FDA Approves Remdesivir for Babies and Young Children to Treat COVID-19

written by GEG | April 29, 2022

The US Food and Drug Administration announced that full approval will be granted to Remdesivir, a COVID-19 drug to treat babies and children aged 28 days and older. Reports show that Remdesivir causes severe side effects that includean dysfunction, septic shock and kidney and liver damage. While other COVID-19 treatments have received emergency use authorization for children younger than 12, Remdesivir, marketed under the name Veklury by Gilead Sciences, is the first to receive full FDA approval.

Summary by Jw Williams

Remdesivir is an investigational drug that was developed as a way to treat Ebola. In April 2020, clinical trials showed that 68% of people in that trial had improved symptoms. However, another trial concluded that remdesivir did not work. *The Guardian* revealed that this information came from a report accidentally posted by the World Health Organization that was subsequently taken down. According to that report, the trial was halted early in part because some patients were having negative side effects.

Gilead, the manufacturer, admitted that 10% of people in a study showed adverse reactions to remdesivir that included nausea, acute respiratory failure, and elevated liver enzymes. *BioSpace* reported that “About 25% of patients receiving it have severe side effects, including multiple-organ dysfunction syndrome, septic shock, acute kidney injury, and low blood pressure. Another 23% demonstrated evidence of liver damage on lab tests.”

In November 2020, the United Nations’ World Health Organization (WHO) issued a conditional recommendation against the use of remdesivir in hospitalized patients

regardless of disease severity, as there was no evidence that remdesivir improves survival and other outcomes in these patients.

WHO has updated its recommendation for remdesivir in April 2022 for the treatment of COVID-19 and now suggests the use of remdesivir in mild or moderate COVID-19 patients who are at high risk of hospitalization.

According to a study of acute renal failure (ARF) related to remdesivir last year, the international pharmacovigilance postmarketing databases (VigiBase) under WHO was searched and a combination of the terms “acute renal failure” and “remdesivir” yielded a statistically significant disproportionality signal with 138 observed cases instead of the 9 expected.

Sources:

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