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 – RECEIPT OF A POSITIVE OPINION FROM THE COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE OF THE EUROPEAN MEDICINES AGENCY FOR 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).

The board (the "**Board**") of directors (the "**Directors**") of the Company is pleased to announce that a positive opinion from the Committee for Medicinal Products for Human Use (the "**CHMP**") of the European Medicines Agency (the "**EMA**") has been obtained for the marketing authorization application (the "**MAA**") of toripalimab (European trade name: LOQTORZI®), which recommends approval 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**"). The European Commission (the "**EC**") will take into account the CHMP's positive opinion when making the final decision on the MAA for toripalimab.

ABOUT TORIPALIMAB

Drug name: Toripalimab Injection

European trade name: 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 of the nasopharynx and is one of the most common types of head and neck cancers globally. 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 CHMP's positive opinion on 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 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 Jo*urnal of the American Medical Association* (*JAMA*, IF: 63.1).

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 CHMP's positive opinion on the ESCC indications is primarily based on the results from the JUPITER-06 study (a randomized, double blinded, placebo-controlled, multi-center Phase III clinical study, NCT03829969), which 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.

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. At present, 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 April 2024, the Drug Office, Department of Health, the Government of the Hong Kong Special Administration Region (DO) accepted the new drug application (the "**NDA**") 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.

In terms of international layout, toripalimab had been approved for marketing as the first nasopharyngeal cancer drug in the United States in October 2023. In addition to the MAA currently reviewed by the EC, the U.K. Medicines and Healthcare products Regulatory Agency (MHRA) accepted the 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 ESCC. The Australia Therapeutic Goods Administration (TGA) and the Singapore Health Sciences Authority (HSA) accepted the new chemical entity application and the NDA 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

The EC will take into account the CHMP's positive opinion when making the final decision on the MAA for toripalimab. The decision will be applicable to all 27 member states of the European Union, Iceland and Norway. If approved, toripalimab would become 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 Europe. The European market is an important component of the overseas commercialization strategy of the Company. The positive opinion from the CHMP will be conducive to the approval of the MAA of toripalimab by the EC, and will be conducive to the further expansion in overseas markets of the Company and the enhancement of 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 there is uncertainty as to the period and outcome of the approval, and the commercialization of the drug is susceptible to various factors, including local policies and change in market environment, there is uncertainty as to whether the drug will ultimately be approved and its expected approval date for marketing and whether it will be able to ultimately achieve its commercial purpose after being approved. Investors are advised to make cautious decisions and pay careful attention to investment risks. The Company will actively pursue the described project and fulfill its information disclosure obligations in a timely manner for subsequent progress in strict compliance with relevant regulations.

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

Shanghai, the PRC, 26 July 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 a non-executive Director; and Mr. Zhang Chun, Dr. Feng Xiaoyuan, Dr. Meng Anming, Dr. Shen Jingkang and Dr. Yang Yue as independent non-executive Directors.

* *For identification purpose only*