C016 study met the pre-defined efficacy boundary. The results showed that in HER2-expressing, locally advanced or metastatic UC, toripalimab in combination with disitamab vedotin as a first-line treatment significantly improved PFS and OS compared to gemcitabine in combination with cisplatin/carboplatin. Toripalimab has a good safety profile that is consistent with previous studies with no new safety signals identified. Further details will be presented at major international academic conferences.

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 company-sponsored toripalimab clinical studies 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 12 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, ten 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 melanoma, perioperative treatment of non-small cell lung cancer, treatment of renal carcinoma and treatment of triple negative breast cancer. In October 2024, toripalimab for the treatment of recurrent or metastatic nasopharyngeal carcinoma was 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 the United States, the European Union, India, the United Kingdom, Jordan, Australia, Singapore and other countries and regions, 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 of
Shanghai Junshi Biosciences Co., Ltd.*
Mr. Xiong Jun
Chairman

Shanghai, the PRC, 8 August 2025

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, Dr. Yang Yue, Mr. Li Zhongxian and Ms. Lu Kun as independent non-executive Directors.

* *For identification purposes only*