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 – ACCEPTANCE OF THE SUPPLEMENTAL NEW DRUG APPLICATION FOR TORIPALIMAB IN COMBINATION WITH BEVACIZUMAB FOR THE FIRST-LINE TREATMENT OF ADVANCED HEPATOCELLULAR CARCINOMA

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 17 July 2024.

The board (the "**Board**") of directors (the "**Directors**") of the Company is pleased to announce that the Company has received the Acceptance Notice (《受理通知書》) issued by the National Medical Products Administration and the supplemental new drug application ("**NDA**") for the Company's product toripalimab (trade name: TUOYI®, product code: JS001), in combination with bevacizumab for the first-line treatment of unresectable or metastatic hepatocellular carcinoma ("**HCC**") patients has been accepted.

ABOUT TORIPALIMAB

Drug name: Toripalimab Injection
Application matter: Registration of Domestic Production of Pharmaceutical Product
Acceptance Nos.: CXSS2400069, CXSS2400070
Applicant: Shanghai Junshi Biosciences Co., Ltd.*
Review conclusion: It is decided to be accepted upon review according to the requirements of Article 32 of the Administrative License Law of the People's Republic of China* (《中華人民共和國行政許可法》

Liver cancer is a common malignant tumor of the digestive system worldwide, and the main pathological type is HCC (accounting for about 90%). According to data released by the GLOBOCAN for 2022, the annual number of new cases and deaths of liver cancer worldwide in 2022 was 866,000 and 759,000, respectively. China has high liver cancer incidence. In 2022, the number of new cases of liver cancer reached 368,000 (accounting for 42.4% of global cases), ranking fourth among domestic malignant tumors, with 317,000 deaths (accounting for 41.7% of global cases), ranking second among domestic malignant tumors. Due to the insidious onset, about 70%-80% of liver cancer patients in China are already at intermediate or advanced stage at first

diagnosis, with a median OS of only approximately 10 months and a five-year survival rate of approximately 12%. In recent years, with the continuous emergence of the combination therapy based on the immunotherapeutic drugs, the treatment pattern of advanced liver cancer has changed, and it is gradually becoming possible to achieve radical cure after down-stage transformation.

The supplemental NDA is based on the HEPATORCH study (NCT04723004), which is a multi-center, randomized, open-label, active controlled phase III clinical study, aiming to evaluate the efficacy and safety of toripalimab in combination with bevacizumab for the first-line treatment of unresectable or metastatic HCC compared to the standard treatment of sorafenib. The study was launched in 57 centers nationwide in China, led by Professor Fan Jia (樊嘉), an academician of the Chinese Academy of Sciences, from Zhongshan Hospital affiliated to Fudan University* (復旦大學附屬中山醫院) as the principal investigator.

In June 2024, the primary endpoints of progression free survival ("**PFS**", based on independent radiological review) and overall survival ("**OS**") of the HEPATORCH study met the pre-defined efficacy boundary. The results of the study showed that toripalimab in combination with bevacizumab for the first-line treatment of patients with advanced HCC could significantly prolong the PFS and OS of the patients compared with sorafenib, while improving the secondary endpoints such as objective response rate and time to progression. The safety profile of toripalimab was consistent with the known risks, and no new safety signals were identified. The detailed data of this study would be presented at a subsequent international academic conference.

Toripalimab injection is the first domestic 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 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 NDA for toripalimab 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.

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 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 (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.

RISK WARNING

Due to the high-tech, high-risk and high-value-added characteristics of pharmaceutical products, there are substantial risks and uncertainties in the process of drug research, development and commercialization. These many stages make it susceptible to uncertainties and therefore, 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
Shanghai Junshi Biosciences Co., Ltd.*
Mr. Xiong Jun
Chairman

Shanghai, the PRC, 17 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 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*