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 – NEW INDICATIONS OF TUOYI® HAVE BEEN INCLUDED IN THE NATIONAL REIMBURSEMENT DRUG LIST

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 November 2024.

The board (the "**Board**") of directors (the "**Directors**") of the Company is pleased to announce that four new indications of the Company's product Toripalimab Injection (trade name: TUOYI®, product code: JS001) were successfully included in Category B of the National Drug List for Basic Medical Insurance, Work-Related Injury Insurance and Maternity Insurance (Year 2024) (the "**NRDL**"). The new edition of the NRDL will be officially come into effect on 1 January 2025. As of the date of this announcement, ten approved indications of TUOYI® in Chinese mainland were all included in the NRDL and it 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 ("**NSCLC**"), treatment of renal carcinoma and treatment of triple-negative breast cancer ("**TNBC**").

ABOUT TUOYI®

Drug name: Toripalimab Injection
Classification of registration: Therapeutic biological product
Class of drug: Antineoplastic drug and immune modulator – monoclonal antibody and antibody drug conjugates -PD-1/PD-L1 inhibitor
Class of medical insurance: Category B
Dosage form: Injection

Indications: 1. Treatment for unresectable or metastatic melanoma after failure of standard systemic therapy; 2. Treatment for locally advanced or metastatic urothelial carcinoma that failed platinum containing chemotherapy or progressed within 12 months of neoadjuvant or adjuvant platinum containing chemotherapy; 3. Treatment for patients with recurrent/metastatic nasopharyngeal carcinoma ("**NPC**") after failure of at least two lines of prior systemic therapy; 4. First-line treatment for patients with locally recurrent or metastatic NPC; 5. First-line treatment for patients with unresectable locally advanced/recurrent or metastatic esophageal squamous cell carcinoma; 6. First-line treatment for patients with EGFR mutation-negative and ALK mutation-negative, unresectable, locally advanced or metastatic non-squamous NSCLC; 7. The product in combination with chemotherapy as perioperative treatment and subsequently, monotherapy as adjuvant therapy for the treatment of adult patients with resectable stage IIIA-IIIB NSCLC; 8. The product in combination with axitinib for the first-line treatment of patients with medium to high risk unresectable or metastatic renal cell carcinoma; 9. The product in combination with etoposidein plus platinum for the first-line treatment of extensive-stage small cell lung cancer (ES-SCLC); 10. The product in combination with paclitaxel for injection (albumin-bound) for the first-line treatment of recurrent or metastatic TNBC with a well-validated test to evaluate PD-L1 positive (CPS ≥ 1). Items 7 to 10 are new indications included in the NRDL.
Validity period: From 1 January 2025 to 31 December 2025

Toripalimab injection is the first domestic anti-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 clinical studies covering more than fifteen indications have been conducted globally, including in China and the United States, Southeast Asia and Europe. 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 ten approved indications for toripalimab in Chinese mainland. In December 2020, toripalimab injection was successfully negotiated into the NRDL (2020 edition) for the first time. At present, all of its ten approved indications are included in the NRDL, being the only anti-PD-1 monoclonal antibody in the NRDL for the treatment of melanoma, perioperative treatment of NSCLC, treatment of renal carcinoma and treatment of TNBC. In October 2024, the toripalimab for the treatment of recurrent/metastatic NPC was approve 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 UK, Jordan and other countries and regions. In addition, the Australia Therapeutic Goods Administration (TGA) and Singapore Health Sciences Authority (HSA) accepted the new chemical entity application and the new drug application for toripalimab in combination with cisplatin and gemcitabine, for the first-line treatment of adults with metastatic or recurrent locally advanced NPC, and for toripalimab, as a single agent, for the treatment of adults with recurrent, unresectable, or metastatic NPC with disease progression on or after platinum-containing chemotherapy, respectively.

IMPACTS ON THE COMPANY AND RISK WARNING

The inclusion of the new indications of TUOYI® in the NRDL demonstrated the National Healthcare Security Administration's (the "**NHSA**") recognition of the clinical value, benefit to patients and novelty of the above drug, highlighting the state's emphasis on and support for the R&D and industrialization of drugs by local innovative pharmaceutical enterprises. All ten approved indications of TUOYI® are included in the NRDL, which will further expand the scope of patients benefiting from different tumor types, and reduce the burden of medical treatment for patients and their families. In addition, the successful inclusion of the 4 new indications of TUOYI® in the NRDL is the first time that the NRDL included immunotherapy for perioperative NSCLC, renal carcinoma, small cell lung cancer and TNBC, which is expected to enable the Company to gain a first-mover advantage in the market promotion of corresponding indications.

The results of NRDL negotiations will help the Company to further improve the affordability and accessibility of the aforesaid drug to patients, which will be conducive to further promoting the marketing of the drug and enhancing the sales scale, and will have a positive impact on the long-term development of the Company. The Company will actively work with relevant parties to implement the related medical insurance and reimbursement policies, promote the accessibility of the drug to hospitals with continuous efforts, and expand the coverage of core markets and other markets, with a view to constantly enhancing the accessibility of medicines to patients. Details of medical insurance reimbursement and other relevant information shall be subject to the information published by the NHSA and other relevant government departments. Investors are advised to make cautious decisions and pay careful attention to investment risks.

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

Shanghai, the PRC, 28 November 2024

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 non-executive Director; and Mr. Zhang Chun, Dr. Feng Xiaoyuan, Dr. Meng Anming and Dr. Yang Yue as independent non-executive Directors.

* *For identification purpose only*