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)

INSIDE INFORMATION – FDA APPROVAL FOR MARKETING OF TORIPALIMAB

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**") pursuant to Rule 13.09(2) of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited (the "**Listing Rules**") as well as the Inside Information Provisions (as defined under the Listing Rules) under Part XIVA of the Securities and Futures Ordinance (Chapter 571 of the Laws of Hong Kong). Reference is also made to the overseas regulatory announcement of the Company dated 29 October 2023.

The board (the "**Board**") of directors (the "**Directors**") of the Company is pleased to announce that Coherus BioSciences, Inc. ("**Coherus**"), a partner of the Company, recently received a notice from the U.S. Food and Drug Administration (the "**FDA**") regarding the approval of the Biologics License Application (the "**BLA**") for toripalimab (U.S. trade name: LOQTORZI™), in combination with cisplatin and gemcitabine, for the first-line treatment of adults with metastatic or recurrent locally advanced nasopharyngeal carcinoma ("**NPC**"), and for toripalimab, as a single agent, for the treatment of adults with recurrent, unresectable, or metastatic NPC with disease progression on or after platinum-containing chemotherapy. Toripalimab is the first and only drug approved in the United States for the treatment of NPC and is also the first innovative biological drug independently developed and manufactured in China that has been approved for marketing by the FDA.

ABOUT TORIPALIMAB

Drug name: Toripalimab
U.S. trade name: LOQTORZI™
Application matter: Biologics License Application
Indications: Toripalimab, in combination with cisplatin and gemcitabine, is indicated for the first-line treatment of adults with metastatic or recurrent locally-advanced NPC, and toripalimab, as a single agent, is indicated for the treatment of adults with recurrent, unresectable, or metastatic NPC with disease progression on or after platinum-containing chemotherapy.

NPC is a malignant tumor that occurs in the nasopharyngeal mucosal epithelium and is one of the most common types of head and neck cancer. According to the World Health Organization, the number of newly diagnosed NPC cases in 2020 exceeded 130,000 worldwide. Due to the location of the primary tumor, surgery is rarely an option, while radiotherapy alone or in combination with chemotherapy are the main treatment options for localized cancers. Prior to this approval, there were no drugs approved for the treatment of NPC in the United States, and toripalimab is able to fill the gap in the treatment options of NPC in the United States.

This BLA is supported by the results from JUPITER-02, a randomized, double blind, placebo-controlled, multinational multi-center Phase III clinical study (NCT03581786), for the first-line treatment of NPC and the results from POLARIS-02, a multi-center, open-label, pivotal Phase II clinical study (NCT02915432), for second-line or more prior treatments for recurrent or metastatic NPC.

The results of JUPITER-02, the first international multi-center, double blind and randomized controlled Phase III clinical study with largest sample size, were first presented in June 2021 at the plenary session of the American Society of Clinical Oncology (ASCO) annual meeting (#LBA2) and were subsequently published as the cover article of the September 2021 issue of Nature Medicine (IF: 82.9). The results showed that toripalimab in combination with chemotherapy significantly improved progression-free survival (PFS) as compared to chemotherapy alone, as assessed by independent review, in a prespecified interim analysis. The results of the final analysis of overall survival ("**OS**"), presented in June 2023 at the ASCO annual meeting (#6009), demonstrated a statistically significant and clinically meaningful improvement. Overall, treatment with toripalimab reduced the risks of disease progression or death by 48%, and the risk of death by 37% as compared to chemotherapy alone. Moreover, a higher objective response rate ("**ORR**"), longer duration of response (DoR) and higher disease control rate ("**DCR**") were observed in patients treated with toripalimab in combination with chemotherapy and no additional safety-related signs were observed.

The POLARIS-02 results were published online in January 2021 in the Journal of Clinical Oncology (IF: 45.3). The results showed that toripalimab demonstrated durable antitumor activity in patients with recurrent or metastatic NPC who failed previous chemotherapy, with an ORR of 20.5%, a DCR of 40.0%, and a median OS of 17.4 months with acceptable safety profile.

Toripalimab 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. 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 registration activities, in addition to the approval of BLA by the FDA, the Company's 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 had been submitted to and accepted by the European Medicines Agency (EMA) and the Medicines and Healthcare products Regulatory Agency (MHRA).

The Company has granted Coherus an exclusive license for toripalimab in the United States and Canada, further details of which are set out in the announcement of the Company dated 1 February 2021.

IMPACT ON THE COMPANY

Toripalimab is the second product of the Company approved by the FDA for commercialization in the United States, the first and only drug approved in the United States for the treatment of NPC and also the first innovative biological drug independently developed and manufactured in China that has been approved for marketing by the FDA. The approval of the BLA will further advance the international layout process of the Company and enhance the international influence of the Company's products, which is expected to have a positive impact on the long-term operating results of the Company.

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 fulfill its information disclosure obligations regarding the subsequent progress of the projects in a timely manner and in strict compliance with relevant regulations.

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

Shanghai, the PRC, 29 October 2023

As at the date of this announcement, the board of directors of the Company comprises Mr. Xiong Jun, Dr. Li Ning, Mr. Zhang Zhuobing, Dr. Yao Sheng, Mr. Li Cong, Dr. Zou Jianjun and Dr. Wang Gang as executive directors; Dr. Feng Hui, Mr. Tang Yi and Dr. Li Xin as non-executive Directors; and Dr. Roy Steven Herbst, Mr. Qian Zhi, Mr. Zhang Chun, Dr. Feng Xiaoyuan and Dr. Meng Anming as independent non-executive directors.

* *For identification purposes only*