Junshi Biosciences Announces Approval for Marketing of VV116 in China

SHANGHAI, China, January 30, 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, announced today that the National Medical Products Administration (the "NMPA") has conducted urgent review and approval under Special Examination and Approval of Drugs, and conditionally approved for marketing Deuremidevir Hydrobromide Tablets (project code: JT001/VV116, "VV116"), an oral nucleoside analog anti-SARS-CoV-2 drug, for the treatment of adult patients with mild to moderate coronavirus disease 2019 ("COVID-19").

VV116 is a new oral nucleoside analog antiviral drug, which can be non-covalently bound to the active center of RNA-dependent RNA polymerase ("RdRp") of SARS-CoV-2 in the form of nucleoside triphosphate, directly inhibiting the activity of RdRp of the virus and blocking the replication of virus, thus realizing the antiviral effect. Preclinical studies have shown that VV116 exhibited significant antiviral effects against both the original COVID-19 strain and mutant strains, including Omicron, and exhibited no genetic toxicity.

VV116 was jointly developed by the Shanghai Institute of Materia Medica at the Chinese Academy of Sciences, Wuhan Institute of Virology at the Chinese Academy of Sciences, Xinjiang Technical Institute of Physics and Chemistry at the Chinese Academy of Sciences, Central Asian Center of Drug Discovery and Development of Chinese Academy of Sciences) / China-Uzbekistan Medicine Technical Park ("the Belt and Road" Joint Laboratory of the Ministry of Science and Technology), Lingang Laboratory, Vigonvita Life Sciences Co., Ltd. ("Vigonvita") and Junshi Biosciences

This approval is mainly based on a multi-center, double-blind, randomized, placebo-controlled phase III clinical study (NCT05582629) evaluating the efficacy and safety of VV116 among mild to moderate COVID-19 patients with or without high risk of progression to severe COVID-19. The study was led by academician Lanjuan LI, Director of the State Key Laboratory for Diagnosis & Treatment of Infectious Diseases (Zhejiang University) as primary investigator. The primary endpoint of the study was the time to sustained clinical symptoms resolution, while the secondary endpoints included the time to sustained clinical symptoms alleviation, percentage of participants with disease progression to severe or critical COVID-19 or death by any cause by day 28, changes in SARS-CoV-2 nucleic acid and viral load, safety, and etc.

The study results showed that as of the data cut-off date of the interim analysis, among 1,277 randomized and treated subjects, the primary endpoint, or the time from first administration to sustained clinical symptoms resolution (The score of 11 COVID-19 related clinical symptom =0 and lasted for 2 days) of the VV116 group was significantly shortened when compared with that of the placebo

group, and the median time difference was 2 days; similarly, the time to sustained clinical symptoms alleviation was also significantly shortened, and the change of viral load from baseline and other virological indicators were better than those of the placebo group.

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About Deuremidevir Hydrobromide Tablets (VV116/JT001)

VV116 is an oral nucleoside analog drug that can inhibit the replication of SARS-CoV-2. During preclinical pharmacodynamic studies, VV116 exerted an antiviral effect on the original strain of the novel corinavirus and its known variants in vitro; in the mice model, a low dose of VV116 reduced the virus titers below the detection limit, significantly lowered the chances of lung injury and displayed a strong antiviral effect. Preclinical pharmacokinetics and other research results also show that VV116 has high oral bioavailability. Following oral administration and absorption, VV116 is rapidly metabolized into parent nucleoside and widely distributed throughout the body.

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Junshi Biosciences and Vigonvita have completed three Phase I studies with healthy Chinese subjects, and one Phase III study in the patients with mild-to moderate COVID-19 at high risk to progression to severe COVID-19 in China (NCT05341609). Research results have been published in Acta Pharmacologica Sinica, and NEJM respectively. Aside from that, one Phase III study in the patients with or without high risk of progression to severe COVID-19 has completed its pre-specified interim analysis, and met the pre-defined primary efficacy endpoint.

In December 2021, VV116 was approved in Uzbekistan for the treatment of patients diagnosed with moderate to severe COVID-19. In January 2023, VV116 was approved for marketing in China for the treatment of adult patients with mild to moderate COVID-19.

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. 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. As of December 3 2021, over 700,000 patients have been treated with bamlanivimab or bamlanivimab and etesevimab, potentially preventing more than 35,000 hospitalizations and at least 14,000 deaths. Meanwhile, VV116, a new 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 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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