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# 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– FORMATION OF A JOINT VENTURE WITH RXILIENT BIOTECH TO JOINTLY DEVELOP AND COMMERCIALIZE TORIPALIMAB IN MULTIPLE COUNTRIES IN SOUTHEAST ASIA

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 28 March 2023.

The board (the "**Board**") of directors (the "**Directors**") of the Company is pleased to announce that the Company entered into a shareholders agreement (the "**Shareholders Agreement**") with Rxilient Biotech Pte. Ltd. ("**Rxilient Biotech**") and its wholly-owned subsidiary, Excellmab Pte. Ltd. ("**Excellmab**") on 27 March 2023, pursuant to which the Company will subscribe for newly issued shares of Excellmab by payment in kind to obtain 40% equity interest in Excellmab. Subject to the fulfillment of the conditions precedent as agreed under the Shareholders Agreement, the Company will substantially perform its capital contribution obligations, and intends to enter into an exclusive license agreement ("**License Agreement**") with Excellmab in the form as agreed upon by the parties at the time of entering into the Shareholders Agreement, thereby granting Excellmab an exclusive license and other related rights to develop and commercialize intravenous toripalimab in Thailand, Brunei, Cambodia, Indonesia, Laos, Malaysia, Myanmar, the Philippines, and Vietnam (the "**Cooperation Territory**") (together with the entering into of the Shareholders Agreement, the "**Cooperation Territory**").

# PRINCIPAL TERMS OF THE SHAREHOLDERS AGREEMENT

Rxilient Biotech will subscribe for the newly issued shares of Excellmab for US\$4,999,999, and the Company will pay for the subscription amount under the Shareholders Agreement by way of granting Excellmab with the relevant rights under the License Agreement. Upon completion of the issuance, Excellmab will be owned as to 60% by Rxilient Biotech and 40% by the Company, respectively.

Excellmab will be responsible for the development, medical affairs, production of finished products, and commercialization of the relevant products within the Cooperation Territory. The profits available for distribution by Excellmab will be distributed in proportion to the respective shareholdings of the parties.

#### PRINCIPAL TERMS OF THE LICENSE AGREEMENT

#### (I) Content of License

- 1. Toripalimab: Excellmab is granted an exclusive license and other related rights to develop and commercialize intravenous toripalimab (including any human oncology indications approved and to be aproved by applicable regulatory authorities) in the Cooperation Territory.
- 2. The right of first negotiation: Excellmab shall have the right of first negotiation for commercialization, in the event that the Company determines to grant any third party the relevant rights of the other four drug candidates as agreed in the License Agreement in one or more countries within the Cooperation Territory.

#### (II) Financial Terms

According to the progress of the research and development of toripalimab and other matters, the Company may receive a milestone payment of up to approximately US\$4.52 million, plus a percentage of royalties on net sales.

#### (III) Applicable Laws

The License Agreement is governed by the laws of Singapore.

# **ABOUT TORIPALIMAB**

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 thirty 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 including cancers of the lung, nasopharynx, esophagus, stomach, bladder, breast, liver, kidney and skin etc. 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 layout, as of the date of this announcement, toripalimab has been granted two Breakthrough Therapies, one Fast Track, one Priority Review and five Orphan Drug Designations by the U.S. Food and Drug Administration (the "FDA") for the treatment of mucosal melanoma, nasopharyngeal carcinoma ("NPC"), soft tissue sarcoma, esophageal cancer and small cell lung cancer. At present, the biological license application (BLA) for toripalimab, in combination with gemcitabine and cisplatin, for the first-line treatment of patients with advanced recurrent or metastatic NPC and toripalimab monotherapy for the secondline or above treatment of recurrent or metastatic NPC after platinum containing chemotherapy, is under review by the FDA. In December 2022 and February 2023, the European Medicines Agency (EMA) and the 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, respectively.

