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First COVID-19 treatment recommended for EU authorisation

EMA's human medicines committee (CHMP) has recommended granting a conditional marketing authorisation to Veklury (remdesivir) for the treatment of COVID-19 in adults and adolescents from 12 years of age with pneumonia who require supplemental oxygen.

Remdesivir is the first medicine against COVID-19 to be recommended for authorisation in the EU. Data on remdesivir were assessed in an exceptionally short timeframe through a rolling review procedure, an approach used by EMA during public health emergencies to assess data as they become available. From 30 April 2020, the CHMP began assessing data on quality and manufacturing, non-clinical data, preliminary clinical data and supporting safety data from compassionate use programmes, well in advance of the submission of the marketing authorisation application on 8 June.

The assessment of the dossier has now concluded with today's recommendation, which is mainly based on data from study NIAID-ACTT-1[1], sponsored by the US National Institute of Allergy and Infectious Diseases (NIAID), plus supporting data from other studies on remdesivir.

Study NIAID-ACTT-1 evaluated the effectiveness of a planned 10-day course of remdesivir in over 1,000 hospitalised patients with COVID-19. Remdesivir was compared with placebo (a dummy treatment) and the main measure of effectiveness was patients' time to recovery (defined as no longer being hospitalised and/or requiring home oxygen or being hospitalised but not requiring supplemental oxygen and no longer requiring ongoing medical care).

Overall, the study showed that patients treated with remdesivir recovered after about 11 days, compared with 15 days for patients given placebo. This effect was not observed in patients with mild to moderate disease: time to recovery was 5 days for both the remdesivir group and the placebo group. For patients with severe disease, who constituted approximately 90% of the study population, 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 ECMO (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.

Taking into consideration the available data, the Agency considered that the balance of benefits and risks had been shown to be positive in patients with pneumonia requiring supplemental oxygen; i.e., the patients with severe disease. Remdesivir is given by infusion (drip) into a vein and its use is limited

[1] https://www.niaid.nih.gov/news-events/nih-clinical-trial-shows-remdesivir-accelerates-recovery-advanced-covid-19

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to healthcare facilities in which patients can be monitored closely; liver and kidney function should be monitored before and during treatment, as appropriate. Treatment should start with a 200-mg infusion on the first day, followed by one 100-mg infusion a day for at least 5 days and no more than 10 days.

Remdesivir is recommended for a conditional marketing authorisation, one of the EU regulatory mechanisms to facilitate early access to medicines that fulfil an unmet medical need, including in emergency situations in response to public health threats such as the current pandemic. This type of approval allows the Agency to recommend a medicine for marketing authorisation with less complete data than normally expected, if the benefit of a medicine's immediate availability to patients outweighs the risk inherent to the fact that not all the data are yet available.

In order to better characterise the effectiveness and safety of remdesivir, the company will have to submit the final reports of the remdesivir studies to the Agency by December 2020, and further data on the quality of the medicine, as well as the final data on mortality, by August 2020. As for all medicines, a risk management plan (RMP) will ensure rigorous safety monitoring of remdesivir once authorised across the EU. Further efficacy and safety data will be collected through on-going studies and post-marketing reports and will be regularly reviewed by the CHMP and EMA's safety committee (PRAC). Since April 2020, the PRAC has also been reviewing safety data on patients treated outside clinical studies, which are being submitted as monthly safety reports; these will continue to be submitted and assessed after the medicine is on the market.

During the assessment of remdesivir, the CHMP had the support of experts from the COVID-19 EMA pandemic task force (COVID-ETF), which was established to bring together the most relevant expertise from the European medicines regulatory network to assist Member States and the European Commission in dealing with the development, authorisation and safety monitoring of medicines and vaccines against COVID-19.

The European Commission, which was kept informed by EMA throughout the evaluation, will fast-track the decision-making process and aims to grant a decision on the conditional marketing authorisation for remdesivir in the coming week, allowing the product to be marketed in the EU.