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 HSA ACCEPTED NEW DRUG APPLICATION 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**") on a voluntary basis. Reference is also made to the overseas regulatory announcement of the Company dated 1 February 2024.

The board (the "**Board**") of directors (the "**Directors**") of the Company is pleased to announce that the Company has received a notice from the Singapore Health Sciences Authority (the "**HSA**") that the New Drug Application (the "**NDA**") for toripalimab (product code: TAB001/JS001) 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 has been accepted by the HSA.

ABOUT TORIPALIMAB

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.

This NDA 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 multinational multi-center, double blind and randomized controlled Phase III clinical study with the largest sample size, were published at the plenary session of the 2021 American Society of Clinical Oncology (ASCO) annual meeting (#LBA2), and in Nature Medicine (IF: 82.9) and the Journal of the American Medical Association (IF: 120.7). The results showed that as compared to chemotherapy alone, toripalimab in combination with chemotherapy for the first-line treatment of recurrent or metastatic NPC significantly improved progression-free survival ("**PFS**") and overall survival ("**OS**"), with a median PFS of 21.4 months, and a 3-year OS rate of 64.5%, reduced the risks of disease progression or death by 48%, and the risk of death by 37% and demonstrated a manageable safety profile.

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 objective response rate (ORR) of 20.5%, a median duration of response (DoR) of 12.8 months, and a median OS of 17.4 months with a manageable safety profile.

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. As of the date of this announcement, there are seven 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, six indications have been included in the NRDL (2023 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, toripalimab has been approved for marketing as the first nasopharyngeal cancer drug in the United States in October 2023. In addition to the acceptance of the NDA by the HSA, the European Medicines Agency (EMA) and the U.K. Medicines and Healthcare products Regulatory Agency (the "**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. The Australia Therapeutic Goods Administration (the "**TGA**") accepted the new chemical entity application for toripalimab in combination with cisplatin and gemcitabine, for the first-line treatment of adults with metastatic or recurrent locally advanced 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.

IMPACT ON THE COMPANY

This NDA was submitted under the pathway of Project Orbis. Project Orbis is an initiative of the Oncology Center of Excellence (OCE) of the U.S. Food and Drug Administration (the "**FDA**") that provides a collaborative mechanism and framework among the FDA and regulatory partners in other countries and regions, for concurrent submission and review of oncology drugs. At present, eight regulatory agencies have joined Project Orbis, including the FDA, the TGA, the HSA, Health Canada (HC), the MHRA etc. Project Orbis currently accepts applications for oncology indications. An application should generally be qualified for priority review by the FDA, that is, the drug is intended to treat a serious disease and if approved, would significantly improve the safety or efficacy of the treatment, and furthermore has a high impact and significant clinical benefits. Under the framework of Project Orbis, collaboration among international regulators may allow patients with cancer to receive earlier access to new treatments in other countries.

Toripalimab for the treatment of NPC meets the application requirements and is the first domestic oncology drug to be included in Project Orbis. Previously, two NDAs of toripalimab for the treatment of NPC had been submitted by the Company to the TGA through Project Orbis and had been accepted. The Company will explore the possibility of fast marketing in these countries and regions where the pathway is applicable. If approved, it will further enhance the international influence of the Company's products and broaden the Company's international strategic layout, which is expected to have a positive impact on the long-term operating results of the Company.

RISK WARNING

Due to the uncertainties of the review cycle and result of the HSA, there is uncertainty as to whether the NDA will be approved. Investors are advised to make cautious decisions and pay careful attention to investment risks. The Company will actively promote the above project and fulfill its information disclosure obligations regarding the subsequent progress of the above project 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, 1 February 2024

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*