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 – ACCEPTANCE OF THE SUPPLEMENTAL NEW DRUG APPLICATION FOR TORIPALIMAB AS THE FIRST-LINE TREATMENT OF MELANOMA

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 August 2024.

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 ("**NDA**") for toripalimab (trade name: TUOYI®, product code: JS001) as the first-line treatment for unresectable or metastatic melanoma has been accepted.

ABOUT TORIPALIMAB

Drug name: Toripalimab Injection
Application matter: Registration of Domestic Production of Pharmaceutical Product
Acceptance Nos.: CXSS2400084, CXSS2400085
Applicant: Shanghai Junshi Biosciences Co., Ltd.*
Review conclusion: It is decided to be accepted upon review according to the requirements of Article 32 of the Administrative License Law of the People's Republic of China* (《中華人民共和國行政許可法》).

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 (5,000 deaths amongst approximately 9,000 new cases in 2022) and its incidence rate is rising year by year. As of the date of this announcement, anti-PD-1 monoclonal antibodies have been approved for the second-line or later treatment of advanced melanoma in China, however, the first-line standard treatment of advanced melanoma is still dominated by traditional chemotherapy or targeted therapy (limited to patients with BRAF V600 mutation). Therefore, there is an urgent clinical need for first-line immunotherapy options for patients with advanced melanoma in China.

The supplemental NDA is mainly based on the MELATORCH study (NCT03430297). The MELATORCH study is a multi-center, randomized, open-label, positive-controlled Phase III clinical study, and is 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. 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. 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.

In September 2023, MELATORCH's primary endpoint of progression-free survival ("**PFS**", based on independent radiological review) met the pre-defined efficacy boundary. The results showed that compared with dacarbazine, toripalimab as the first-line treatment for unresectable or metastatic melanoma significantly prolonged the PFS of patients. The safety profile of toripalimab was comparable to that of prior studies, and no new safety signals were identified. The detailed data of this study will be presented by the Company at a recent 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 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. At present, six approved 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 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 July 2024, a positive opinion from the Committee for Medicinal Products for Human Use (the "**CHMP**") of the European Medicines Agency (EMA) was obtained for the marketing authorization application (the "**MAA**") of toripalimab, which recommends approval for the treatment of two indications: toripalimab in combination with cisplatin and gemcitabine for the first-line treatment of adult patients with recurrent, not amenable to surgery or radiotherapy, or metastatic NPC, and toripalimab in combination with cisplatin and paclitaxel for the first-line treatment of adult patients with unresectable advanced, recurrent, or metastatic esophageal squamous cell carcinoma ("**ESCC**"). The European Commission (EC) will take into account the CHMP's positive opinion when making the final decision on the MAA for toripalimab. In addition, the U.K. Medicines and Healthcare products Regulatory Agency (MHRA) accepted the 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 ESCC. 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

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

* *For identification purpose only*