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 – REGULAR APPROVAL OF TORIPALIMAB AS THE SECOND-LINE OR LATER TREATMENT OF MELANOMA BY THE NATIONAL MEDICAL PRODUCTS ADMINISTRATION

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 6 January 2025.

The board (the "**Board**") of directors (the "**Directors**") of the Company is pleased to announce that the Company has received the Notice of Approval for Supplemental Drug Application* (《藥品補充申請批准通知書》) issued by the National Medical Products Administration (the "**NMPA**"). The indication for toripalimab (trade name: TUOYI®, product code: JS001) as the treatment for unresectable or metastatic melanoma after failure of standard systemic therapy has been approved by the NMPA for conversion from conditional approval to regular approval.

ABOUT TORIPALIMAB

Drug name: Toripalimab Injection
Application matter: Supplemental application
Acceptance Nos.: CXSB2300139, CXSB2300140
Notice number: 2024B06341, 2024B06342
Marketing Authorization Holder: Shanghai Junshi Biosciences Co., Ltd.*
Review conclusions: 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 requirements, upon review, the application for the drug satisfied the relevant requirements for drug registration and the supplemental application is approved. It is agreed that the approval in relation to the drug's indication for "treatment of unresectable or metastatic melanoma after failure of standard systemic therapy" has been converted from conditional approval to regular approval.

Melanoma is the most malignant type of skin cancer. According to GLOBOCAN 2022 statistics, approximately 332,000 new melanoma cases and approximately 59,000 death cases were recorded globally that year. Though melanoma is relatively uncommon in China, its mortality rate is high (approximately 5,000 deaths amongst approximately 9,000 new cases in 2022) and its incidence rate is rising year by year.

The review policy of conditional approval is designed to encourage clinical value-oriented drug innovation and accelerate the market launch of clinically urgent drugs with significant clinical value. On 17 December 2018, based on a multi-center, single-arm, open-label Phase II clinical study (POLARIS-01 Study, NCT03013101), toripalimab received conditional approval from the NMPA for the treatment of unresectable or metastatic melanoma after failure of standard systemic therapy, becoming the first domestic anti-PD-1 monoclonal antibody approved for marketing in China. Receiving regular approval indicates that toripalimab has completed necessary clinical trials on drug validation as required by regulatory authorities, and demonstrates its efficacy and safety among the target population.

The regular approval is mainly based on the MELATORCH study (NCT03430297). The MELATORCH study is a multi-center, randomized, open-label, positive-controlled Phase III clinical study. The study was designed to compare the efficacy and safety of toripalimab versus dacarbazine for the systemic treatment-naive patients with unresectable or metastatic melanoma, with a primary endpoint of progression-free survival ("**PFS**", based on independent radiological review). The study was led by Professor Guo Jun from Peking University Cancer Hospital* (北京大學腫瘤醫院) as the Principal Investigator and was conducted in 11 clinical centers across the country. The study is also the first and only pivotal registrational clinical study of a PD-(L)1 inhibitor as the first-line treatment for advanced melanoma that has yielded positive results in China. The results have shown that compared with the dacarbazine group (N=128), the toripalimab group (N=127) has a significantly prolonged PFS based on independent radiological review, with disease progression or mortality risk reduced by 29.2% (HR=0.708; 95% CI: 0.526-0.954; P=0.0209), and other efficacy endpoints (including PFS evaluated by researchers, objective response rate, duration of response and overall survival) have shown positive trend as well. Toripalimab has a good safety profile that is consistent with previous studies with no new safety signals identified. Based on the above studies, the supplemental new drug application of toripalimab as the first-line treatment for unresectable or metastatic melanoma was accepted by the NMPA in August 2024.

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 National Reimbursement Drug List (the "**NRDL**") for the first time and all of the ten approved indications are currently included in the NRDL (2024 Edition), being the only anti-PD-1 monoclonal antibody in the NRDL for the treatment of melanoma, perioperative treatment of non-small cell lung cancer, treatment of renal carcinoma and treatment of triple-negative breast cancer. In October 2024, the toripalimab for the treatment of recurrent/metastatic nasopharyngeal carcinoma ("**NPC**") was approved 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 the Singapore Health Sciences Authority (HSA) accepted the new chemical entity application and the new drug application for toripalimab in combination with cisplatin or 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 characterised by high technology, high risk and high added-value, and there is uncertainty since the commercialization of the drug is susceptible to various factors, including local policies and change in market environment, investors are advised to make cautious decisions and pay careful attention to investment risks. The Company will actively pursue the aforementioned 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, 6 January 2025

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 a non-executive Director; and Mr. Zhang Chun, Dr. Feng Xiaoyuan, Dr. Yang Yue, Mr. Li Zhongxian and Ms. Lu Kun as independent non-executive Directors.

* *For identification purpose only*