

「FDA approves first COVID-19 drug, remdesivir」

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On Oct. 22, the U.S. Food and Drug Administration (FDA) approved the Gilead's antiviral drug Veklury (remdesivir) for use in adult and pediatric patients 12 years of age and older and weighing at least 40 kilograms (about 88 pounds) for the treatment of COVID-19 requiring hospitalization. Veklury should only be administered in a hospital or in a healthcare setting capable of providing acute care comparable to inpatient hospital care. The drug is the first approved treatment for COVID-19 and was also the drug that U.S. President Donald Trump received when he contracted the virus earlier this month. [1]

Remdesivir, which was originally developed as a treatment for Ebola and hepatitis C, interferes with the reproduction of viruses by jamming itself into new viral genes. Remdesivir had been authorized for use on an emergency basis since the spring. However, it now becomes the first drug to win full FDA approval for treating COVID-19. The approval of remdesivir was supported by the agency's analysis of data from three randomized, controlled clinical trials that included patients hospitalized with mild-to-severe COVID-19. According to the trial data, remdesivir reduced patients' symptoms more quickly than standard care alone and significantly shortened patients' hospital stays, according to the statement. In one trial that included more than 1,000 patients, those who received the drug spent about five fewer days in the hospital than those who didn't. [2, 3]

However, despite being the first FDA-approved COVID-19 drug in the U.S., remdesivir isn't a highly effective treatment. A recent trial conducted by the World Health Organization (WHO) contradicts these positive findings. The trial, which included more than 11,200 people from 30 countries, found that remdesivir did not significantly reduce patients' time in the hospital, nor did it reduce the risk of being placed on a ventilator. And most importantly, the drug did not increase patients' chance of survival. [3] But the WHO trial has not yet been peer-reviewed, and it has drawn some critique from researchers such as the study did not include a placebo group and the trial took place at 405 different hospitals around the world where patients' care may have differed greatly. [4]

Its price has been controversial as well. Gilead charges \$2,340 for a typical treatment course for people covered by government health programs in the United States and other developed countries, and \$3,120 for patients with private insurance. This seems to be an unaffordable price for many families.

On Oct. 25, the U.S. recorded its highest seven-day average of new COVID-19 cases since the start of the pandemic. The seven-day average number of new daily cases reached 68,767, breaking the previous record of 67,293 reported on July 22, according to CNN. On both Oct. 23 and Oct. 24, the U.S. recorded more than 83,000 new cases of COVID-19, the highest daily counts yet, shattering the records set in July.

Hospitalizations are up 40 percent and deaths are creeping up in several states. France and several European countries have also come to a national lockdown again.[5] Apparently, Covid-19 is still raging in this world and we still have a long-term battle to fight against this virus.

Reference:

1. 22 Oct, 2020. "FDA Approves First Treatment for COVID-19" FDA news press.
2. Nicoletta Lanese, 23 Oct, 2020. "FDA approves first COVID-19 drug. But it's 'not a blockbuster.'" Live Science news.
3. Michael Levenson, 23 Oct, 2020. "F.D.A. Approves First Drug for Treating Coronavirus Patients" The New York Times news.
4. Nicoletta Lanese, 16 Oct, 2020. "Remdesivir has 'no meaningful impact' on COVID-19 survival, huge study finds" Live Science news.
5. Yasemin Saplakoglu, 26 Oct, 2020. "US hits highest average number of new COVID-19 cases since start of the pandemic" Live Science news.

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