Junshi Biosciences Announces Acceptance of the sNDA for Ongericimab

SHANGHAI, China, April 2, 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 accepted two supplemental new drug applications ("sNDA") for the company's recombinant humanized anti-PCSK9 monoclonal antibody, ongericimab injection (product code: JS002). The accepted indications are 1) heterozygous familial hypercholesterolemia and 2) primary hypercholesterolemia and mixed dyslipidemia where statins are not tolerated or contraindicated. The specifications are 150 mg (1 ml) in a single dose (pre-filled syringe) and 150 mg (1 ml) in a single dose (pre-filled auto syringe), respectively.

According to the Chinese Guidelines for Lipid Management (2023), cardiovascular disease, particularly atherosclerotic cardiovascular disease ("ASCVD"), is the leading cause of death among urban and rural residents in China. 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. Despite statins currently being the cornerstone of lipid-lowering treatment, approximately 9.1% of patients clinically exhibit statin intolerance, with a disproportionately higher prevalence 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 ASCVD risk reduction in affected patients.

Heterozygous familial hypercholesterolemia ("HeFH"), a common type of familial hypercholesterolemia with an estimated prevalence of 1:250 – 1:200, is a diagnosis that refers to individuals with significantly elevated LDL-C levels and an increased risk of early-onset 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 LDL-C levels, the PCSK9 inhibitor has been recommended in the guidelines for the management of lipids in China and overseas and is widely recognized by clinicians.

The sNDAs 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 study in adult patients with HeFH. JS002-007 (NCT05621070) is a randomized, double-blind, placebo-controlled Phase III clinical study in adult patients with primary hypercholesterolemia and mixed hyperlipidemia who are unable to tolerate or contraindicated for statin therapy.

About Ongericimab

Ongericimab is a recombinant humanized anti-PCSK9 monoclonal antibody independently developed by Junshi Biosciences. Junshi Biosciences is the first domestic company in China to obtain clinical trial approval for a drug targeting PCSK9. Junshi Biosciences has 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) has finished its primary analysis.

In April 2023, the new drug application for ongericimab was accepted by the NMPA 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 older.

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 and the US. 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 3,000 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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