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 – APPROVAL BY THE MHRA 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**") on a voluntary basis.

The board (the "**Board**") of directors (the "**Directors**") of the Company is pleased to announce that the UK Medicines and Healthcare products Regulatory Agency (the "**MHRA**") has issued the marketing authorisation and approved toripalimab (trade name in the UK: LOQTORZI®), a product of the Company's wholly-owned subsidiary TopAlliance Biosciences Inc., for the treatment of two indications: toripalimab in combination with cisplatin and gemcitabine for the first-line treatment of adult patients with recurrent, not amenable to surgery or radiotherapy, or metastatic nasopharyngeal carcinoma ("**NPC**"), and toripalimab in combination with cisplatin and paclitaxel for the first-line treatment of adult patients with unresectable advanced, recurrent, or metastatic oesophageal squamous cell carcinoma ("**ESCC**"). Toripalimab becomes the first and only drug for the treatment of NPC and the only first-line treatment for advanced or metastatic ESCC regardless of PD-L1 status in the UK.

ABOUT TORIPALIMAB

Drug name: Toripalimab Injection

Trade name in the UK: LOQTORZI®

Indications: Toripalimab in combination with cisplatin and gemcitabine for the first-line treatment of adult patients with recurrent, not amenable to surgery or radiotherapy, or metastatic NPC, and toripalimab in combination with cisplatin and paclitaxel for the first-line treatment of adult patients with unresectable advanced, recurrent, or metastatic ESCC.

NPC is a malignant tumor that occurs in the epithelium mucosae of the nasopharynx and is one of the most common types of head and neck cancers. According to GLOBOCAN 2022 statistics, the number of newly diagnosed NPC cases in 2022 exceeded 120,000 worldwide. Due to the location of the primary tumor, surgery is rarely an option. The European Society for Medical Oncology ("**ESMO**") Guidelines recommend immunotherapy combined with chemotherapy as the first-line treatment for recurrent or metastatic NPC.

The approval of the NPC indications is primarily based on the results from JUPITER-02 study (a randomized, double-blind, placebo-controlled, multinational multi-center Phase III clinical study, NCT03581786). The JUPITER-02 study is the first international multi-center, double-blind, randomized controlled Phase III clinical study in NPC immunotherapy with the largest sample size, and is the world's first Phase III clinical study in which there is preset statistical verification (Type I error control) for Overall Survival ("**OS**") in first-line immunotherapy combined with chemotherapy for NPC compared to chemotherapy alone that demonstrated a survival benefit. The results of the study were presented in an oral report during the Plenary Session of the 2021 annual meeting of the American Society of Clinical Oncology (ASCO) (#LBA2), and were subsequently featured on the cover of *Nature Medicine* (IF: 58.7). The results were also published in full in the *Journal of the American Medical Association* (*JAMA,* IF: 63.1). The results of the study showed that, compared to chemotherapy alone, toripalimab in combination with chemotherapy reduced the risk of disease progression by 48% and the risk of death by 37%. The median progression-free survival ("**PFS**") in the toripalimab in combination with chemotherapy group was prolonged by 13.2 months compared to chemotherapy alone, from 8.2 months to 21.4 months. In addition, patients treated with this combined therapy achieved a higher objective response rate (ORR) and longer duration of response (DoR), with a complete response (CR) rate of 26.7%, and no new safety signal was identified. Long-term survival follow-up data was presented at ASCO 2024, with a 5-year survival rate of 52%.

Esophageal cancer is one of the most common malignant tumors in digestive tract. According to GLOBOCAN 2022 statistics, esophageal cancer is the eleventh most commonly diagnosed cancer and the seventh leading cause of cancer death worldwide, with over 511,000 new cases and over 445,000 deaths in 2022. ESCC and esophageal adenocarcinoma are the two main histological subtypes of esophageal cancer. The ESMO Guidelines recommend PD-1 blocking antibodies combined with chemotherapy for the first-line treatment of patients with advanced or metastatic ESCC with PD-L1 positive status.

The approval of the ESCC indications is primarily based on the results from the JUPITER-06 study (a randomized, double-blind, placebo-controlled, multi-center Phase III clinical study, NCT03829969). The study aimed to evaluate the efficacy and safety of toripalimab in combination with paclitaxel/cisplatin (TP) for the first-line treatment of advanced ESCC compared with placebo in combination with chemotherapy. The results were first presented in an oral session during the ESMO Congress 2021, and later published in *Cancer Cell* (IF: 48.8) and *Journal of Clinical Oncology* (IF: 42.1), two leading international oncology journals. The results of the study showed that toripalimab in combination with chemotherapy resulted in superior PFS and OS in patients with advanced or metastatic ESCC, the median OS was prolonged by 6 months to 17 months and the risk of disease progression or death in patients was significantly reduced by 42%, with a significant improvement in survival benefit, and proved to be beneficial regardless of PD-L1 status.

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 at the date of this announcement, there are ten approved indications for toripalimab in Chinese mainland. In December 2020, toripalimab injection was successfully negotiated into the National Reimbursement Drug List (the "**NRDL**") for the first time, and six approved 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 October 2024, toripalimab for the treatment of recurrent or metastatic NPC was approved in Hong Kong SAR, China.

In terms of international layout, as of the date of this announcement, toripalimab has been approved for marketing in the United States, the European Union, India, the UK, Jordan and other countries and regions. In addition, the Australia Therapeutic Goods Administration (TGA) and the Singapore Health Sciences Authority (HSA) accepted the new chemical entity application and the new drug 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, respectively.

IMPACT ON THE COMPANY

Following the approval, toripalimab becomes the first and only drug for the treatment of NPC and the only first-line treatment for advanced or metastatic ESCC regardless of PD-L1 status in the UK. The UK market is an important component of the overseas commercialization strategy of the Company. The approval will be conducive to the Company in further expanding to overseas markets and enhancing the international influence of the Company's products, which will have a positive impact on the Company's long-term operating results.

RISK WARNING

As pharmaceutical products are characterised by high technology, high risk and high added-value, and there is uncertainty since the commercialization of the drug is susceptible to various factors, including local policies and change in market environment, investors are advised to make cautious decisions and pay careful attention to investment risks. The Company will actively pursue the above projects and fulfill its information disclosure obligations in a timely manner for subsequent progress in strict compliance with relevant regulations.

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

Shanghai, the PRC, 15 November 2024

As at the date of this announcement, the Board of Directors of the Company comprises Mr. Xiong Jun, Dr. Li Ning, Dr. Zou Jianjun, Mr. Li Cong, Mr. Zhang Zhuobing, Dr. Yao Sheng, Dr. Wang Gang and Dr. Li Xin as executive Directors; Mr. Tang Yi as non-executive Director; and Mr. Zhang Chun, Dr. Feng Xiaoyuan, Dr. Meng Anming and Dr. Yang Yue as independent non-executive Directors.

* *For identification purpose only*