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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 – WHOLLY-OWNED SUBSIDIARY OBTAINING THE EU GMP CERTIFICATE

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 10 July 2024.

The board (the “**Board**”) of directors (the “**Directors**”) of the Company is pleased to announce that, Suzhou Union Biopharm Co., Ltd.* (蘇州眾合生物醫藥科技有限公司), a wholly-owned subsidiary of the Company, received the CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER issued by The Ireland Health Products Regulatory Authority in accordance with the relevant regulations of the European Medicines Agency (the “**EMA**”). The relevant particulars are hereby announced as follows:

ABOUT THE GMP CERTIFICATE

Company name: Suzhou Union Biopharm Co., Ltd.*

Site address: 999 Longqiao Road, Wujiang, Suzhou

Certificate No.: 34482

Certified production lines: drug substance workshop 1, drug product workshop 1

Validity period of the certificate: valid for three years commencing from the inspection date on 22 March 2024

Issuing authority: The Ireland Health Products Regulatory Authority

IMPLICATIONS ON THE COMPANY

This is the first time that the relevant production facilities of toripalimab injection, a core product of the Company, have obtained the GMP certificate of a member state of the European Union (the “**EU**”). According to the GMP mutual recognition system among the EU member states, the obtaining of the GMP certificate indicates that the production facilities with the certificate have met the GMP standards of the EU.

The marketing authorization application (the “MAA”) for toripalimab in combination with cisplatin and gemcitabine for the first-line treatment of patients with locally recurrent or metastatic nasopharyngeal cancer, 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 have been accepted by the EMA. According to local regulations, toripalimab injection is still subject to the approval for the MAA by the EU before it can be marketed in the EU.

The EU market is an important component of the overseas commercialization strategy of the Company. The obtaining of the GMP certificate is conducive to the further expansion in overseas markets of the Company and the enhancement of its market competitiveness, which will have a positive impact on the operations of the Company in the future.

RISK WARNING

The Company expects that obtaining of the EU GMP certificate will not have a significant impact on the results of the Company in the short term. As there is uncertainty as to whether the MAA of toripalimab injection can be approved in the EU, and the production and sale of drugs is susceptible to various factors, including change in market environment, therefore, investors are advised to make cautious decisions and pay careful attention to investment risks. The Company will actively pursue the above project and fulfill its information disclosure obligations in a timely manner in respect of the subsequent progress of the project in strict compliance with relevant regulations.

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

Shanghai, the PRC, 10 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 Jinggang and Dr. Yang Yue as independent non-executive Directors.

* *For identification purpose only*