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Junshi Biosciences Announces FDA Approval of Investigational New Drug Application for Anti-CD112R Monoclonal Antibody for Treatment of Advanced Solid Tumors

SHANGHAI, China, April 03, 2022 (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 that the U.S. Food and Drug Administration (FDA) has approved its Investigational New Drug (IND) application for its anti-CD112R monoclonal antibody (TAB009/JS009) for the treatment of advanced solid tumors.

TAB009/JS009 is a recombinant humanized IgG4 monoclonal antibody against human CD112R developed independently by Junshi Biosciences, for the treatment of advanced malignant tumors. CD112R, also known as PVRIG (Poliovirus receptor-related immunoglobulin domain-containing protein), is a new immune checkpoint pathway discovered by the company. Dr. Sheng Yao, Senior Vice President of the company, is one of the discoverers of this novel pathway.

CD112R is a single-pass transmembrane protein of the PVR family, mainly expressed on T cells and NK cells, and is significantly upregulated upon activation. CD112R and TIGIT share a common ligand, CD112, which is expressed on the surface of antigen-presenting cells and certain tumor cells. CD112R can inhibit the anti-tumor effect of T cells and NK cells after ligand engagement. TAB009/JS009 binds specifically to CD112R with high affinity and effectively blocks the interaction between CD112R and its ligand CD112, thereby facilitating the activation and proliferation of T cells and NK cells and enhancing the immune system's ability to kill tumor cells. To date, no product targeting CD112R has been approved for marketing globally.

TIGIT is another immunosuppressive target of the PVR family. Its ligands include PVR and CD112, and its binding site for CD112 is different from that of CD112R. TAB009/JS009 can work synergistically with TIGIT blocking antibodies to promote T cell activation. Pre-clinical in vivo pharmacodynamics has shown that TAB009/JS009 in combination with the anti-TIGIT monoclonal antibody (TAB006/JS006) developed independently by the company exhibits significant synergistic anti-tumor effects. The investigational new drug application for TAB006/JS006 has already been approved by both China's National Medical Products Administration (NMPA) and the U.S. FDA.

In addition, TAB009/JS009 in combination with TAB006/JS006 as well as the company's commercialized product toripalimab, the anti-PD-1 monoclonal antibody, can further increase T-cell activation and improve the efficacy of clinical treatment. Junshi Biosciences plans to actively explore drug combinations to maximize the synergistic anti-tumor potential of its self-developed products.

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 tumors 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. Among the many drug candidates is JS016 (etesevimab), China's first neutralizing fully human monoclonal antibody against SARS-CoV-2 and the result of the combined efforts of Junshi Biosciences, the Institute of Microbiology of the Chinese Academy of Science and Lilly. JS016

administered with bamlanivimab has been granted Emergency Use Authorizations ("EUA") in over 15 countries and regions worldwide. Meanwhile, VV116, a new oral nucleoside analog anti-SARS-CoV-2 drug designed to hinder virus replication, is in global Phase III clinical trials. The JS016 and VV116 programs are a part of the company's continuous innovation for disease control and prevention of the global pandemic.

Junshi Biosciences has more than 2,800 employees in the United States (San Francisco and Maryland) and China (Shanghai, Suzhou, Beijing and Guangzhou). For more information, please visit: http://junshipharma.com.

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