Junshi Biosciences Announces Ongericimab's sNDA Approval in China

SHANGHAI, China, May 27, 2025 -- Shanghai Junshi Biosciences Co., Ltd (Junshi Biosciences, HKEX: 1877; SSE: 688180), a leading innovation-driven biopharmaceutical company dedicated to the discovery, development, and commercialization of novel therapies, announced that the National Medical Products Administration (the "NMPA") has approved two supplemental new drug applications for the ongericimab injection (a recombinant humanized anti-PCSK9 monoclonal antibody injection, trade name: JUNSHIDA (君适达®)) for: 1) adult patients with heterozygous familial hypercholesterolemia ("HeFH"); 2) alone or in combination with ezetimibe, in adult patients with non-familial hypercholesterolemia and mixed dyslipidemia who are statin-intolerant or statins contraindicated. Ongericimab has become China's first domestic PCSK9-targeted drug approved for statin-intolerant patients.

According to the Chinese Guidelines for Lipid Management (2023), cardiovascular disease is the leading cause of death among both urban and rural residents in China, with atherosclerotic cardiovascular disease ("ASCVD") being the predominant subtype. The rise of low-density lipoprotein cholesterol ("LDL-C") levels is a major cause of ASCVD. Lowering LDL-C levels can significantly decrease the incidence of ASCVD and risk of death.

HeFH is a common type of familial hypercholesterolemia with an estimated prevalence of 1:250 ~ 1:200, and its main clinical features are significantly elevated LDL-C and 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 for control recommended by the guidelines. Failure to achieve target LDL-C levels after treatments such as statins will result in patients being at high cardiovascular risk.

In addition, 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, thereby failing to effectively reduce the patient's ASCVD risk.

As a new lipid-lowering drug that effectively reduces LDL-C levels, PCSK9 inhibitor has been recommended in the guidelines for the management of lipids both in China and overseas and is widely recognized by clinicians. The significant lipid-lowering effects of ongericimab have been demonstrated in multiple phase 3 clinical studies, and ongericimab was approved by the NMPA for the treatment of adult patients with primary hypercholesterolemia (non-familial) and mixed dyslipidemia in October 2024.

The approval of the two supplemental new drug applications are mainly based on two registered clinical trials—JS002-005 (NCT05325203) and JS002-007 (NCT05621070).

JS002-005 is a randomized, double-blind, placebo-controlled Phase 3 clinical study in adult patients with HeFH. JS002-005 was led by Professor Changsheng MA and Professor Jie LIN from Beijing Anzhen Hospital affiliated to Capital Medical University as the principal investigators. A total of 135 patients with HeFH were enrolled. This study is the first Phase 3 clinical study evaluating an anti-PCSK9 monoclonal antibody in Chinese patients diagnosed with HeFH (DLCN>8).

The latest data on JS002-005 has been published in full in *Atherosclerosis*. The results showed that, compared with placebo, the ongericimab subcutaneous injection (150 mg every 2 weeks (Q2W) or 450 mg every 4 weeks (Q4W)) significantly reduced LDL-C levels by 69.4% and 80.6% ($p<0.0001$), respectively, for a 24-week treatment, with steady reduction during the treatment. At the same time, ongericimab also demonstrated significant improvements in other lipid parameters. Non-high density lipoprotein cholesterol (non-HDL-C), apolipoprotein B (ApoB), total cholesterol (TC), and lipoprotein (a) ("Lp(a)") levels all markedly decreased from baseline. Notably, Lp(a) levels decreased by 50% from baseline. The overall safety profile was favorable, with the incidence of treatment-emergent adverse events (TEAEs) being comparable to that of the placebo group.

JS002-007 is a randomized, double-blind, placebo-controlled Phase 3 clinical study conducted in adult patients with primary hypercholesterolemia and mixed hyperlipidemia who are statin-intolerant. JS002-007 was led by Professor Yida TANG from Peking University Third Hospital as the principal investigator. This is the first Phase 3 clinical study of anti-PCSK9 monoclonal antibody in Chinese patients with primary hypercholesterolemia or mixed dyslipidemia who are statin-intolerant. The results will be published in an international academic journal shortly.

Dr. Jianjun ZOU, General Manager and CEO of Junshi Biosciences, said, "As of now, ongericimab has received approval for three key indications, including heterozygous familial hypercholesterolemia, non-familial hypercholesterolemia or mixed dyslipidemia who are statin-intolerant or statins contraindicated. This achievement not only represents a remarkable breakthrough in cardiovascular therapy, it also means that Chinese patients with cardiovascular disease will have more treatment options. Moving forward, our focus will continue 'In China' as we address more unique needs of local patients. Through innovative drug discovery, we aim to tackle more therapeutic areas while accelerating the development of and access to novel treatments."

About Ongericimab

Ongericimab is a recombinant humanized anti-PCSK9 monoclonal antibody injection independently developed by Junshi Biosciences. It was approved for marketing by the NMPA in October 2024. To date, ongericimab has been approved for three indications in the Chinese mainland: 1) adult patients with primary hypercholesterolemia (non-familial) and mixed dyslipidemia; 2) adult patients with HeFH; 3) alone or in combination with ezetimibe, in adult patients with non-familial hypercholesterolemia and mixed dyslipidemia who are statin-intolerant or statins contraindicated. The approved specifications are 150 mg (1 ml) in a single dose (pre-filled syringe), 150 mg (1 ml) in a single dose (pre-filled autosyringe).

In October 2023, Junshi Biosciences signed an agreement with Chongqing Bochuang Pharmaceuticals Co., Ltd. ("Bochuang Pharmaceuticals"), pursuant to which the company granted Bochuang Pharmaceuticals an exclusive license to conduct research and development on, manufacture and commercialize ongericimab for the licensed purposes and within the Chinese Mainland. Bochuang Pharmaceuticals will be responsible for the subsequent commercialization of ongericimab in the Chinese Mainland and will make corresponding milestone payments and sales commissions to Junshi Biosciences.

About Junshi Biosciences

Founded in December 2012, Junshi Biosciences (HKEX: 1877; SSE: 688180) is an innovation-driven biopharmaceutical company dedicated to the discovery, development and commercialization of innovative therapeutics. The company has established a diversified R&D pipeline comprising over 50 drug candidates, with five therapeutic focus areas covering cancer, autoimmune, metabolic, neurological, and infectious diseases. Five of the company's products have received approvals in China and international markets, one of which is toripalimab, China's first domestically produced and independently developed anti-PD-1 monoclonal antibody. Toripalimab has been approved in over 35 countries and regions including China, the US, and Europe. During the COVID-19 pandemic, Junshi Biosciences actively shouldered the social responsibilities of a Chinese pharmaceutical company through its involvement in developing etesevimab, MINDEWEI®, and other novel therapies for the prevention and treatment of COVID-19.

With a mission of "providing patients with world-class, trustworthy, affordable, and innovative drugs", Junshi Biosciences is "In China, For Global". At present, the company boasts approximately 2,500 employees in the United States (Maryland) and China (Shanghai, Suzhou, Beijing, Guangzhou, etc.). For more information, please visit: http://www.junshipharma.com.

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