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 INFORMATION – THE TGA ACCEPTED NEW CHEMICAL ENTITY 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 December 2023.

The board (the "**Board**") of directors (the "**Directors**") of the Company is pleased to announce that the Company has received a notice from the Therapeutic Goods Administration of the Australian Government Department of Health and Aged Care (the "**TGA**") that the New Chemical Entity (the "**NCE**") application for toripalimab (project 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. Additionally, the TGA has also granted an orphan drug designation to toripalimab for the treatment of NPC.

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 NCE application 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 the 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 metastatic or recurrent NPC significantly improved progression-free survival (PFS) and overall survival ("**OS**"), 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 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 October 2023, the U.S. Food and Drug Administration (the "**FDA**") has approved the Biologics License 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. And in addition to the acceptance of the NCE application by the TGA, 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 U.K. Medicines and Healthcare products Regulatory Agency (the "**MHRA**").

IMPACT ON THE COMPANY

This NCE application was submitted under the pathway of Project Orbis. Project Orbis is an initiative of the FDA's Oncology Center of Excellence (OCE) that provides a collaborative mechanism and framework among FDA and regulatory partners in other countries and regions, for concurrent submission and review of oncology drugs. At present, other seven regulatory agencies have joined Project Orbis, including TGA, Singapore Health Sciences Authority (HSA), Health Canada (HC), MHRA and etc. Project Orbis currently accepts applications for oncology indications. An application should generally be qualified for the FDA priority review, 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. 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 TGA, there is uncertainty as to whether the NCE application will be approved. 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 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 December 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*