# 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 GRANTED TO SUPPLEMENTAL NEW DRUG APPLICATION FOR TORIPALIMAB FOR PATIENTS WITH LOCALLY ADVANCED OR METASTATIC UROTHELIAL CARCINOMA WHO FAILED PLATINUM-CONTAINING CHEMOTHERAPY

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 12 April 2021.

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**"). Conditional approval has been granted to the supplemental new drug application (the "**NDA**") for toripalimab (trade name: TUOYI®, product code: JS001) 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. Relevant information is as follows:

## ABOUT TORIPALIMAB

Drug name: Toripalimab Injection

Application matter: Registration of pharmaceutical product (domestic production)

Acceptance No.: CXSS2000018, CXSS2000019

Certificate No.: 2021S00344, 2021S00345

Marketing Authorization Holder: 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 determined after review that the product meets the relevant requirements for drug registration and conditional approval is granted for the additional indications of the product, according to the Pharmaceutical Administration Law of the People's Republic of China and relevant regulations. Specifically, the product is suitable 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.

Urothelial carcinoma is a common type of bladder cancer that accounts for more than 90% of all bladder cancer cases. Listed among the ten most common types of cancer in China, urothelial carcinoma has become one of the major disease-related burdens in China due to its rapid metastasis, high chance of recurrence and limited treatment options and poses a serious threat to the patients' survival time and quality of life.

In May 2020, the supplemental NDA for toripalimab for the treatment of locally advanced or metastatic urothelial carcinoma after prior systemic therapy was accepted by the NMPA, and the company received priority review designation from the NMPA in July 2020.

The supplemental NDA is based on the POLARIS-03 study (NCT03113266) jointly led by Professor Guo Jun of the Peking University Cancer Hospital and Professor Huang Yiran of Renji Hospital under the Shanghai Jiao Tong University School of Medicine. Among the 136 patients with locally advanced or metastatic urothelial carcinoma who failed platinum-containing chemotherapy or progressed with 12 months of neoadjuvant or adjuvant chemotherapy, the evaluation results of the Independent Review Committee (IRC) indicated that the overall objective response rate (the "**ORR**") was 27.2%, the disease control rate (DCR) was 46.3% and the median overall survival (mOS) reached 14.6 months. The median duration of response (DOR) has not reached a mature stage, with 67.1% of patients with objective responses continuing after a 12-month period. POLARIS-03 is the first pivotal clinical study on the treatment of advanced urothelial carcinoma with an unselected population after failure of first-line standard treatment in China. Data showed that toripalimab demonstrated explicit anti-tumor activity and continuous efficacy among all patients and within each subgroup. ORR of all patients was 27.2%. ORR of PD-L1 positive patients reached 42.2%. ORR of PD-L1 negative patients reached 18.8%. Therefore, advanced urothelial carcinoma patients benefit from toripalimab regardless of PD-L1 expression. In addition, the safety and tolerability of toripalimab are consistent with previous research results.

Toripalimab was the first domestic anti-PD-1 monoclonal antibody approved for marketing in China. More than thirty company-sponsored clinical studies covering more than fifteen indications have been conducted globally, including in China and the United States. On 17 December 2018, toripalimab obtained a conditional approval from the NMPA for the second-line treatment of unresectable or metastatic melanoma. Toripalimab was included in the 2019 and 2020 Guidelines of the Chinese Society of Clinical Oncology (CSCO) for the Diagnosis and Treatment of Melanoma. In December 2020, toripalimab was successfully included in the new catalogue of the National Reimbursement Drug List upon negotiations. In February 2021, toripalimab received a conditional NDA approval from the NMPA for the treatment of patients with recurrent or metastatic nasopharyngeal carcinoma after failure of at least two lines of prior systemic therapy.

In September 2020, toripalimab was granted a breakthrough therapy designation by the U.S. Food and Drug Administration (the "**FDA**") for the treatment of recurrent or metastatic nasopharyngeal carcinoma. In February 2021, the supplemental NDA of toripalimab in combination with chemotherapy for the first-line treatment of patients with advanced, recurrent or metastatic nasopharyngeal carcinoma was accepted by the NMPA. As of the date of this announcement, toripalimab has been granted one breakthrough therapy designation, one fast track designation and three orphan-drug designations by the FDA for the treatment of mucosal melanoma, nasopharyngeal carcinoma and soft tissue sarcoma. In March 2021, toripalimab was included in the Drug List of the Procedure for Breakthrough Therapy Designation for the first-line treatment of advanced mucosal melanoma by the NMPA.

**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 described research and development project and fulfill its information disclosure obligations in a timely manner for subsequent progress in strict accordance with relevant regulations.

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

Shanghai, the PRC, 12 April 2021

*As at the date of this announcement, the board of directors of the Company comprises Mr. Xiong Jun, Dr. Li Ning, Dr. Feng Hui, Mr. Zhang Zhuobing and Dr. Yao Sheng as executive Directors; Dr. Wu Hai, Mr. Tang Yi, Mr. Li Cong, Mr. Yi Qingqing and Mr. Lin Lijun as non-executive Directors; and Dr. Chen Lieping, Mr. Qian Zhi, Mr. Zhang Chun, Dr. Jiang Hualiang and Dr. Roy Steven Herbst as independent non-executive Directors.*

* *For identification purpose only*