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 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 12 June 2024.

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

ABOUT TORIPALIMAB

Drug name: Toripalimab Injection
Application matter: Registration of pharmaceutical product (domestic production)
Acceptance Nos.: CXSS2300052, CXSS2300053
Certificate Nos.: 2024S01121, 2024S01122
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: According to the Drug Administration Law of the People's Republic of China* (《中華人民共和國藥品管理法》) and relevant regulations, upon review, the product meets the relevant requirements for drug registration and the additional indication of the product is approved, in particular, the product in combination with etoposide plus platinum for the first-line treatment of extensive-stage small cell lung cancer (ES-SCLC).

According to data released by GLOBOCAN 2022, 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, 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 approval of the supplemental new drug application is mainly based on data from the EXTENTORCH study (NCT04012606), 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, led by principal investigator Professor Cheng Ying (程穎) from Jilin Cancer Hospital* (吉林省腫瘤醫院). The study was conducted across 51 clinical centers nationwide. In May 2023, the primary endpoints of the EXTENTORCH study met their pre-defined efficacy boundary, and toripalimab thus became the first PD-1 inhibitor in the world to meet the primary endpoints of both overall survival ("**OS**") and progression-free survival ("**PFS**") in a Phase III study for the first-line treatment of ES-SCLC.

At the European Society for Medical Oncology (ESMO) held in October 2023, the EXTENTORCH data was released in the form of an oral presentation for the first time. The study results showed that, compared to chemotherapy alone, toripalimab in combination with chemotherapy could significantly prolong the PFS and OS of patients, and demonstrated a favorable safety profile. This suggests that toripalimab may be an optimal immunotherapy for ES-SCLC. In particular, the median PFS of the toripalimab group reached 5.8 months, and the risk of disease progression or death was reduced by 33.3% (P=0.0002). The one-year PFS was nearly four times higher in the toripalimab group compared with the chemotherapy group (18.1% vs. 4.9%). The median OS of the toripalimab group reached 14.6 months, the risk of death was reduced by 20.2% (P=0.0327), and the one-year OS rate reached 63.1%.

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 nine 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, six indications have been included in the NRDL (2023 Edition). Toripalimab is the only anti-PD-1 monoclonal antibody included in the NRDL for the treatment of melanoma. In April 2024, the Drug Office, Department of Health, the Government of the Hong Kong Special Administration Region (DO) accepted the New Drug Application (the "**NDA**") for toripalimab in combination with cisplatin and gemcitabine, for the first-line treatment of adults with metastatic or recurrent locally advanced nasopharyngeal carcinoma ("**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.

In terms of international layout, toripalimab had been approved for marketing as the first nasopharyngeal cancer drug in the United States in October 2023. In addition, the European Medicines Agency (EMA) and the U.K. Medicines and Healthcare products Regulatory Agency (MHRA) 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. The Australia Therapeutic Goods Administration (TGA) and the Singapore Health Sciences Authority (HSA) accepted the new chemical entity application and the NDA 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.

RISK WARNING

As pharmaceutical products are characterized as being of high technology, of high risks and with high added value, and the commercialization of drugs after being approved for marketing is subject to certain uncertainties, investors are advised to make cautious decisions and pay careful attention to investment risks. The Company will actively pursue the described 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 of
Shanghai Junshi Biosciences Co., Ltd.*
Mr. Xiong Jun
Chairman

Shanghai, the PRC, 12 June 2024

As at the date of this announcement, the board of directors of the Company comprises Mr. Xiong Jun, Dr. Li Ning, Mr. Zhang Zhuobing, Dr. Yao Sheng, Mr. Li Cong, Dr. Zou Jianjun, Dr. Wang Gang and Dr. Li Xin as executive Directors; Dr. Feng Hui 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*