Junshi Biosciences Announces *Lancet Infectious Diseases* Publication of Results from the 2nd Phase 3 Study of VV116 for Treating COVID-19

SHANGHAI, China, November. 23, 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 a new publication in *the Lancet Infectious Diseases*. The paper presents final analysis results from a multicenter, double-blind, phase 3, randomized controlled study (NCT05582629) evaluating the efficacy and safety of VV116 (mindeudesivir hydrobromide tablets, product code: VV116/JT001) in patients with mild-to-moderate COVID-19. This study demonstrated that VV116 significantly reduced the time to sustained clinical symptom resolution compared to placebo, with no observed safety concerns.

During the study, academician Lanjuan LI, Director of the State Key Laboratory for Diagnosis & Treatment of Infectious Diseases (Zhejiang University), served as the primary investigator and corresponding author. Co-first authors include Prof. Xiaohong FAN and Prof. Yun Ling from Shanghai Public Health Clinical Center, Prof. Xiahong DAI, Prof. Lihua WU and Prof. Lingling TANG from Shulan (Hangzhou) Hospital Affiliated to Zhejiang Shuren University Shulan International Medical College.

Efficacy analyses were conducted on 1296 enrolled adult patients (646 in the VV116 group and 650 in the placebo group), with a median age of 35.0 years, of whom about 43.1% carried high-risk factors for progression to severe COVID-19. According to the SARS-CoV-2 genetic variation evaluated at enrollment, BA.5.2.48 and BF.7.14 were the leading subvariants.

At the interim analysis, VV116 was superior to placebo in reducing the time to sustained clinical symptom resolution among 1229 patients (hazard ratio [HR] 1.21, 95% CI 1.04–1.40; p=0.0023). In the final analysis of the study, a substantial reduction in the time to sustained clinical symptom resolution was observed with VV116 compared to placebo (median: 10.9 vs.12.9 days; HR=1.17; 95% CI: 1.04 - 1.33; p=0.0009), consistent with the interim analysis. For the elderly patient subgroup (≥60 years old), the time to sustained clinical symptom resolution was also shorter in the VV116 group compared to the placebo group, with an HR of 1.22 (95% CI: 0.74-2.01), which is consistent with the overall population.

Previously, an active comparator-controlled phase 3 study of VV116 (NCT05341609) published in *the New England Journal of Medicine* showed that VV116 was non-inferior to nirmatrelvir/ritonavir in reducing the time to sustained clinical symptom resolution among patients with mild-to-moderate COVID-19 at risk for progression (median time: 7 vs. 7 days; HR=1.06; 95% CI: 0.91, 1.22).

By day 5 of the study treatment, compared to the placebo group, a substantial increase in the SARS-CoV-2 Ct value, as well as a more rapid decrease in the viral load, were observed in the VV116 group.

Notably, the efficacy of a 5-day treatment with VV116, including the significant shortening of time to sustained clinical symptom resolution and clinical symptom alleviation in patients, were observed regardless of the presence of high-risk factors for progression to severe COVID-19 or SARS-CoV-2 vaccination status.

VV116 was well-tolerated in patients with mild-to-moderate COVID-19. Among 1347 patients in the safety data set (674 patients in the VV116 group and 673 patients in the placebo group), the incidence of treatment-emergent adverse events (TEAEs) of any grade was similar between groups (35.9% vs. 42.1%). The incidence of treatment-releated adverse events (TRAEs) assessed by the investigator was 17.4% in the VV116 group and 23.2% in the placebo group. Most of the TEAEs were grade 1 or 2. Only 1 patientin the placebo group, progressed to severe COVID-19, and no deaths occurred.

"As of today, more than 3000 patients worldwide are actively participating in our clinical trials for VV116, including several domestic and international phase 3 trials," said Dr. Jianjun ZOU, Global Research and Development President at Junshi Biosciences, "This extensive participation provides robust data, establishing VV116 as the most evidence-based, domestically-made oral anti-viral medication for COVID-19. Within a single year, VV116 was featured twice in leading international medical journals, which reflected the global recognition of the VV116 R&D team's research capabilities and R&D quality. We take great pride in these achievements. The rise of innovative domestic COVID-19 treatments stands as a testament to the Chinese pharmaceutical industry's advancement towards innovation and serves as a commitment to ensuring health and safety for all. Along with our fellow collaborators, Junshi Biosciences will continue onward, propelling further development and benefiting more patients!"

About Mindeudesivir Hydrobromide Tablets (VV116/JT001)

VV116 is an oral nucleoside analog drug that can inhibit the replication of SARS-CoV-2. In preclinical pharmacodynamic studies, VV116 exerted an antiviral effect on the original strain of the novel coronavirus 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 risk of lung injury and displayed a strong antiviral effect. Preclinical pharmacokinetics and other research results also show that VV116 has high oral bioavailability. After oral administration, VV116 is rapidly metabolized into parent nucleoside and widely distributed throughout the body.

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

During the pandemic, several multi-center trials were conducted for VV116 in China and abroad. One phase 3 study in patients with mild to moderate COVID-19 at high risk of progression to severe COVID-19 (NCT05341609) published results in the *New England Journal of Medicine*, and another phase 3 study (NCT05582629) conducted among mild to moderate COVID-19 patients with or without high risk of progression to severe COVID-19 published results in the *Lancet Infectious Diseases*.

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. Four of the company's innovations have already reached the Chinese or international markets, one of which is toripalimab, first China's homegrown and self-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 (JS016), MINDEWEI® (VV116/JT001), 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 (California and Maryland) and China (Shanghai, Suzhou, Beijing, Guangzhou, etc). For more information, please visit: http://junshipharma.com.

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