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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 –
ACCEPTANCE OF THE SUPPLEMENTAL APPLICATION FOR
TORIPALIMAB IN COMBINATION WITH CHEMOTHERAPY AS
PERIOPERATIVE TREATMENT FOR RESECTABLE
STAGE II-III 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 21 July 2026.

The board (the “**Board**”) of directors (the “**Directors**”) of the Company is pleased to announce that the Company has recently received the Acceptance Notice (《受理通知書》) issued by the National Medical Products Administration. The supplemental application for the revised indication of toripalimab (trade name: TUOYI®, product code: JS001) in combination with platinum-containing chemotherapy as perioperative treatment and subsequently, monotherapy as adjuvant therapy for the treatment of adult patients with resectable stage II-III non-small cell lung cancer (“**NSCLC**”) has been accepted. The indication in the application is expanded from adult patients with resectable stage IIIA-IIIB NSCLC to adult patients with resectable stage II-III NSCLC.

ABOUT TORIPALIMAB

Drug name: Toripalimab Injection

Application matter: Supplemental Application for Domestic Production of Pharmaceutical Product

Acceptance Nos.: CYSB2600212, CYSB2600213

Applicant: Shanghai Junshi Biosciences Co., Ltd.* (上海君實生物醫藥科技股份有限公司)

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》).

Lung cancer is currently a malignant tumor with the highest prevalence and mortality rate in the world. According to data released by National Clinical Research Center for Cancer, in 2024, there were approximately 1.18 million new lung cancer cases in China, accounting for 22.83% of all new cancer cases in China; there were approximately 0.74 million lung cancer deaths in China, representing 28.79% of all cancer deaths in China. Amongst these patients, 20%-25% were surgically resectable at first diagnosis, but even after radical surgical treatment, 30%-55% of such patients suffered from post-surgical recurrence and death. Radical surgery in combination with chemotherapy is a way to prevent recurrence, but chemotherapy, as preoperative neoadjuvant or postoperative adjuvant therapy, has limited clinical benefit and can only raise the 5-year survival rate of patients by approximately 5%.

Recently, immunotherapy represented by PD-(L)1 inhibitors has been transforming the landscape of cancer treatment. It has a long-term effect in respect of tumor control or elimination by relieving the immune suppression of immune cells by tumor cells and reactivating the patients' own immune cells to kill the tumor. PD-1/PD-L1 inhibitors have been recommended by authoritative lung cancer treatment guidelines both domestically and internationally as one of the standard perioperative treatments for resectable stage II-III NSCLC.

The supplemental application is principally based on the NEOTORCH (NCT04158440), a randomized, double-blind, placebo-controlled phase III clinical study aiming to compare the efficacy and safety of toripalimab or placebo in combination with chemotherapy as perioperative treatment for resectable stage II/III NSCLC patients. Led by Professor Lu Shun (陸舜) of Shanghai Chest Hospital, School of Medicine, Shanghai Jiao Tong University* (上海交通大學醫學院附屬胸科醫院) as primary researcher, the study included a total of 501 patients with resectable stage II-III NSCLC. The primary endpoints are event-free survival (“**EFS**”) in patients with stage III and stage II-III disease as assessed by researchers, and major pathological response (“**MPR**”) rate in patients with stage III and stage II-III disease as assessed by the Blind Independent Pathology Review Committee (“**BIPR**”). The secondary endpoints include overall survival (“**OS**”), EFS as assessed by Independent Review Committee (IRC), pathological complete remission (“**pCR**”) rate, disease free survival (DFS) and safety.

In January 2023, the EFS interim analysis of patients with resectable stage III NSCLC of NEOTORCH met the primary endpoint. The latest study results were presented as oral presentation at the April 2023 session of the American Society of Clinical Oncology (ASCO) Plenary Series and the 2023 ASCO Annual Meeting. NEOTORCH was the world's first phase III clinical study of an anti-PD-1 monoclonal antibody for NSCLC perioperative treatment (including neoadjuvant and adjuvant) with positive EFS results published in the Journal of the American Medical Association (JAMA), a leading international journal in January 2024. The results showed that compared to perioperative chemotherapy alone, toripalimab in combination with chemotherapy as perioperative treatment led to a significant improvement in EFS (median EFS: not reached vs. 15.1 months, $P<0.001$), reduced risk of disease recurrence, progression events or death by 60% ($HR=0.40$, 95% CI: 0.28-0.57). Meanwhile, the OS in the toripalimab in combination with chemotherapy group showed a clear trend toward improved outcomes ($HR=0.62$, 95% CI: 0.38-1.00). Moreover, toripalimab in combination with chemotherapy as perioperative treatment increased the pCR rate to nearly 25-fold (pCR rate: 24.8% vs. 1.0%) and the MPR rate to nearly 6-fold (MPR rate: 48.5% vs. 8.4%).

