

Hong Kong Exchanges and Clearing Limited and The Stock Exchange of Hong Kong Limited take no responsibility for the contents of this announcement, make no representation as to its accuracy or completeness and expressly disclaim any liability whatsoever for any loss howsoever arising from or in reliance upon the whole or any part of the contents of this announcement.



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 - JS012 INJECTION RECEIVED THE CLINICAL TRIAL APPROVAL

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 19 November 2021.

The board (the “**Board**”) of directors (the “**Directors**”) of the Company is pleased to announce that, the Company has received the Clinical Trial Approval (《藥物臨床試驗批准通知書》) issued by the National Medical Products Administration. The investigational new drug application for the JS012 injection (project code: “**JS012**”) has been approved. Relevant information is as follows:

ABOUT JS012 INJECTION

Drug name: JS012 injection

Application matter: Clinical Trial of Domestic Production Registration of Pharmaceutical Product
Acceptance No.: CXSL2101324

Applicant: 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 and relevant regulations, upon review, the JS012 injection accepted on 10 September 2021 meets the relevant requirements for drug registration and is approved to conduct clinical trials in accordance with the submitted protocol for advanced malignant solid tumors.

The active ingredient of JS012 injection is recombinant humanised anti-Claudin18.2 monoclonal antibody, which can target Claudin18.2, inhibit related signal pathway, kill tumor cells by initiating antibody-dependent cell-mediated cytotoxicity (ADCC) and complement-dependent cytotoxicity (CDC), and is intended to be used for the treatment of advanced malignant tumors, such as gastric cancer and pancreatic cancer.

Claudin protein is one kind of important molecule of tight junctions, and 27 members of this protein family have been found. Claudin18 is a member of Claudin protein family, which is encoded by Claudin18 gene in human body. Claudin18 has two protein subtypes, Claudin18.1 and Claudin18.2, both of which have tissue specificity. Claudin18.2 is mainly expressed in differentiated gastric epithelial cells in normal tissues, but not in gastric stem cells. However, abnormal initiation and overexpression of Claudin18.2 have been found in various primary malignant tumors such as gastric cancer, pancreatic cancer, esophageal adenocarcinoma, colon cancer and liver cancer, etc. Claudin18.2 has become a potential target because of its high specificity in normal tissues and initiation expression in various cancers. As of the date of this announcement, no similar target product has been approved for marketing globally.

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 commercialisation. These 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 above research and development projects and fulfill its information disclosure obligations in a timely manner for subsequent progress in strict accordance with relevant regulations.

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

Shanghai, the PRC, 19 November 2021

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, Mr. Qian Zhi, Mr. Zhang Chun, Dr. Jiang Hualiang and Dr. Roy Steven Herbst as independent non-executive Directors.

* For identification purpose only