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 AS THE FIRST-LINE TREATMENT OF ES-SCLC

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 19 July 2023.

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 for toripalimab (trade name: TUOYI®, product code: JS001) in combination with etoposidein plus platinum as the first-line treatment of extensive-stage small cell lung cancer ("**ES-SCLC**") has been accepted.

ABOUT TORIPALIMAB

Drug name: Toripalimab Injection
Application matter: Registration of Domestic Production of Pharmaceutical Product
Acceptance No.: CXSS2300052, CXSS2300053
Applicant: Shanghai Junshi Biosciences Co., Ltd.*
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.

According to data released by GLOBOCAN 2020, lung cancer is currently the most prevalent malignant tumor with the highest mortality rate in China. Small cell lung cancer ("**SCLC**") is the most aggressive subtype of lung cancer, accounting for approximately 15%-20% of all lung cancer cases with characteristics including rapid progression, early metastasis and poor prognosis. SCLC is divided into limited-stage small cell lung cancer ("**LS-SCLC**") and ES-SCLC. For patients with LS-SCLC, currently, an objective response rate of approximately 90% and a five-year survival rate of approximately 25% could be achieved through standard chemotherapy and radiotherapy. However, most patients have already been diagnosed with ES-SCLC when seeking medical treatment, with a median survival time of less than one year and a two-year survival rate of less than 10%, which remains a major unmet clinical problem.

The supplemental new drug application is mainly based on the EXTENTORCH study (NCT04012606), which is a randomized, double-blind, placebo-controlled, multi-center Phase III clinical study, aiming to compare the efficacy and safety of toripalimab or placebo in combination with etoposide plus platinum for the first-line treatment of ES-SCLC. This study is led by Professor Cheng Ying (程穎), vice president of Chinese Society of Clinical Oncology (CSCO), from Jilin Cancer Hospital* (吉林省腫瘤醫院) as the principal investigator. The study was launched in 51 centers nationwide, where patients were randomly allocated in the ratio of 1:1 to receive treatment of toripalimab or placebo in combination with etoposide plus platinum for 4-6 cycles, and then continued to receive maintenance treatment with toripalimab or placebo until disease progression, intolerable toxicity or other conditions requiring termination of treatment as specified in the protocol. In May 2023, the primary endpoints of the EXTENTORCH study met the pre-defined efficacy boundary, and toripalimab thus became the first PD-1 inhibitor in the world which had met the primary endpoints of both overall survival ("**OS**") and progression-free survival ("**PFS**") in the Phase III study for the first-line treatment of ES-SCLC. The results showed that, compared to chemotherapy alone, toripalimab in combination with chemotherapy for the first-line treatment of ES-SCLC could significantly prolong the PFS and OS of patients. The safety profile of toripalimab was similar with previous studies, and no new safety signals were identified. Detailed data will be presented at upcoming international academic conference.

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 toripalimab clinical studies covering more than fifteen indications have been conducted globally, including in China, 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 six approved indications for toripalimab in China. In December 2020, toripalimab injection was successfully negotiated into the National Reimbursement Drug List (the "**NRDL**") for the first time. At present, three indications have been included in the NRDL (2022 Edition). Toripalimab is the only anti-PD-1 monoclonal antibody included in the NRDL for the treatment of melanoma.

In terms of international layout, the Biologics License Application (BLA) for toripalimab in combination with gemcitabine/cisplatin, for the first-line treatment of patients with advanced recurrent or metastatic nasopharyngeal carcinoma ("**NPC**") and toripalimab monotherapy for the second-line or later treatment of recurrent or metastatic NPC after platinum-containing chemotherapy is under review by the U.S. Food and Drug Administration (FDA). The European Medicines Agency (EMA) and the Medicines and Healthcare products Regulatory Agency (MHRA) have accepted the marketing authorization application (MAA) for toripalimab in combination with cisplatin and gemcitabine for the first-line treatment of patients with locally recurrent or metastatic NPC, and toripalimab in combination with paclitaxel and cisplatin for the first-line treatment of patients with unresectable locally advanced/recurrent or metastatic esophageal squamous cell carcinoma, respectively.

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 compliance with relevant regulations.

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

Shanghai, the PRC, 19 July 2023

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, Mr. Li Cong and Dr. Zou Jianjun as executive Directors; Dr. Wu Hai and Mr. Tang Yi as non-executive Directors; and Dr. Roy Steven Herbst, Mr. Qian Zhi, Mr. Zhang Chun, Dr. Feng Xiaoyuan and Dr. Meng Anming as independent non-executive Directors.

* *For identification purpose only*