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 – THE ACCEPTANCE OF THE SUPPLEMENTAL NEW DRUG APPLICATION FOR TORIPALIMAB IN COMBINATION WITH CHEMOTHERAPY AS FIRST-LINE TREATMENT FOR ADVANCED NON-SMALL CELL LUNG CANCER

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 10 December 2021.

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 "**NMPA**"). The supplemental new drug application (the "**sNDA**") for toripalimab (trade name: TUOYI®, product code: JS001) in combination with standard chemotherapy as the first-line treatment of patients with treatment-naive advanced non-small cell lung cancer ("**NSCLC**") with no EGFR or ALK tumor aberrations has been accepted. Relevant information is as follows:

ABOUT TORIPALIMAB

Drug name: Toripalimab Injection
Application matter: Registration of domestic production of pharmaceutical product
Acceptance No.: CXSS2101057, CXSS2101058
Applicant: Shanghai Junshi Biosciences Co., Ltd.* (上海君實生物醫藥科技股份有限公司)
Review conclusion: Following the review, the application is accepted pursuant to Article 32 of the Administrative License Law of the People's Republic of China.

Lung cancer is currently the second most prevalent malignant tumor with the highest mortality rate in the world, and the most prevalent with the highest mortality rate in China. According to data released by the World Health Organization, in 2020, the number of new lung cancer cases in China amounted to 816,000 and accounted for 17.9% of all new cancer cases in China. In the same year, the number of lung cancer deaths in China amounted to 715,000 and accounted for 23.8% of all cancer deaths in China. NSCLC is a major subtype of lung cancer, accounting for approximately 85% of all cases. Existing domestic and overseas studies have shown that monotherapy or combination chemotherapy of anti-PD-(L)1 monoclonal antibody has already become new standard for the first-line treatment of NSCLC.

The sNDA is based on the CHOICE-01 study (NCT03856411), which is the first domestic randomized, double-blind, placebo parallel-controlled, multi-center, Phase III clinical study of anti-PD-1 monoclonal antibody in combination with chemotherapy as first-line treatment that recruits both histological types of patients with advanced squamous and non-squamous NSCLC. Professor Wang Jie from Cancer Hospital, Chinese Academy of Medical Sciences is the leading principal investigator for the study. The study enrolled 465 NSCLC patients in 63 centers in China, among which 220 were squamous NSCLC patients and 245 were non-squamous NSCLC patients. Based on the interim analysis results of the CHOICE-01 study, the Independent Data Monitoring Committee (IDMC) determined that the primary endpoint of progression-free survival ("**PFS**") has crossed the pre-defined efficacy boundary. The results of the study were presented in the oral session (abstract no.: MA13.08) at the 2021 World Conference on Lung Cancer (WCLC), and the results showed that compared with chemotherapy alone, toripalimab in combination with chemotherapy as the first-line treatment for advanced NSCLC significantly prolonged the PFS of patients, reduced the risk of disease progression, and showed a positive trend in terms of overall survival ("**OS**"). The Company will subsequently submit further analysis results of OS of the CHOICE-01 study to the regulatory authorities on a rolling basis, and communicate with the US Food and Drug Administration (the "**FDA**") on the matters related to the submission of the new drug application.

Toripalimab was 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. So far, more than 30 clinical studies covering more than 15 indications have been conducted globally, including in China and the United States. On 17 December 2018, toripalimab obtained a conditional approval by the NMPA for the second-line treatment of unresectable or metastatic melanoma. In December 2020, toripalimab injection passed the national medical insurance negotiation for the first time. At present, three indications have been included in the National Reimbursement Drug List. In February 2021, toripalimab obtained a conditional 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 April 2021, toripalimab obtained a conditional approval from the NMPA for the treatment of patients with locally advanced or metastatic urothelial carcinoma after failure of platinum-containing chemotherapy or progressed within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy. In November 2021, toripalimab in combination with cisplatin and gemcitabine as the first-line treatment for patients with locally recurrent or metastatic nasopharyngeal carcinoma was approved by the NMPA. In addition, toripalimab has been recommended in the Guidelines of Chinese Society of Clinical Oncology for the Diagnosis and Treatment of Melanoma, Head and Neck Tumors, Nasopharyngeal Carcinoma, Urothelial Carcinoma and Immune Checkpoint Inhibitor Clinical Practice.

In March 2021, toripalimab was included in the Breakthrough Therapy Designation for the first-line treatment of advanced mucosal melanoma by the NMPA. In July 2021, the sNDA for toripalimab in combination with platinum-containing chemotherapy as the first-line treatment for patients with locally advanced or metastatic esophageal squamous cell carcinoma was accepted by the NMPA. In terms of international layout, the first Biologics License Application (the "**BLA**") for toripalimab has been accepted by the FDA and was granted Priority Review Designation. Toripalimab is also the first domestic anti-PD-1 monoclonal antibody to submit BLA to the FDA. As of the date of this announcement, toripalimab has been granted 2 Breakthrough Therapy, 1 Fast Track, 1 Priority Review and 4 Orphan Drug Designations by the FDA for the treatment of mucosal melanoma, nasopharyngeal carcinoma, soft tissue sarcoma and esophageal cancer.

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, 10 December 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, Dr. Yao Sheng and Mr. Li Cong as executive Directors; Dr. Wu Hai, Mr. Tang Yi 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*