Junshi Biosciences Announces Acceptance of the New Drug Application for JS002 (anti-PCSK9 mAb)

SHANGHAI, China, April 25, 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 acceptance of the new drug application for the company's recombinant humanized anti-PCSK9 monoclonal antibody (product code: JS002) by the National Medical Products Administration ("NMPA").

According to the *Chinese Guidelines for Lipid Management (2023)*, in recent years, the Chinese population has seen a notable increase in both the blood lipid levels and the prevalence of dyslipidemia, with up to 35.6% of adults currently experiencing dyslipidemia in China. Dyslipidemia, especially the rise of low-density lipoprotein cholesterol ("LDL-C") level, is a major risk factor for atherosclerotic cardiovascular diseases ("ASCVD"). Reducing the level of LDL-C can significantly lower the incidence of ASCVD and the risk of death. Although an existing statinbased lipid lowering treatment can significantly reduce the LDL-C level and the ASCVD risk, the LDL-C compliance rate is concerningly low for patients at high/extremely high risk of ASCVD. This indicates a relatively large unmet medical need for lipid-lowering treatments.

Homozygous familial hypercholesterolemia ("HoFH") is familial hypercholesterolemia caused by genetic factors (mainly mutations in the LDLR gene) and a rare and life-threatening disease. A HoFH patient is exposed to extremely high LDL-C levels (usually >13 mmol/L) from birth, and most develop extensive atherosclerosis during adolescence. Most patients die before the age of 30 without active treatment. Due to the markedly elevated LDL-C levels of HoFH patients, none of the existing intensive lipid-lowering treatments based on statins (including the combination of lipid-lowering drugs) can reach the targets recommended by the guidelines, nor can they meet the demand for effective lipid-lowering treatment in HoFH patients. Consequently, HoFH patients remain at very high risk for cardiovascular complications.

As a new lipid-lowering drug that effectively reduces LDL-C levels, PCSK9 inhibitors have been recommended in the lipid management guidelines in China and overseas, and is widely recognized by clinicians around the world.

The new drug application is mainly based on three registered clinical trials (JS002-003, JS002-004 and JS002-006). JD002-003 and JS002-006 are two randomized, double-blind, placebo-controlled Phase III clinical studies conducted on patients with primary hypercholesterolemia (including both familial and non-familial heterozygous) and mixed hyperlipidemia. JS002-004 is an open-label, single-arm Phase II study conducted on HoFH patients.

"JS002 marks the first product from Junshi Biosciences' chronic metabolic pipeline to enter the commercial application stage," said Dr. Jianjun ZOU, Global Research and Development President of Junshi Biosciences. "Our new drug applications for two indications have been accepted for review, and these indications comprehensively address the clinical needs of patients with primary hypercholesterolemia and mixed hyperlipidemia, as well as HoFH, a clinically rare disease that is often overlooked. They fully embody our patient-centered approach towards clinical efforts. We look forward to JS002's marketing approvals, which will bring new treatment options to countless patients."

About JS002

JS002 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 an anti-PCSK9 monoclonal antibody. Junshi Biosciences 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 about 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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