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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 –  
TORIPALIMAB PLUS CHEMOTHERAPY AS  
FIRST-LINE TREATMENT FOR ADVANCED OR METASTATIC ESOPHAGEAL  
CANCER REACHED PRIMARY ENDPOINTS IN A PHASE III CLINICAL STUDY**

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 22 April 2021.

The board (the “**Board**”) of directors (the “**Directors**”) of the Company is pleased to announce that the Independent Data Monitoring Committee (IDMC) has determined that toripalimab (trade name: TUOYI®, product code: JS001) in combination with paclitaxel/cisplatin as the first-line treatment for patients with advanced or metastatic esophageal squamous cell carcinoma (ESCC) has reached its pre-specified primary endpoints of Progression Free Survival (PFS) and Overall Survival (OS) at the interim analysis of a randomized, double-blind, placebo-controlled, multi-center, phase III clinical study “**JUPITER-06**” (Clinicaltrials.gov identifier: NCT03829969). The Company will communicate with the regulatory authorities regarding the supplemental New Drug Application (“**sNDA**”) matters in the near future.

**ABOUT TORIPALIMAB**

Toripalimab is the first domestic anti-PD-1 monoclonal antibody to obtain marketing approval in China. So far, more than thirty company sponsored clinical studies covering more than fifteen indications have been conducted globally including in China and the United States. On 17 December 2018, toripalimab obtained a conditional approval from the National Medical Products Administration (the “**NMPA**”) for the second-line treatment of patients with unresectable or metastatic melanoma. In December 2020, toripalimab injection was successfully included in the updated National Reimbursement Drug List. In February 2021, the sNDA for toripalimab for the treatment of patients with recurrent or metastatic nasopharyngeal carcinoma after failure of at least two lines of prior systemic therapy has been granted a conditional approval by the NMPA. In April 2021, the sNDA for toripalimab for the treatment of patients with locally advanced or metastatic urothelial carcinoma who failed platinum-containing chemotherapy or progressed within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy has been granted a conditional approval. Moreover, toripalimab was included in the Guidelines of the Chinese Society of Clinical Oncology (CSCO) for the Diagnosis and Treatment of Melanoma, the Guidelines of CSCO for the Diagnosis and Treatment of Head and Neck Tumors and the Guidelines of CSCO for the Diagnosis and Treatment of Urothelial Carcinoma.

In February 2021, the sNDA application of toripalimab in combination with chemotherapy for the first-line treatment of patients with advanced, recurrent or metastatic nasopharyngeal carcinoma was accepted by the NMPA. In March 2021, toripalimab was included in the Drug List of the Procedure for Breakthrough Therapy Designation for the first-line treatment of advanced mucosal melanoma by the NMPA. In March 2021, TopAlliance Biosciences, Inc., a subsidiary of the Company, submitted the Biologics License Application of toripalimab for the treatment of recurrent or metastatic nasopharyngeal carcinoma to the US Food and Drug Administration (“FDA”). As of the date of this announcement, toripalimab has been granted 1 Breakthrough, 1 Fast Track and 3 Orphan Drug Designations (“ODD”) by the FDA for the treatment of mucosal melanoma, nasopharyngeal carcinoma, and soft tissue sarcoma.

## **ABOUT JUPITER-06 STUDY**

Esophageal cancer is a primary malignant tumor of the esophageal mucosa epithelium, which is one of the most common cancers in the world. According to data released by GLOBOCAN 2020, in 2020, esophageal cancer is the seventh most common malignant tumor in the world and the sixth leading cause of cancer death. In 2020, approximately 320,000 new esophageal cancer cases and approximately 300,000 deaths due to esophageal cancer occurred in China, with the incidence and death rates ranking fifth and fourth among all malignant tumors, respectively. Esophageal squamous cell carcinoma and adenocarcinoma are the two main histological subtypes of esophageal cancer. Esophageal squamous cell carcinoma is the main subtype in China, accounting for 90% of all esophageal cancer. For patients with advanced or metastatic esophageal squamous cell carcinoma, the current standard first-line treatment is platinum based chemotherapy, but the 5-year overall survival rate is less than 20%.

The JUPITER-06 study was a randomized, double-blind, placebo-controlled, multicenter phase III trial, that aimed to compare the efficacy and safety of toripalimab combined with paclitaxel/cisplatin versus placebo combined with paclitaxel/cisplatin as first-line treatments for advanced or metastatic esophageal squamous cell carcinoma. Professor Xu Ruihua from the Sun Yat-sen University Cancer Hospital is the principal investigator of the JUPITER-06 study. A total of 514 patients were enrolled in the study. The primary endpoints were progression-free survival (PFS) as assessed by the Blinded Independent Review Committee (BICR) and overall survival (OS). Secondary endpoints included the PFS assessed by investigator, objective response rate (ORR), disease control rate (DCR) and duration of response (DOR).

Based on the results of interim analysis, the Independent Data Monitoring Committee (IDMC) determined that both primary endpoints of PFS and OS have crossed the prespecified efficacy boundaries, and the results show that compared with the paclitaxel/cisplatin chemotherapy, toripalimab combined with paclitaxel/cisplatin significantly prolonged the PFS and OS of patients with advanced or metastatic esophageal squamous carcinoma.

## **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 accordance with relevant regulations.

By order of the Board  
**Shanghai Junshi Biosciences Co., Ltd.**  
**Mr. Xiong Jun**  
*Chairman*

Shanghai, the PRC, 22 April 2021

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

\* *For identification purpose only*