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 OF THE SUPPLEMENTAL NEW DRUG APPLICATION FOR TORIPALIMAB AS THE FIRST-LINE TREATMENT OF RCC

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 7 April 2024.

The board (the "**Board**") of directors (the "**Directors**") of the Company is pleased to announce that the Company has received the Drug Registration Certificate* (《藥品註冊證書》) issued by the National Medical Products Administration. The supplemental new drug application for toripalimab (trade name: TUOYI®, product code: JS001) in combination with axitinib for the first-line treatment of patients with medium to high risk unresectable or metastatic renal cell carcinoma ("**RCC**") has been approved. This is the first approved immunotherapy for renal carcinoma in China.

ABOUT TORIPALIMAB

Drug name: Toripalimab Injection
Application matter: Registration of pharmaceutical product (domestic production)
Acceptance Nos.: CXSS2300050, CXSS2300051
Certificate No.: 2024S00501, 2024S00502
Marketing Authorization Holder: Shanghai Junshi Biosciences Co., Ltd.* (上海君實生物醫藥科技股份有限公司)
Review conclusion: According to the Drug Administration Law of the People's Republic of China* (《中華人民共和國藥品管理法》) and relevant regulations, upon review, the product meets the relevant requirements for drug registration and the additional indication of the product is approved, in particular, the product in combination with axitinib for the first-line treatment of patients with medium to high risk unresectable or metastatic renal cell carcinoma.

Renal carcinoma is the third most common malignancy of the urinary system globally, and RCC accounts for 80%~90% of all cases of renal carcinoma. Based on the data published in the Chinese Medical Journal, there were approximately 77,000 new cases of and 46,000 deaths due to renal carcinoma in China in 2022. Distant metastasis occurred in about one-third of renal carcinoma patients at initial diagnosis, and in 20%-50% of localized patients after nephrectomy. According to the risk classification of the International Metastatic Renal Cell Carcinoma Database Consortium (IMDC), the median overall survival ("**OS**") of patients with low, medium and high risk metastatic RCC receiving anti-vascular targeted treatment were 35.3, 16.6 and 5.4 months, respectively. Therefore, compared to low-risk patients, the clinical needs for new treatment options are more urgent for patients with medium and high risk advanced RCC.

The approval of the supplemental new drug application is mainly based on data from the RENOTORCH study (NCT04394975), a multi-center, randomized, open-label, active-controlled Phase III clinical study led by principal investigators Professor Guo Jun from Peking University Cancer Hospital* (北京大學腫瘤醫院) and Professor Huang Yiran from Renji Hospital Affiliated to Shanghai Jiao Tong University School of Medicine* (上海交通大學醫學院附屬仁濟醫院). The study was conducted across 47 medical centers nationwide, and represents the first pivotal Phase III clinical study of immunotherapy for patients with advanced RCC in China. A total of 421 randomized patients with medium to high risk unresectable or metastatic RCC were enrolled in the study and randomly assigned in a 1:1 ratio to receive toripalimab in combination with axitinib (n=210) or sunitinib alone (n=211). The primary endpoint is progression free survival ("**PFS**") as assessed by the Independent Review Committee ("**IRC**"), and secondary endpoints include PFS as assessed by investigators, objective response rate ("**ORR**") as assessed by IRC or investigators, duration of response ("**DoR**"), disease control rate (DCR), OS, safety profile, etc.

Previously, the study results of RENOTORCH made its debut at the Proffered Paper Session of the European Society for Medical Oncology (ESMO) congress 2023. The full text was simultaneously published in Annals of Oncology (IF: 50.5), the official journal of ESMO. The study data showed that, based on the assessment results of IRC, compared with sunitinib monotherapy, toripalimab in combination with axitinib for the treatment significantly prolonged the PFS of patients by nearly twofold (median PFS: 18.0 vs. 9.8 months, P=0.0028), and the risk of disease progression or death was reduced by 35% (hazard ratio [HR]=0.65; 95% CI: 0.49, 0.86). In addition, the ORR was higher (56.7% vs. 30.8%, P<0.0001) and the DoR was longer (median DoR: not reached vs 16.7 months; HR=0.61) in the toripalimab group. The OS of the toripalimab group also showed a clear trend of benefit (median OS: not reached vs 26.8 months), and the risk of death was reduced by 39% (HR=0.61; 95%CI: 0.40, 0.92). In terms of safety, toripalimab in combination with axitinib demonstrated a favorable safety and tolerability profile, and no new safety signals were observed.

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 eight 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 layout, toripalimab had been approved for marketing as the first nasopharyngeal cancer drug in the United States in October 2023. In addition, the European Medicines Agency (EMA) and the U.K. Medicines and Healthcare products Regulatory Agency (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 nasopharyngeal carcinoma ("**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, respectively. The Australia Therapeutic Goods Administration (TGA) and the Singapore Health Sciences Authority (HSA) accepted the MAA 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.

RISK WARNING

As pharmaceutical products are characterized as being of high technology, of high risks and with high added value, and the commercialization of drugs after being approved for marketing is subject to certain uncertainties, investors are advised to make cautious decisions and pay careful attention to investment risks. The Company will actively pursue the described research and development 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, 7 April 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, Dr. Wang Gang and Dr. Li Xin as executive directors; Dr. Feng Hui and Mr. Tang Yi 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 purpose only*