In December 2023, based on the results of the interim analysis of NEOTORCH, the supplemental new drug application for the new indication of toripalimab in combination with platinum-containing doublet chemotherapy for perioperative treatment of resectable stage IIIA-IIIB NSCLC patients was approved. It was the first approved perioperative therapy for lung cancer domestically and the second one worldwide, and has been included in the National Reimbursement Drug List (2025). Such therapy received the highest-level recommendation in the 2024 edition of the Guidelines of Chinese Society of Clinical Oncology (“CSCO”) for the Diagnosis and Treatment of NSCLC* (《CSCO非小細胞肺癌診療指南》).

In May 2026, the NEOTORCH finished the final analysis. The primary endpoints of EFS and MPR rate in the stage II-III population, as well as the MPR rate in the stage III population met the pre-defined efficacy boundary.

In July 2026, the full results of a post hoc analysis of surgical outcomes from the NEOTORCH of toripalimab in combination with chemotherapy for perioperative treatment of resectable stage III NSCLC patients were officially published in JAMA Surgery, a leading international journal in the field of surgery. The analysis focused on stage III NSCLC patients who underwent surgery in the NEOTORCH and systematically evaluated the effects of toripalimab in combination with chemotherapy as perioperative treatment on surgical feasibility, complications, survival and other outcomes. The results demonstrated that toripalimab in combination with chemotherapy significantly reduced the surgery cancellation rate (17.8% vs. 26.7%; $p=0.03$), thereby enabling more patients to undergo surgical resection without increasing perioperative risks or giving rise to any new safety signals. Among the 314 patients who completed surgery, compared with placebo in combination with chemotherapy, toripalimab in combination with chemotherapy effectively achieved higher rates of tumor downstaging and lymph node downstaging (tumor downstaging rate: 80.7% vs. 50.7%, lymph node downstaging rate: 67.5% vs. 48.6%), and improved the EFS benefit of the patients ($HR=0.50$, 95% CI: 0.33-0.74; $p<0.001$). Among the patients who achieved tumor downstaging or lymph node downstaging, toripalimab in combination with chemotherapy significantly improved EFS compared with placebo in combination with chemotherapy ($HR=0.45$ for both, $p=0.002$ and $p=0.009$).

Toripalimab injection is the first domestic 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 toripalimab clinical studies sponsored by the Company covering more than fifteen indications have been conducted globally, including in China, the United States, Europe, and Southeast Asia. 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 13 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, 12 approved indications have been included in the NRDL. Toripalimab is the only anti-PD-1 monoclonal antibody included in the NRDL for the treatment of renal carcinoma, triple negative breast cancer and melanoma. Three indications of toripalimab for the treatment of advanced nasopharyngeal carcinoma and esophageal squamous cell carcinoma were 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 nearly 50 countries and regions including the United States, the European Union, India, the United Kingdom, Australia, Singapore, Malaysia and South Africa, and is also under review for marketing in various countries and regions worldwide.

RISK WARNING

Due to the high-tech, high-risk, and high value-added characteristics of pharmaceutical products, there is uncertainty as to whether the supplemental application will be approved and the commercialization of drugs after being approved for marketing is susceptible to various uncertain factors. Investors are advised to make cautious decisions and pay careful attention to investment risks. The Company will actively pursue the above R&D 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, 21 July 2026

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. Wang Gang and Dr. Li Xin as executive Directors; Dr. Yao Sheng and Mr. Tang Yi as non-executive Directors; and Dr. Feng Xiaoyuan, Mr. Li Zhongxian, Ms. Lu Kun, Dr. Yang Jin and Mr. Chen Liang as independent non-executive Directors.

* *For identification purposes only*