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Covid-19: Remdesivir is recommended for authorisation by European Medicines Agency

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The antiviral drug remdesivir is the first medicine against covid-19 to be recommended for authorisation in the European Union.

The European Medicines Agency's (EMA) human medicines committee has granted a conditional marketing authorisation for remdesivir to treat covid-19 in adults and adolescents from age 12 with pneumonia who require supplemental oxygen.[1] The authorisation allows a drug to be sold for a year in the EU before all necessary data on its efficacy and side effects are available.

Since May remdesivir has been made available in the UK to selected NHS patients in hospital with covid-19 through the Early Access to Medicines Scheme, after a positive scientific opinion from the Medicines and Healthcare Products Regulatory Agency.[2] The drug has also been approved for emergency use in severely ill patients in the United States, India, and South Korea and has received full approval in Japan.

Remdesivir has previously been tested against Ebola and two coronaviruses: Middle East respiratory syndrome and severe acute respiratory syndrome.

Time to recovery

The EMA's positive recommendation is mainly based on preliminary data from a trial sponsored by the National Institute of Allergy and Infectious Diseases and published in the *New England Journal of Medicine*.[3] This trial showed that remdesivir reduced the median time to recovery from 15 days to 11 days when compared with placebo. This effect was not observed in patients with mild to moderate disease: time to recovery was five days in both the remdesivir group and the placebo group.

Among patients with severe disease, who constituted about 90% of the patient group, time to recovery was 12 days in the remdesivir group and 18 days in the placebo group. However, no difference was seen in time to recovery in patients who started remdesivir when they were already on mechanical ventilation or extracorporeal membrane oxygenation. Data on the proportion of patients who died up to 28 days after starting treatment are currently being collected for final analysis.

Considering the available data, the EMA said that the balance of benefits and risks had been shown to be positive in patients with severe disease. Remdesivir is given by infusion into a vein, and its use is limited to healthcare facilities in which patients can be monitored closely, where liver and kidney function are monitored before and during treatment as appropriate.

The manufacturer, Gilead, will have to submit final reports of the remdesivir studies to the EMA by December 2020 and final data on mortality by August 2020.

1 European Medicines Agency. First COVID-19 treatment recommended for EU authorisation. 25 Jun 2020. https://www.ema.europa.eu/en/news/first-covid-19-treatment-recommended-eu-authorisation.
2 Kmietowicz Z. Covid-19: Selected NHS patients will be treated with remdesivir. *BMJ* 2020;369:m2097. doi: 10.1136/bmj.m2097 pmid: 32457029
3 Beigel JH, Tomashek KM, Dodd LE, etalACTT-1 Study Group Members. ACTT-1 Study Group Members Remdesivir for the treatment of covid-19: preliminary report. *N Engl J Med* 2020. doi: 10.1056/NEJMoa2007764. pmid: 32445440