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 – THE ACCEPTANCE OF THE SUPPLEMENTAL NEW DRUG APPLICATION FOR TORIPALIMAB PLUS CHEMOTHERAPY AS FIRST-LINE TREATMENT FOR LOCALLY ADVANCED OR METASTATIC ESOPHAGEAL SQUAMOUS CELL CARCINOMA

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 29 July 2021.

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 "**NMPA**"). The supplemental new drug application (the "**sNDA**") for toripalimab (trade name: TUOYI®, product code: JS001) in combination with platinum-containing chemotherapy as the first-line treatment for patients with locally advanced or metastatic esophageal squamous cell carcinoma has been accepted. Relevant information is as follows:

ABOUT TORIPALIMAB

Drug name: Toripalimab Injection
Application matter: Registration of Domestic Production of Pharmaceutical Product
Acceptance No.: CXSS2101014, CXSS2101015
Applicant: Shanghai Junshi Biosciences Co., Ltd.*
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.

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 sNDA is based on the JUPITER-06 study (Clinicaltrials.gov identifier: NCT03829969), which is a randomized, double-blind, placebo-controlled Phase III clinical study led by Professor Xu Ruihua from Sun Yat-sen University Cancer Center. A total of 514 patients were enrolled in the JUPITER-06 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), duration of response (DOR) and safety. Based on the results of the 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 demonstrate that compared with the placebo chemotherapy combination, toripalimab combined with standard chemotherapy as a first-line treatment significantly prolonged the PFS and OS of patients with advanced or metastatic esophageal squamous cell carcinoma.

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 was granted 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, toripalimab received NMPA's conditional approval 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 received NMPA's conditional approval 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 included in the Guidelines of the Chinese Society of Clinical Oncology (CSCO) for the Diagnosis and Treatment of Melanoma, Head and Neck Tumors, Urothelial Carcinoma and other indications.

In February 2021, the sNDA of toripalimab combined with cisplatin and gemcitabine as the first-line treatment for patients with locally recurrent or metastatic nasopharyngeal carcinoma was accepted for review by the NMPA. In March 2021, toripalimab received Breakthrough Therapy Designation for the first-line treatment of advanced mucosal melanoma by the NMPA. In terms of international layout, in March 2021, the Company started a rolling submission of a Biologics License Application of toripalimab for the second-line 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 by the FDA for the treatment of mucosal melanoma, nasopharyngeal carcinoma, and soft tissue sarcoma.

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, 29 July 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 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*