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EMA recommends expanding remdesivir compassionate use to patients not on mechanical ventilation

EMA's human medicines committee (CHMP) has recommended expanding the compassionate use of the investigational medicine remdesivir so that more patients with severe COVID-19 can be treated.

In addition to patients undergoing invasive mechanical ventilation, the compassionate use recommendations now cover the treatment of hospitalised patients requiring supplemental oxygen, non-invasive ventilation, high-flow oxygen devices or ECMO (extracorporeal membrane oxygenation).

The updated recommendations are based on preliminary results from the NIAID-ACTT study, which suggest a beneficial effect of remdesivir in the treatment of hospitalised patients with severe COVID-19. EMA is currently evaluating these data in the context of the rolling review of remdesivir.

In addition, a treatment duration of 5 days has been introduced alongside the longer 10-day course, based on preliminary results from another study (GS-US-540-5773) suggesting that for patients not requiring mechanical ventilation or ECMO, the treatment course may be shortened from 10 to 5 days without any loss of efficacy. Patients who receive a 5-day treatment course but do not show clinical improvement will be eligible to continue receiving remdesivir for an additional 5 days. The option to shorten treatment duration also means that more patients may be able to receive the medicine, which is in very high demand worldwide.

Although remdesivir is not yet authorised for marketing in the European Union, these recommendations for compassionate use will help some patients with severe COVID-19 access the medicine while EMA evaluates data on its benefits and risks. When the evaluation is complete, EMA will make a recommendation on whether or not remdesivir should receive a marketing authorisation.

More information is available in the summary on compassionate use and the conditions of use of remdesivir.

More about the medicine

Remdesivir is an antiviral medicine which is being investigated for the treatment of COVID-19. Remdesivir is a 'viral RNA polymerase inhibitor' (a medicine that interferes with the production of viral genetic material, preventing the virus from multiplying). It has shown broad in vitro activity against

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different RNA viruses, including SARS-CoV-2 and was originally developed for the treatment of Ebola virus disease.

Remdesivir is being developed by Gilead Sciences Ireland CU and is given by infusion (drip) into a vein.

More about the procedure

National competent authorities can ask EMA for an opinion on how to administer, distribute and use certain medicines for compassionate use under Article 83 of Regulation (EC) No 726/2004.

Compassionate use programmes enable patients to gain access to unauthorised medicines in emergency situations. This complements the possibility to enroll patients in ongoing clinical trials.

More information on compassionate use is available on the Agency's website: https://www.ema.europa.eu/en/human-regulatory/research-development/compassionate-use.