# ABOUT RXILIENT BIOTECH AND EXCELLMAB

Rxilient Biotech, established in November 2021, is a subsidiary controlled by China Medical System Holdings Limited ("China Medical System", a company whose shares are listed on The Stock Exchange of Hong Kong Limited (stock code: 867)). Rxilient Biotech and other companies related to China Medical System that are involved in Southeast Asian businesses (together with Rxilient Biotech, "Rxilient") form an open platform integrating innovative R&D, preparation contract development and manufacturing organization (CDMO), manufacturing, marketing and promotion. By virtue of China Medical System's capability in global investment and acquisition of high-quality for over 20 years products, excellent market commercialization experience, strong self-owned cash flow and leading venture capital and investment and financing concepts, Rxilient cooperates with the world's leading biopharmaceutical companies to introduce high-quality medicines into Southeast Asia and ultimately realize local manufacturing, explore the construction of a "bridgehead" in Southeast Asia for global pharmaceutical companies to step into the global market.

According to the financial statements of China Medical System (prepared in accordance with the International Financial Reporting Standards and audited), as of 31 December 2022, the total assets and net assets of China Medical System were RMB17,754 million and RMB14,737 million, respectively. For the fiscal year 2022, China Medical System achieved revenue of RMB9,150 million and net profit of RMB3,276 million.

Established in February 2023, Excellmab was a wholly-owned subsidiary of Rxilient Biotech prior to the execution of the Shareholders Agreement.

To the best knowledge, information and belief of the Company having made all reasonable enquiries, Rxilient Biotech, Excellmab and their ultimate beneficial owners are not connected persons (as defined in the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited (the "Listing Rules")) of the Company. Save for the abovementioned cooperation, there is no other relationship between Rxilient Biotech and Excellmab and the Company in terms of property rights, businesses, assets, credits and debts or human resources. Therefore, this transaction does not constitute a connected transaction of the Company under Chapter 14A of the Listing Rules. In addition, this transaction does not constitute a notifiable transaction of the Company under Chapter 14 of the Listing Rules.

# **REASONS FOR AND BENEFITS OF THE COOPERATION**

The Cooperation is an important step for the Company to continue to expand its global commercialization network, which will further propel rapid penetration of the Company's products in Southeast Asian markets. Through the cooperation model of establishing a joint venture, we will achieve mutual complementarity and strong alliance by combining the advantages of Rxilient in terms of registration and commercialization with our strong research and development capability. Toripalimab is one of the key Chinese innovative drugs to be promoted overseas. With the Cooperation, the Company and Rxilient will introduce such key innovative drug into Southeast Asian markets, which is expected to realize the first commercialization of Chinese anti-PD-1 monoclonal antibody product in Southeast Asian countries. Using the joint venture as a platform, the Company also plans to conduct in-depth cooperation with Rxilient to introduce more high-quality innovative drugs into Southeast Asian markets to achieve joint and long-term development between the two parties.

#### **RISK WARNING**

As pharmaceutical product is characterized by high technology, high risk and high added value with a long life cycle constituted of R&D, clinical development, drug approval and commercial production, the development process involves many stages and is susceptible to uncertainties, thus the successful commercialization of toripalimab injection in the Cooperation Territory is subject to certain uncertainties. In addition, the payments as agreed under the License Agreement are subject to the fulfillment of certain conditions precedent, and the ultimate payments and the impact on the Company's future revenue and profit remain uncertain. Investors are therefore advised to make decisions cautiously and pay attention to investment risks. The Company will fulfill its information disclosure obligations in a timely manner in relation to the subsequent progress of the project in strict accordance with the relevant regulations.

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

Shanghai, PRC, 28 March 2023

As at the date of this announcement, the Board of Directors of the Company comprises Mr. Xiong Jun, Dr. Li Ning, Dr. Feng Hui, Mr. Zhang Zhuobing, Dr. Yao Sheng, Mr. Li Cong and Dr. Zou Jianjun as executive Directors; Dr. Wu Hai and Mr. Tang Yi as non-executive Directors; and Dr. Chen Lieping, Dr. Roy Steven Herbst, Mr. Qian Zhi, Mr. Zhang Chun and Dr. Feng Xiaoyuan as independent non-executive Directors.

\* For identification purpose only