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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 – UPDATE ON DRUG REGISTRATION OF ADALIMUMAB INJECTION

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 2 March 2022.

The board (the "**Board**") of directors (the "**Directors**") of the Company is pleased to announce that, as informed by the website of the National Medical Products Administration (the "**NMPA**"), the new drug application (the "**NDA**") of adalimumab injection (project code: UBP1211, trade name: 君邁康<sup>®</sup>) for the treatment of rheumatoid arthritis, ankylosing spondylitis and psoriasis submitted by the Company is at the stage of "Approval completed – Certificates to be prepared", which means that the NMPA has approved the NDA and its relevant administrative department is preparing the approval document for drug registration. Relevant information is as follows:

## ABOUT ADALIMUMAB INJECTION

Drug name: Adalimumab injection Dosage form: Injection (Packaged in pre-filled syringes) Specification: 40mg (0.8ml)/vial Acceptance number: CXSS1900041 Indications: Rheumatoid arthritis, ankylosing spondylitis and psoriasis Marketing Authorization Holder: Shanghai Junshi Biosciences Co., Ltd.\* (上海君實生物醫藥科技 股份有限公司) Tumor necrosis factor (TNF- $\alpha$ ) is secreted by macrophages, mast cells and activated Th cells. It is a potent inducer of inflammatory response and a key regulator of innate immunity, playing a key role in the occurrence and development of various inflammatory conditions. The binding of TNF- $\alpha$  to TNF- $\alpha$  receptors can induce inflammatory responses, and it has been proven that rheumatoid arthritis, psoriasis, Crohn's disease, ankylosing spondylitis and many other autoimmune diseases are closely related to TNF- $\alpha$ . Anti-TNF- $\alpha$  monoclonal antibodies can bind to TNF- $\alpha$  receptors and reduce the immune response activated by TNF- $\alpha$ , thereby preventing the occurrence of inflammatory diseases with the special characteristics of being highly efficient, safe, and can be administrated conveniently. 君邁康<sup>®</sup> has been supported by the national "Major New Drug Creation", a major scientific and technological project, during the "Twelfth Five-Year Plan".

In August 2017, the Company and Jiangsu T-mab BioPharma Co., Ltd. ("**T-mab Bio**")\* (江蘇泰 康生物醫藥有限公司), a wholly-owned subsidiary of Mabwell (Shanghai) Bioscience Co., Ltd. ("**Mabwell Bio**")\* (邁威 (上海) 生物科技股份有限公司) entered into a collaborative research, development and commercialization agreement to jointly develop 君邁康<sup>®</sup> and enjoy all related intellectual property rights. In November 2020, the Company entered into a supplemental agreement with Mabwell Bio and T-mab Bio, pursuant to which the parties agreed that a company jointly invested by the Company and Mabwell Bio will be the marketing authorization holder of 君邁康<sup>®</sup> after it is marketed, and the profits of the company jointly invested will be distributed between the Company and Mabwell Bio on a 50:50 basis, while Mabwell Bio or its controlled subsidiaries will be responsible for the production and sales of 君邁康<sup>®</sup>.

## **RISK WARNING**

Due to the high-tech, high-risk and high-value-added characteristics of pharmaceutical products, there are uncertainties in the manufacture and sales of a drug after it has been approved for marketing and 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 Shanghai Junshi Biosciences Co., Ltd.\* Mr. Xiong Jun Chairman

Shanghai, the PRC, 2 March 2022

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 and Mr. Li Cong as executive Directors; Dr. Wu Hai, Mr. Tang Yi and Mr. Lin Lijun 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