# 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 PERIOPERATIVE TREATMENT FOR OPERABLE 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 11 April 2023.

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 for toripalimab (trade name: TUOYI®, product code: JS001) in combination with chemotherapy as perioperative treatment and monotherapy as consolidation therapy after adjuvant therapy for the treatment of resectable stage III non-small cell lung cancer ("**NSCLC**") has been accepted.

### ABOUT TORIPALIMAB

Drug name: Toripalimab Injection
Application matter: Registration of Domestic Production of Pharmaceutical Product
Acceptance Nos.: CXSS2300017, CXSS2300018
Applicant: Shanghai Junshi Biosciences Co., Ltd.*（上海君實生物醫藥科技股份有限公司）
Review conclusion: Following the review, the application is accepted pursuant to Article 32 of the Administrative License Law of the People's Republic of China.

Lung cancer is currently the second most prevalent malignant tumor with the highest mortality rate in the world. According to data released by the World Health Organization, in 2020, the number of new lung cancer cases in China amounted to 816,000 and accounted 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 and accounted 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 such patients will suffer 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%.

The supplemental new drug application is based on the Neotorch study (NCT04158440), which is a randomized, double-blind, placebo-controlled, multi-center phase III clinical study led by Professor Lu Shun (陸舜) of Shanghai Chest Hospital* (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. Patients with operable NSCLC received toripalimab/placebo in combination with platinum-containing doublet chemotherapy as neoadjuvant and adjuvant therapy, and received toripalimab/placebo monotherapy as consolidation therapy after postoperative adjuvant therapy. Platinum-containing doublet chemotherapy was selected by investigators according to treatment practices of therapeutic institutions, of which paclitaxel in combination with cisplatin was given to patients with squamous NSCLC, while pemetrexed in combination with cisplatin was given to patients with non-squamous NSCLC. In January 2023, the Independent Data Monitoring Committee (IDMC) determined in an interim analysis that the primary endpoint event-free survival ("**EFS**") of the Neotorch study had met the pre-defined efficacy boundary. Neotorch is the world's first phase III registered study which demonstrate that perioperative treatment with anti-PD-1 monoclonal antibody significantly extends EFS of patients with operable NSCLC. Results of the interim analysis showed that, compared with chemotherapy alone, toripalimab in combination with chemotherapy as perioperative treatment for stage III operable NSCLC patients and toripalimab monotherapy for consolidation therapy thereafter could significantly extend EFS of patients. The detailed data will be published globally for the first time in the form of an oral presentation at the ASCO Plenary Series at 3 p.m. on 20 April 2023 (U.S. Eastern time).

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 including cancers of the lung, nasopharynx, esophagus, stomach, bladder, breast, liver, kidney and skin etc. As of the date of this announcement, there are six approved indications for toripalimab in China. In December 2020, toripalimab injection was successfully negotiated into the National Reimbursement Drug List (the "**NRDL**") for the first time. At present, three indications have been included in the NRDL (2022 Edition). Toripalimab is the only anti-PD-1 monoclonal antibody included in the NRDL for the treatment of melanoma.

In terms of international layout, as of the date of this announcement, toripalimab has been granted two Breakthrough Therapies, one Fast Track, one Priority Review and five Orphan Drug Designations by the U.S. Food and Drug Administration (the "**FDA**") for the treatment of mucosal melanoma, nasopharyngeal carcinoma ("**NPC**"), soft tissue sarcoma, esophageal cancer and small cell lung cancer. At present, the biological license application (BLA) for toripalimab, in combination with gemcitabine and cisplatin, for the first-line treatment of patients with advanced recurrent or metastatic NPC and toripalimab monotherapy for the second-line or later treatment of recurrent or metastatic NPC after platinum-containing chemotherapy, is under review by the FDA. In December 2022 and February 2023, the European Medicines Agency (EMA) and the 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.

## 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, 11 April 2023

*As at the date of this announcement, the Board of Directors of the Company comprises Mr. Xiong Jun, Dr. Li Ning, Dr. Feng Hui, Mr. Zhang Zhuobing, Dr. Yao Sheng, Mr. Li Cong and Dr. Zou Jianjun as executive Directors; Dr. Wu Hai and Mr. Tang Yi as non-executive Directors; and Dr. Chen Lieping, Dr. Roy Steven Herbst, Mr. Qian Zhi, Mr. Zhang Chun and Dr. Feng Xiaoyuan as independent non-executive Directors.*

* *For identification purpose only*