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 FOR THE FIRST-LINE TREATMENT OF ADVANCED TNBC

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 25 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 (the "**NDA**") for the Company's product toripalimab (trade name: TUOYI®, product code: JS001) in combination with paclitaxel for injection (albumin-bound) for the first-line treatment of recurrent or metastatic triple-negative breast cancer ("**TNBC**") with a well-validated test to evaluate PD-L1 positive (CPS ≥ 1) has been approved. This is the 10th indication for toripalimab approved in Chinese mainland.

ABOUT TORIPALIMAB

Drug name: Toripalimab Injection
Application matter: Registration of pharmaceutical product (domestic production)
Acceptance No.: CXSS2300036, CXSS2300037
Certificate No.: 2024S01291, 2024S01292
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 paclitaxel for injection (albumin-bound) for the first-line treatment of recurrent or metastatic triple-negative breast cancer (TNBC) with a well-validated test to evaluate PD-L1 positive (CPS ≥ 1).

According to GLOBOCAN 2022 statistics, breast cancer became the most common cancer in the world, with 2.31 million new cases and 0.67 million deaths in 2022. In China, there were 0.36 million new cases and 0.07 million deaths due to breast cancer in 2022, accounting for 15.5% and 11.2% of global cases. Amongst these, TNBC accounts for about 10% to 15% of all breast cancer cases, making TNBC a more aggressive type of cancer with a higher risk of recurrence and poor prognosis. Advanced TNBC is not responsive to targeted or endocrine therapies, and lacks specific treatment methods. Chemotherapy remains the standard treatment for advanced TNBC in China, but both mono-chemotherapy and combined chemotherapy have poor efficacy, with a median survival time of about 9 to 12 months and a 5-year survival rate of less than 30%.

The supplemental NDA approval is based on the TORCHLIGHT study (NCT04085276), a randomized, double-blind, placebo-controlled, multi-center Phase III clinical study jointly conducted in 56 centers across the country, with Professor Jiang Zefei, Vice President and Secretary General of the Chinese Society of Clinical Oncology (CSCO) and from the Department of Oncology of the Chinese People's Liberation Army General Hospital, served as the principal investigator. In February 2023, the Independent Data Monitoring Committee (IDMC) determined in an interim analysis that the primary endpoint of the TORCHLIGHT study had met the pre-defined efficacy boundary. TORCHLIGHT is the first registered domestic Phase III study to achieve positive results in the field of advanced TNBC immunotherapy.

In January 2024, the top international medical journal *Nature Medicine* (Impact Factor: 58.7) published the interim results of the TORCHLIGHT study. The findings showed that, compared with paclitaxel for injection (albumin-bound), toripalimab in combination with paclitaxel for injection (albumin-bound) in patients with an initial diagnosis of stage IV or recurrent metastatic TNBC can significantly prolong the progression-free survival ("**PFS**") of PD-L1 positive patients. The overall survival ("**OS**") also showed a positive trend, achieving a breakthrough in immunotherapy for advanced TNBC in China. The median PFS in the toripalimab group was 8.4 months, and the risk of disease progression or death was reduced by 35% (P=0.0102). The median OS in the toripalimab group was extended by 13.3 months (32.8 months vs 19.5 months) and the risk of death was reduced by 38% (P=0.0148). The safety profile of toripalimab remained consistent with the established safety profile, with no new safety signals identified.

Toripalimab 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 10 approved indications for toripalimab in the 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 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/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, 25 June 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*