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 IS GRANTED THE ORPHAN-DRUG DESIGNATION BY THE FDA

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 15 November 2021.

The board (the "**Board**") of directors (the "**Directors**") of the Company is pleased to announce that TopAlliance Biosciences, Inc., a subsidiary of the Company, has received a designation letter from the US Food and Drug Administration (the "**FDA**"), indicating that toripalimab for the treatment of esophageal cancer has been granted the Orphan-drug Designation by the FDA, which is the fourth Orphan-drug Designation obtained by toripalimab. Toripalimab for the treatment of mucosal melanoma, nasopharyngeal carcinoma and soft tissue sarcoma were previously granted the Orphan-drug Designation by the FDA.

ABOUT TORIPALIMAB

Esophageal cancer is one of the most common malignant tumors in alimentary tract. According to data released by GLOBOCAN 2020, in 2020, esophageal cancer is the seventh most common malignant tumor and the sixth leading cause of cancer death globally, among which, approximately 320,000 new esophageal cancer cases and approximately 300,000 deaths due to esophageal cancer occurred in China in 2020, accounting for approximately 50% and 56% of the global total respectively. According to estimates from the American Cancer Society, approximately 19,000 newly diagnosed cases and 15,000 deaths due to esophageal cancer would occur in the United States in 2021. The prognosis of patients with advanced esophageal cancer is poor, 5-year overall survival rate after the first-line platinum-based chemotherapy treatment remains less than 20%.

The Company has conducted two Phase III registered clinical studies in relation to toripalimab for esophageal cancer, among which, JUPITER-06 study (NCT03829969) is a randomized, double-blind, placebo-controlled and multi-center Phase III clinical study aiming to compare the efficacy and safety of toripalimab in combination with chemotherapy and placebo in combination with chemotherapy in the first-line treatment for patients with advanced or metastatic esophageal squamous cell carcinoma. In September 2021, the results of JUPITER-06 study were released at the European Society for Medical Oncology (ESMO) Congress 2021 for the first time. The study met the co-primary endpoints with statistically significant and clinically meaningful improvements in progression free survival (PFS) and overall survival (OS) for patients treated with the toripalimab and chemotherapy combination, compared to chemotherapy alone. In addition, a randomized, double-blind, placebo-controlled and multi-center Phase III clinical study (NCT04848753) on toripalimab in combination with neoadjuvant chemotherapy for the treatment of resectable locally advanced thoracic esophageal squamous cell carcinoma in the preoperative period is in progress.

Toripalimab was the first domestic anti-PD-1 monoclonal antibody approved for marketing 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 was granted a conditional approval by the National Medical Products Administration (the "**NMPA**") for the second-line treatment of unresectable or metastatic melanoma. In December 2020, toripalimab was successfully included in the updated National Reimbursement Drug List upon negotiations. In February 2021, toripalimab obtained a conditional approval from the NMPA for the treatment of patients with recurrent or metastatic nasopharyngeal carcinoma after failure of at least two lines of prior systemic therapy. In April 2021, toripalimab obtained a conditional approval from the NMPA 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. In addition, toripalimab has been recommended in the Guidelines of Chinese Society of Clinical Oncology for the Diagnosis and Treatment of Melanoma, Head and Neck Tumors, Nasopharyngeal Carcinoma, Urothelial Carcinoma and Immune Checkpoint Inhibitor Clinical Practice.

In February 2021, the supplemental new drug application for toripalimab in combination with cisplatin and gemcitabine as the first-line treatment for patients with locally recurrent or metastatic nasopharyngeal carcinoma was accepted by the NMPA. In March 2021, toripalimab was included in the Breakthrough Therapy Designation for the first-line treatment of advanced mucosal melanoma by the NMPA. In July 2021, the supplemental new drug application for toripalimab in combination with platinum-containing chemotherapy as the first-line treatment for patients with locally advanced or metastatic esophageal squamous cell carcinoma was accepted by the NMPA. In October 2021, the Biologics License Application (the "**BLA**") for toripalimab in combination with gemcitabine and cisplatin for the first-line treatment for patients with advanced recurrent or metastatic nasopharyngeal carcinoma and toripalimab monotherapy for second-line or above treatment of recurrent or metastatic nasopharyngeal carcinoma after platinum-containing chemotherapy has been accepted by the FDA. According to the filing letter, the FDA has granted Priority Review Designation and indicated that it does not plan to hold an advisory committee meeting for the BLA. The Prescription Drug User Fee Act (PDUFA) action date is set on or around April 2022.

As of the date of this announcement, toripalimab has been granted 2 Breakthrough Therapy, 1 Fast Track, 1 Priority Review and 4 Orphan Drug Designations by the FDA for the treatment of mucosal melanoma, nasopharyngeal carcinoma, soft tissue sarcoma and esophageal cancer.

THE IMPLICATION OF THE DESIGNATION FOR THE COMPANY

"Orphan-drug" refers to pharmaceutical products developed for the prevention, diagnosis, and treatment of rare diseases or conditions. The Orphan-drug Designation granted by the FDA is granted to drugs and biologics intended to treat rare diseases with a patient population less than 200,000 in the United States. The Orphan-drug Designation granted by the FDA is beneficial for the continuous development of toripalimab and the enjoyment of certain policy support in terms of registration and commercialization in the United States, including but not limited to (1) tax credits for clinical trial costs; (2) waiver of application fees for new drugs; and (3) 7 years of market exclusivity without being affected by patent upon launching. The designation will reduce the R&D investment on the new drug to a certain extent and accelerate the progress of clinical trials and market registration.

RISK WARNING

After obtaining the Orphan-drug Designation, the Company still needs to communicate and negotiate with the FDA in relation to, among other things, the follow-up clinical trials of toripalimab for the treatment of esophageal cancer, and its registration and declaration plan. It is uncertain whether it can obtain the final approval from the FDA and whether and when the drug will successfully enter the market.

In case another similar drug of similar indication is launched before the launch of toripalimab for the treatment of esophageal cancer is approved by the FDA, the further justification of clinical superiority of toripalimab is required; otherwise, it will be deprived of the policy support for the Orphan-drug Designation such as market exclusivity. Thus, there is uncertainty in the value of the Orphan-drug Designation obtained.

As pharmaceutical products are characterized by high technology, high risks and high added value, and the research and development of the medicine depends on various factors such as technology, review and policies, the assessment and approval policies and the future situation of market competition of the product are subject to risk of uncertainties. Investors are advised to exercise caution and beware of investment risks when making investment decisions.

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

Shanghai, the PRC, 15 November 2021

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 and Mr. Li Cong as executive Directors; Dr. Wu Hai, Mr. Tang Yi 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*