Junshi Biosciences Announces Ongericimab (anti-PCSK9 mAb) Met Primary Endpoints in Two Phase 3 Clinical Studies

SHANGHAI, China, February 27, 2023 (GLOBE NEWSWIRE) -- 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, today announced the successful completion of two randomized, double-blind, placebo-controlled, multi-center phase III clinical studies (Study nos.: JS002-003 and JS002-006) evaluating the company's product ongericimab (a recombinant humanized anti-PCSK9 monoclonal antibody, product code: JS002) for the treatment of primary hypercholesterolemia and mixed hyperlipedemia, and both studies have met their primary endpoints.

According to the *Report on Cardiovascular Health and Diseases in China (2021)*, in recent years, both the blood lipid levels and the prevalence of dyslipidemia of the Chinese population have been on the rise, and dyslipidemia affects up to 40.4% of adults. Dyslipidemia, specifically the increase of low-density lipoprotein cholesterol ("LDL-C"), is the most important independent risk factor for atherosclerotic cardiovascular diseases ("ASCVDs"). The growing prevalence of dyslipidemia underscores the urgent need for effective treatments to lower LDL-C levels, which can significantly lower the incidence of ASCVDs and the risk of death.

At present, the awareness, treatment, and control rates of dyslipidemia in adults in China are all relatively low. The current lipid-lowering treatment and compliance rates among individuals at high or extremely high risk of ASCVDs are concerning, and there remains a relatively significant unmet clinical demand for lipid-lowering treatments. As a new lipid-lowering drug that effectively reduces LDL-C levels, PCSK9 inhibitors have been recommended in both Chinese and overseas dyslipidemia management guidelines, and are widely recognized by clinicians. Unfortunately, there are only two imported ant-PCSK9 monoclonal antibodies currently approved for marketing in China, and no domestic anti-PCSK9 monoclonal antibody has been approved for marketing.

Ongericimab is a recombinant humanized anti-PCSK9 monoclonal antibody independently developed by Junshi Biosciences. Two major pivotal registered clinical studies (Study nos.: JS002-003 and JS002-006) of ongericimab have been successfully completed and met their primary endpoints. The JS002-003 study assessed the effectiveness and safety of subcutaneous injection of ongericimab for the treatment of patients with primary hypercholesterolemia and mixed dyslipidemia, while the JS002-006 study assessed the effectiveness and safety of subcutaneous injection using two drug delivery systems (pre-filled syringes and pre-filled automatic syringes) of ongericimab for the same indications. Ongericimab exhibited significant lipid-lowering efficacy in both studies with good safety.

"The emergence of PCSK9 inhibitors has provided better treatment options for dyslipidemia patients, particularly those at high or extremely risk of ASCVD," said Academician Yaling HAN from the General Hospital of Northern Theatre Command. "The positive results of ongericimab's phase III clinical trials are very encouraging and show comparable efficacy and safety to similar PCSK9 inhibitors from overseas. We look forward to the launch of ongericimab to address unmet medical needs, and we hope the incidence and mortality of cardiovascular disease could decrease in China."

"I'm pleased to see a Chinese-developed anti-PCSK9 monoclonal antibody delivering such outstanding lipid-lowering outcomes," said Professor Shuiping ZHAO from the Second Xiangya Hospital of Central South University. "This will equip our clinicians with more lipid-lowering treatment options and benefit countless patients in China. The management of the Chinese population's blood lipid levels requires continuous improvement, and we expect ongericimab to contribute greatly to this process."

"I'm excited to witness the simultaneous success of two phase III studies examining ongericimab," said Dr. Jianjun ZOU, the President of Global Research and Development at Junshi Biosciences. "These achievements were only possible through the joint efforts and dedication of researchers, patients, and R&D teams. With China entering an aging society, we hope that ongericimab can provide additional treatment options for hyperlipidemia patients and address unmet medical needs."

About Ongericimab (JS002)

Ongericimab is a recombinant humanized anti-PCSK9 monoclonal antibody independently developed by Junshi Biosciences for the treatment of primary hypercholesterolemia and mixed hyperlipedemia. Junshi Biosciences is the first company in China to obtain clinical trial approval for the target drug. The company has completed Phase III clinical studies in patients with primary hypercholesterolemia and mixed hyperlipedemia, and Phase II clinical studies in patients with homozygous familial hypercholesterolemia. The enrollment of patients for Phase III clinical studies of heterozygous familial hypercholesterolemia has been completed.

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. Junshi Biosciences was the first Chinese pharmaceutical company that obtained marketing approval for anti-PD-1 monoclonal antibody in China. Its first-in-human anti-BTLA monoclonal antibody for the treatment of various cancers was the first in the world to be approved for clinical trials by the FDA and NMPA and has since entered Phase Ib/II trials in both China and the US. Its anti-PCSK9 monoclonal antibody was the first in China to be approved for clinical trials by the NMPA.

In the face of the pandemic, Junshi Biosciences' response was strong and immediate, joining forces with Chinese and international scientific research institutions and enterprises to develop an arsenal of drug candidates to combat COVID-19, taking the initiative to shoulder the social responsibility of Chinese pharmaceutical companies by prioritizing and accelerating COVID-19 R&D. In 2021, JS016 (etesevimab), China's first neutralizing fully human monoclonal antibody against SARS-CoV-2 administered with bamlanivimab, was granted Emergency Use Authorizations (EUA) in over 15 countries and regions worldwide. Meanwhile, VV116 (deuremidevir hydrobromide), a novel oral nucleoside analog anti-SARS-CoV-2 drug designed to hinder virus replication, has been approved for marketing in China and Uzbekistan. The JS016 and VV116 programs are a part of the company's continuous efforts towards innovation for disease control and prevention of the global pandemic.

Junshi Biosciences has more than 3,100 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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