Junshi Biosciences Announces Ongericimab's NDA Approval in China

SHANGHAI, China, October 11, 2024 -- 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 ("NMPA") has approved the new drug application ("NDA") for ongericimab injection, a recombinant human anti-PCSK9 monoclonal antibody injection (trade name: Junshida (君适达)®) for the treatment of primary hypercholesterolemia and mixed dyslipidemia (in combination with statins)[1], making it the company's fifth commercial product.

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") levels is a dangerous factor in causing ASCVD. Reducing LDL-C levels can significantly lower the incidence of ASCVD and the risk of death. Although the current statin-based lipid-lowering treatment can dramatically lower LDL-C levels and ASCVD risk, the LDL-C lipid-lowering compliance rate remains worrying among people at high risk of ASCVD. In particular, the LDL-C compliance rate is significantly lower for patients at ultra-high/extremely high risk of ASCVD. As a result, there remains a relatively large unmet medical need for lipid-lowering treatments.

The approval is mainly based on two multicenter, randomized, double-blind, placebo-controlled Phase 3 clinical studies (JS002-003 (NCT04781114) and JS002-006 (NCT05532800)). The JS002-003 study, led by Academician Yaling HAN from the General Hospital of the Northern Theater Command of the People's Liberation Army of China, aimed to assess the efficacy and safety of subcutaneous ongericimab injections for treating primary hypercholesterolemia and mixed dyslipidemia in China, enrolling a total of 806 patients. The study results were first announced at the American Heart Association (AHA) Scientific Sessions 2023 and fully published in the *Journal of the American Heart Association* (*JAHA*) in May 2024. The JS002-003 study results demonstrated that compared to placebo, ongericimab administered as a subcutaneous injection at a dose of 150 mg once every 2 weeks (Q2W) or 300 mg once every 4 weeks (Q4W) could significantly reduce LDL-C levels by more than 60% and invariably maintain stable decreases during the 52 weeks of treatment; it also significantly improved other blood lipid parameters, including non-high-density lipoprotein cholesterol (non-HDL-C), apolipoprotein B (ApoB) and total cholesterol (TC). Ongericimab demonstrated a favorable safety profile with no new safety signals identified.

The JS002-006 study, led by Professor Shuiping ZHAO from the Second Xiangya Hospital of Central South University, aimed to assess the effectiveness and safety of subcutaneous ongericimab injections using two drug delivery devices—a pre-filled syringe ("PFS") and an autoinjector ("AI")—for the treatment of primary hypercholesterolemia and mixed hyperlipidemia, enrolling a total of 255 patients. The study results, fully published in the *Nutrition Metabolism And Cardiovascular Diseases* (*NMCD*) in May 2024, showed that the administration of ongericimab using PFS and AI demonstrated significant lipid-lowering effects. Compared to placebo, patients receiving the ongericimab treatment at a dose of 150mg Q2W

[1] Indication: based on dietary control, in combination with statins or statins and ezetimibe for the treatment of adult patients with primary hypercholesterolemia (non-familial) and mixed dyslipidemia, who fail to achieve low-density lipoprotein cholesterol (LDL-C) goals after receiving moderate or higher doses of statins treatment

for 12 weeks saw a significant reduction in LDL-C levels of over 70% (72.7% in the PFS group and 71.1% in the AI group), with a favorable safety profile.

So far, 2 supplemental NDAs for ongericimab are under review by the NMPA: 1) heterozygous familial hypercholesterolemia; 2) primary hypercholesterolemia and mixed dyslipidemia in which statins are not tolerated or contraindicated (as a single agent).

Professor Shuiping ZHAO from the Second Xiangya Hospital of Central South University, said, "Ongericimab's official approval is exciting news, it offers a new treatment option to patients with primary hypercholesterolemia and mixed dyslipidemia in which statins are not tolerated or contraindicated. For patient conveninence, in addition to the PFS option, an AI method has also been developed, which eliminates the need for healthcare providers to administer the injections, allowing for at-home self-administration. Results show that ongericimab is highly effective in lipid-lowering, whether administered via PFS or AI, and we hope it will reach patients soon and improve the lives of many."

Junshi Bioscience's General Manager and CEO, Dr. Jianjun ZOU, said, "Ongericimab is Junshi Biosciences' 5th commercial product, successfully expanding our therapeutic areas from oncology, autoimmune and infectious diseases into chronic metabolic diseases. This approval not only enriches the company's product portfolio, but also serves as a strong endorsement of our full-chain new productive force. As the leading cause of death, ASCVD poses as serious threat to public health, and the approval of ongericimab will provide a powerful tool for patients in the fight against this disease. Meanwhile, two more indications for ongericimab are currently under active review, and we look forward to offering more treatment options to a broader range of ASCVD patients in the future."

About Ongericimab

Ongericimab is a recombinant humanized anti-PCSK9 monoclonal antibody independently developed by Junshi Biosciences. It was approved for marketing in China in October 2024. The approved specification is 150 mg (1 ml) in a single dose (pre-filled syringe) and 150 mg (1 ml) in a single dose (autoinjector). Junshi Biosciences is the first domestic company in China to obtain clinical trial approval for a drug targeting PCSK9.

In October 2023, Junshi Biosciences signed a licensing agreement with Chongqing Bochuang Pharmaceuticals Co., Ltd. ("Bochuang Pharmaceuticals"), pursuant to which the company granted Bochuang Pharmaceuticals the exclusive license to conduct research and development on, manufacture and commercialize the ongericimab within Chinese Mainland and in the license purposes.

In April 2024, the two supplemental NDAs for ongericimab was accepted by the NMPA, for the treatment of (1) heterozygous familial hypercholesterolemia; and (2) primary hypercholesterolemia and mixed dyslipidemia in which statins are not tolerated or contraindicated (as a signle agent).

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. Four of the company's innovations have already reached the Chinese or international markets, one of which is toripalimab, China's first domestically produced and independently developed anti-PD-1 monoclonal antibody, approved in China, the US and European Union. Additionally, more than 30 drugs are currently in clinical development. 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 (San Francisco and Maryland) and China (Shanghai, Suzhou, Beijing, Guangzhou, etc.). For more information, please visit: http://junshipharma.com.

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