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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)

## INSIDE INFORMATION – VV116 VERSUS PAXLOVID FOR EARLY TREATMENT OF MILD TO MODERATE COVID-19 REACHES PRIMARY ENDPOINT IN PHASE III REGISTRATIONAL CLINICAL STUDY

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**") pursuant to Rule 13.09(2) of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited (the "**Listing Rules**") as well as the Inside Information Provisions (as defined under the Listing Rules) under Part XIVA of the Securities and Futures Ordinance (Chapter 571 of the Laws of Hong Kong). Please also refer to the overseas regulatory announcement of the Company published on 23 May 2022.

The board (the "**Board**") of directors (the "**Directors**") of the Company is pleased to announce that the product VV116 tablet (project code: JT001/VV116, "**VV116**"), an oral nucleoside analog anti-SARS-CoV-2 drug jointly developed by Shanghai JunTop Biosciences Co., Ltd.\* (上海君拓 生物醫藥科技有限公司) ("**JunTop Biosciences**"), a subsidiary controlled by the Company, and Vigonvita Life Sciences Co., Ltd.\* (蘇州旺山旺水生物醫藥有限公司) ("**Vigonvita**"), reached its primary endpoint in a phase III registrational clinical study (NCT05341609) of VV116 versus nirmatrelvir tablet/ritonavir tablet (namely PAXLOVID) for early treatment of mild to moderate coronavirus disease 2019 ("**COVID-19**"). The Company will communicate with the regulatory authority in respect of the submission of new drug application ("**NDA**") in the near future.

### ABOUT VV116

In September 2021, JunTop Biosciences entered into a cooperative development agreement with Vigonvita to jointly undertake the clinical development and commercialization of VV116 in the cooperation territory, being the whole world except for the following four territories, namely the five Central Asian countries (Kazakhstan, Uzbekistan, Kyrgyzstan, Tajikistan and Turkmenistan), Russia, North Africa (Egypt, Libya, Tunisia, Algeria, Morocco and Sudan), and the Middle East (19 countries including Saudi Arabia, Iran, Iraq, Turkey, Israel, etc.).

VV116 showed good safety, tolerability and pharmacokinetics in healthy subjects, and the three phase I clinical study results have been published online in Acta Pharmacologica Sinica, a renowned journal in the pharmaceutical field. Currently, VV116 is under the stage of international multi-center phase III clinical studies, and several clinical studies for patients with mild to moderate and moderate to severe COVID-19 are in progress.

#### ABOUT PROGRESS OF THE CLINICAL STUDY (NCT05341609)

The NCT05341609 study is a multi-center, single-blind, randomized, controlled phase III clinical study to evaluate the efficacy and safety of VV116 versus nirmatrelvir tablet/ritonavir tablet (namely PAXLOVID) for early treatment of patients with mild to moderate COVID-19. The principal investigator of the study is academician Ning Guang of Ruijin Hospital affiliated to Shanghai Jiao Tong University School of Medicine\* (上海交通大學醫學院附屬瑞金醫院), and 822 patients have been actually enrolled. Its primary endpoint is "time to sustained clinical recovery", and its secondary endpoints include, among other things, "percentage of participants who have progression of COVID-19 (defined as progression to severe and/or critical COVID-19 or death from any cause) by Day 28".

The results of the clinical study showed that VV116 for the early treatment of mild to moderate COVID-19 reached the primary endpoint in the clinical study.

According to the laws and regulations in relation to drug registration of the PRC, the drug shall be subject to clinical research, and review and approval from the National Medical Products Administration before its production and marketing. The Company will communicate with the drug regulatory authority in respect of the submission of NDA in the near future.

#### **RISK WARNING**

The research and development of new drugs is characterized by a long cycle, high risks and high added values and involves a number of approval processes, which are susceptible to various uncertainties. The approval conclusion is therefore subject to certain uncertainties. Affected by various factors such as the development and control of the global pandemic, the popularization of related preventive vaccines, the successive approval of therapeutic drugs and the subsequent product marketing, the commercialization of the drug in the future is also uncertain. The Company will actively pursue the above research and development project and fulfill its information disclosure obligations in a timely manner for subsequent progress in strict compliance with relevant regulations. Investors are advised to make cautious decisions and pay careful attention to investment risks.

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

Shanghai, the PRC, 23 May 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 purposes only