BioSpectrum
the business of Bio & Health Sciences
ASIA EDITION

Japan approves Remdesivir to treat critically ill COVID-19 patients

13 May 2020 | News

Exceptional Approval is Based on Data from Global Clinical Trials and Gilead's Compassionate Use Program

Gilead Sciences, Inc. has announced that the Japanese Ministry of Health, Labour and Welfare (MHLW) has granted regulatory approval of Veklury® (remdesivir) as a treatment for SARS-CoV-2 infection, the virus that causes COVID-19, under an exceptional approval pathway. The exceptional approval was granted due to the COVID-19 pandemic and references the Emergency Use Authorization of remdesivir in the United States.

The approval is based on clinical data from the U.S. National Institute of Allergy and Infectious Diseases' global Phase 3 trial, Gilead's Phase 3 SIMPLE trial in patients with severe manifestations of COVID-19, and available data from Gilead's compassionate use program, including patients in Japan.

"The Japanese approval of remdesivir is in recognition of the urgent need to treat critically ill patients in Japan. It is a reflection of the exceptional circumstances of this pandemic," said Merdad Parsey, MD, PhD, Chief Medical Officer, Gilead Sciences. "We thank the Japanese Ministry of Health, Labour and Welfare for their leadership and collaboration, as we together work to respond to this public health emergency."

Due to the current public health emergency, the U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization for remdesivir for the treatment of COVID-19. In the United States, remdesivir is an investigational drug that has not been approved by the FDA for any use, and the safety and efficacy of remdesivir for the treatment of COVID-19 has not been established. The distribution of remdesivir in the United States has been authorized only for the treatment of hospitalized patients with severe COVID-19; please see below for additional important information about the authorized use of remdesivir in the United States.

Remdesivir is not yet licensed or approved outside of Japan and ongoing clinical trials continue to evaluate its safety and efficacy. Gilead continues to work with global regulatory authorities to ensure appropriate access to remdesivir.