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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 –  
CONDITIONAL APPROVAL FOR MARKETING OF  
VV116 BY THE NMPA**

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 30 January 2023.

The board (the “**Board**”) of directors (the “**Directors**”) of the Company is pleased to announce that on 28 January 2023, pursuant to relevant regulations of the Drug Administration Law\* (《藥品管理法》), the National Medical Products Administration (the NMPA) conducted urgent review and approval under Special Examination and Approval of Drugs\* (藥品特別審批程序), and conditionally approved Deuremidevir Hydrobromide Tablets (氫溴酸氈瑞米德韋片) (trade name: MINDEWEI\*(民得維®), product code: VV116/JT001, “**VV116**”), an oral nucleoside analog anti-SARS-CoV-2 Category 1 innovative drug for marketing, which was applied by Shanghai Vinnerna Biosciences Co., Ltd.\* (上海旺實生物醫藥科技有限公司), a subsidiary controlled by the Company, for the treatment of adult patients with mild to moderate coronavirus disease 2019 (“**COVID-19**”). VV116 was jointly developed by Shanghai Institute of Materia Medica, Chinese Academy of Sciences\* (中國科學院上海藥物研究所), Wuhan Institute of Virology, Chinese Academy of Sciences\* (中國科學院武漢病毒研究所), Xinjiang Technical Institute of Physics and Chemistry, Chinese Academy of Sciences\* (中國科學院新疆理化技術研究所), Central Asian Center of Drug Discovery and Development of Chinese Academy of Sciences\* (中國科學院中亞藥物研發中心)/China-Uzbekistan Medicine Technical Park (the Belt and Road Joint Laboratory of the Ministry of Science and Technology)\* (中烏醫藥科技城(科技部“一帶一路”聯合實驗室)), Lingang Laboratory\* (臨港實驗室), Vigonvita Life Sciences Co., Ltd.\* (蘇州旺山旺水生物醫藥有限公司) (“**Vigonvita**”) and the Company.

**ABOUT VV116**

VV116 is a new oral nucleoside analog antiviral drug, which can be non-covalently bound to the active center of RNA-dependent RNA polymerase (“**RdRp**”) of SARS-CoV-2 in the form of nucleoside triphosphate, directly inhibiting the activity of RdRp of the virus and blocking the replication of virus, thus realizing the antiviral effect. Preclinical studies have shown that VV116 exhibited significant antiviral effects against both the original COVID-19 strain and mutant strains, including Omicron, and exhibited no genetic toxicity.

In September 2021, Shanghai JunTop Biosciences Co., Ltd.\* (上海君拓生物醫藥科技有限公司), a subsidiary controlled by the Company, 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.). In December 2021, VV116 was approved for the treatment of moderate/severe COVID-19 patients in Uzbekistan.

This approval was mainly based on a multi-center, double-blind, randomized, placebo-controlled phase III clinical study (NCT05582629) to evaluate the efficacy and safety of VV116 among mild to moderate COVID-19 patients with or without high risk for progression to severe COVID-19 led by academician Li Lanjuan (李蘭娟), director of the State Key Laboratory for Diagnosis & Treatment of Infectious Diseases (Zhejiang University)\* (浙江大學傳染病診治國家重點實驗室) as primary researcher. The primary endpoint of the study was the time from the first administration to sustained clinical symptoms resolution, while the secondary endpoints included time to sustained clinical symptoms alleviation, proportion of patients with disease progression through day 28, changes of SARS-CoV-2 nucleic acid and viral load, and safety, etc.

The study results showed that, as of the data cut-off date of the interim analysis, among 1,277 randomized and treated subjects, compared with placebo, the primary endpoint the time from the first administration to sustained clinical symptoms resolution (The score of 11 COVID-19 related clinical symptom =0 and lasted for 2 days) of VV116 was significantly shortened, the median time difference was 2 days; the time to sustained clinical symptoms alleviation was significantly shortened, the change of viral load from baseline and other virological indicators were better than those of the placebo group.

## **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 commercialization. Such stages are 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 project and fulfill its information disclosure obligations in a timely manner for subsequent progress in strict compliance with relevant regulations.

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

Shanghai, the PRC, 30 January 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