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 – THE ACCEPTANCE OF THE SUPPLEMENTAL NEW DRUG APPLICATIONS FOR ONGERICIMAB 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 April 2024.

The board (the "**Board**") of directors (the "**Directors**") of the Company is pleased to announce that recently, the Company has received the Acceptance Notice (《受理通知書》) issued by the National Medical Products Administration. Two supplemental new drug applications for the Company's product Ongericimab injection have been accepted.

ABOUT ONGERICIMAB INJECTION

Drug name: Ongericimab injection*(昂戈瑞西單抗注射液)
Application matter: Registration of Domestic Production of Pharmaceutical Product
Acceptance No.: CXSS2400028, CXSS2400029, CXSS2400030, CXSS2400031
Applicant: Shanghai Junshi Biosciences Co., Ltd.* (上海君實生物醫藥科技股份有限公司)
Specification: 150 mg (1 ml) in a single dose (pre-filled syringe), 150 mg (1 ml) in a single dose (pre-filled autosyringe)
Review conclusion: Following the review, the applications are accepted pursuant to Article 32 of the Administrative License Law of the People's Republic of China* (《中華人民共和國行政許可法》).
Indications: (I) Heterozygous familial hypercholesterolemia. (II) Primary hypercholesterolemia and mixed dyslipidemia in which statins are not tolerated or contraindicated.

Ongericimab is a recombinant humanized anti-PCSK9 monoclonal antibody independently developed by the Company. The Company is the first domestic company in China to obtain clinical trial approval for drug targeting to PCSK9. The Company completed two Phase III clinical studies in patients with primary hypercholesterolemia (including familial and non-familial heterozygous) and mixed hyperlipidemia, a Phase II clinical study in patients with homozygous familial hypercholesterolemia, and a Phase III clinical study in patients with heterozygous hypercholesterolemia. In addition, a Phase III clinical study of monotherapy in patients with primary hypercholesterolemia and mixed hyperlipidemia (statin intolerance and intermediate to low cardiovascular risk) finished the primary analysis.

In April 2023, the new drug application for ongericimab was accepted by the National Medical Products Administration for the treatment of: (1) primary hypercholesterolemia (including familial and non-familial heterozygous) and mixed dyslipidemia; and (2) homozygous familial hypercholesterolemia in adults or adolescents aged 12 or above.

According to the Chinese Guidelines for Lipid Management (2023), cardiovascular disease is the leading cause of death among urban and rural residents in China, with a predominant focus on atherosclerotic cardiovascular disease ("**ASCVD**"). The rise of low-density lipoprotein cholesterol ("**LDL-C**") level is a dangerous factor in causing an ASCVD. Reducing the level of LDL-C can significantly lower the incidence of ASCVD and the risk of death. Despite statins currently being the cornerstone of lipid lowering treatment, approximately 9.1% of patients clinically exhibit statin intolerance, with a higher proportion observed in Asian populations. Discontinuation of statins or the use of only tolerable doses in patients with statin intolerance may lead to suboptimal LDL-C levels, potentially hindering the achievement of reducing the patient's ASCVD risk.

Heterozygous familial hypercholesterolemia ("**HeFH**"), a common type of familial hypercholesterolemia with an estimated prevalence of 1:250 – 1:200, is a diagnosis which refers to individuals with very significantly elevated LDL-C and an increased risk of early onset of coronary artery disease. Compared to patients with non-familial hypercholesterolemia, patients with HeFH exhibit higher baseline LDL-C levels and lower target levels recommended by guidelines. Failure to achieve target LDL-C levels with treatments such as statins will result in patients being at high cardiovascular risk. As a new lipid-lowering drug to effectively reduce the level of LDL-C, PCSK9 inhibitor has been recommended in the guidelines of management of lipid in China and overseas and is widely recognized by clinicians.

The supplemental new drug applications are mainly based on two registered clinical trials (JS002-005 and JS002-007). JS002-005 (NCT05325203) is a randomized, double-blind, placebo-controlled Phase III clinical studies completed for the adult patients of HeFH. JS002-007 (NCT05621070) is a randomized, double-blind, placebo-controlled Phase III clinical studies completed for the adult patients of primary hypercholesterolemia and mixed hyperlipidemia in which statins are not tolerated or contraindicated.

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. These many 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 described research and development project 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, 2 April 2024

As at the date of this announcement, the Board of the Company comprises Mr. Xiong Jun, Dr. Li Ning, Mr. Zhang Zhuobing, Dr. Yao Sheng, Mr. Li Cong, Dr. Zou Jianjun, Dr. Wang Gang and Dr. Li Xin as executive directors; Dr. Feng Hui and Mr. Tang Yi as non-executive directors; and Dr. Roy Steven Herbst, Mr. Qian Zhi, Mr. Zhang Chun, Dr. Feng Xiaoyuan and Dr. Meng Anming as independent non-executive directors.

* *For identification purpose only*