Two Chinese anti-SARS-CoV-2 drugs conditionally approved for marketing

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Two Chinese oral anti-SARS-CoV-2 drugs, Xiannuoxin (simnotrelvir/ritonavir) and VV116 (deuremidevir hydrobromide), were conditionally approved for marketing by China's National Medical

Products Administration (NMPA) in late January after urgent review and approval under the Special Examination and Approval of Drugs Policy.

Both drugs are intended for the treatment of adult patients infected with mild to moderate Covid-19 and should be used strictly under doctors' instructions.

Xiannuoxin is the first 3CL- (3-chymotrypsin-like protease, 3CLpro)-targeted, innovative anti-SARS-CoV-2 drug with intellectual property rights in China. It was jointly developed by the Shanghai Institute of Materia Medica (SIMM) of the Chinese Academy of Sciences (CAS), the Wuhan Institute of Virology (WIV) of CAS, and Simcere Pharmaceutical Group Limited.

Oral small molecule Xiannuoxin targets 3CL protease, which is essential for SARS-CoV-2 virus replication. The combination of low-dose ritonavir with simnotrelvir helps to slow the breakdown of Xiannuoxin in the body in order to improve the antiviral effect. Preclinical animal research indicated that Xiannuoxin showed potent, broad-spectrum anti-SARS-CoV-2 activity with no genotoxicity observed.

Multi-centered, randomized, double-blind, placebo-controlled phase II/III clinical studies in China to evaluate the efficacy and safety of Xiannuoxin met the pre-specified primary efficacy endpoint. The study comprised 1,208 adult patients with symptomatic mild to moderate Covid-19.

Results of the study demonstrated that Xiannuoxin is safe and effective for adult patients infected with mild to moderate Covid-19 and is of extensive clinical value.

VV116 is a new oral nucleoside analog antiviral drug with intellectual

property rights in China. It was jointly developed by SIMM, WIV, the Xinjiang Technical Institute of Physics and Chemistry of CAS, the Central Asian Center of Drug Discovery and Development of CAS and China-Uzbekistan Medicine Technical Park (the "Belt and Road" Joint Laboratory of the Ministry of Science and Technology of China), Lingang Laboratory, Vigonvita Life Sciences Co., Ltd. (Vigonvita) and Shanghai Junshi Biosciences Co. Ltd.

VV116 non-covalently binds 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 viral replication, thus realizing an antiviral effect.

Preclinical studies have demonstrated that VV116 exhibits significant antiviral effects against both the original Covid-19 strain and mutant strains, including Omicron, showing no genetic toxicity.

Multi-center, double-blind, randomized, placebo-controlled phase III clinical studies in China to evaluate the efficacy and safety of VV116 met the pre-defined primary efficacy endpoint. The study was led by Li Lanjuan, academician of the Chinese Academy of Engineering and director of the State Key Laboratory for Diagnosis & Treatment of Infectious Diseases at Zhejiang University.

Results showed that among the 1,277 study participants, the time from first administration to sustained resolution of clinical symptoms for the VV116 group was significantly shorter in comparison with the placebo group, and the change in viral load from baseline as well as other virological indicators for the VV116 group were better than for the placebo group.

The marketing of Xiannuoxin and VV116 is expected to provide patients in China more effective Covid-19 treatment options.

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