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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 PERIOPERATIVE TREATMENT FOR RESECTABLE NSCLC PATIENTS

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 2 January 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 "**sNDA**") for toripalimab (trade name: TUOYI®, product code: JS001) in combination with chemotherapy as perioperative treatment and subsequently, monotherapy as adjuvant therapy for the treatment of adult patients with resectable stage IIIA-IIIB non-small cell lung cancer ("**NSCLC**") has been approved. This is the first approved perioperative therapy for lung cancer domestically and the second one worldwide.

ABOUT TORIPALIMAB

Drug name: Toripalimab Injection
Application matter: Registration of pharmaceutical product (domestic production)
Acceptance Nos.: CXSS2300017, CXSS2300018
Certificate No.: 2023S02054, 2023S02055
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 chemotherapy as perioperative treatment and subsequently, monotherapy as adjuvant therapy for the treatment of adult patients with resectable stage IIIA-IIIB NSCLC.

Lung cancer is currently the world's second most prevalent malignant tumor with the highest mortality rate. According to data released by the World Health Organization, in 2020, the number of new lung cancer cases in China amounted to 816,000, accounting for 17.9% of all new cancer cases in China. In the same year, the number of lung cancer deaths in China amounted to 715,000, accounting for 23.8% of all cancer deaths in China. NSCLC is a major subtype of lung cancer, accounting for approximately 85% of all cases. Amongst these patients, 20%-25% are surgically resectable at first diagnosis, but even after radical surgical treatment, 30%-55% of these patients suffer from post-surgical recurrence and death. Radical surgery in combination with chemotherapy is a way to prevent recurrence, but chemotherapy alone, as preoperative neoadjuvant or postoperative adjuvant therapy, has limited clinical benefits and can only raise patients' 5-year survival rate by approximately 5%.

The approval of the sNDA is primarily based on data from the NEOTORCH study (NCT04158440), a randomized, double-blind, placebo-controlled, multi-center phase III clinical study led by Professor Lu Shun (陸舜) of Shanghai Chest Hospital of the Shanghai Jiao Tong University School of Medicine* (上海交通大學醫學院附屬胸科醫院) as principal investigator. The study was launched in 56 centers nationwide, and is the world's first phase III clinical study of anti-PD-1 monoclonal antibody for NSCLC perioperative treatment (including neoadjuvant and adjuvant) with positive event-free survival ("**EFS**") result. A total of 404 patients with stage IIIA-IIIB NSCLC were enrolled in the study and were randomly allocated in the ratio of 1:1 to receive toripalimab in combination with chemotherapy (n=202) or placebo in combination with chemotherapy (n=202). The patients received three cycles of pre-operative treatment and one cycle of post-operative treatment with toripalimab or placebo in combination with chemotherapy (paclitaxel in combination with cisplatin for patients with squamous NSCLC, while pemetrexed in combination with cisplatin for patients with non-squamous NSCLC), respectively, and then received either toripalimab or placebo for 13 cycles of adjuvant therapy.

Previously, the latest research results of the NEOTORCH study were announced in the form of an oral presentation at the 2023 American Society of Clinical Oncology ("**ASCO**") Plenary Series held in April and the ASCO annual meeting. The study data showed that, as compared to chemotherapy alone, toripalimab in combination with chemotherapy for perioperative treatment of resectable stage III NSCLC could significantly extend EFS of patients (median EFS as assessed by investigators: not reached vs 15.1 months, $P < 0.0001$), and reduce the risk of disease recurrence, progression, or death in patients by 60% (HR=0.40, 95% CI: 0.277-0.565), and EFS benefit in the toripalimab group was observed in all key subgroups, regardless of PD-L1 expression status and histologic type (squamous or non-squamous). Major pathological remission (MPR) rate and pathological complete remission (pCR) rate were significantly better in the toripalimab group, 48.5% vs 8.4% ($P < 0.0001$) and 24.8% vs 1.0% ($P < 0.0001$), respectively, and the overall survival (OS) of the toripalimab group also showed a clear trend of benefit. In terms of safety, the incidence of treatment emergent adverse events (TEAEs) were similar in both groups, and no new safety signals were observed.

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 seven approved indications for toripalimab in China. In December 2020, toripalimab 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 terms of international layout, in October 2023, toripalimab was approved for marketing in the United States as the first nasopharyngeal carcinoma ("**NPC**") drug. 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 Therapeutic Goods Administration of the Australian Government Department of Health and Aged Care (TGA) accepted the new chemical entity application 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.

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 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, 2 January 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 and Dr. Wang Gang as executive Directors; Dr. Feng Hui, Mr. Tang Yi and Dr. Li Xin 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*