Update on remdesivir - EMA will evaluate new data from Solidarity trial

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EMA is aware that the World Health Organization (WHO) has updated its guidelines advising against the use of remdesivir in hospitalised patients with COVID-19, regardless of disease severity based on a recent meta-analysis.

Remdesivir was authorised in the EU in July 2020 as Veklury for the treatment of COVID-19 in adults and adolescents from 12 years of age with pneumonia who require supplemental oxygen. Veklury was authorised on the basis of results from the NIAID-ACTT-1 trial, a randomised controlled trial involving 1,063 hospitalised patients with COVID-19 which showed an improvement in recovery time, reducing the time patients spent in hospital or on treatment. The data package was published on EMA's clinical data website.

At the time of authorisation, EMA requested the company to submit additional data including data on mortality, in order to better characterise the effectiveness and safety of remdesivir. Day 28 mortality data from the NIAID study have also recently been made available and are under review by CHMP.

The WHO recommendation is conditional[1] and based on a systematic review and network meta-analysis of four randomised trials with 7,333 people hospitalised for COVID-19. The meta-analysis included the NIAID-ACTT-1 trial as well as the Solidarity trial.

According to WHO, the certainty for the results of the meta-analysis is low and the evidence did not prove that remdesivir has no benefit. In reaching its recommendations, the WHO also considered implications on health resources in view of remdesivir's cost and the need for it to be given intravenously. The WHO recognised that more research is needed, especially in certain groups of patients, and supported continued enrolment in trials evaluating remdesivir.

When using remdesivir healthcare professionals should follow the authorised product information and follow latest national treatment guidelines.

EMA has requested the full Solidarity data from WHO and the marketing authorisation holder. Once the data are available, EMA will assess the evidence, together with other relevant data, to see if any changes are needed to the marketing authorisation of Veklury (remdesivir) in the EU.

In terms of safety, remdesivir is well tolerated with a similar rate of adverse events for remdesivir and placebo (dummy treatment). EMA is currently evaluating a signal for kidney toxicity, a condition that may have other causes in patients with COVID-19.

EMA will communicate further as necessary.

More about the medicine

Veklury was given a 'conditional marketing authorisation' in the EU on 3 July 2020 for the treatment of COVID-19 in adults and adolescents from 12 years of age with pneumonia who require supplemental oxygen, because the benefits to these severely ill patients outweigh the risks of making the medicine available despite having less complete data than normally expected. This means that more evidence is required to be submitted in the post-authorisation phase. The conditional EU authorisation of Veklury was based on a randomised, double-blinded, placebo-controlled trial, (NIAID-ACTT-1), which showed an improvement in recovery time in hospitalised patients with COVID-19, allowing them to spend less time in hospital or on treatment. The trial involved 1,063 hospitalised patients (120 with mild to moderate disease and 943 with severe disease) which showed the following:

- In the overall trial population, patients treated with Veklury recovered after about 11 days, compared with 15 days for patients given placebo (a dummy treatment).
- For patients with severe disease requiring supplemental oxygen, time to recovery was 12 days for patients given remdesivir, compared with 18 days for patients on placebo.
- No difference was seen in time to recovery in the subgroup of patients with severe disease who started remdesivir when they were already on mechanical ventilation or ECMO (extracorporeal membrane oxygenation). No difference was also observed in patients with mild/moderate disease not requiring supplemental oxygen: time to recovery was 5 days for both the remdesivir group and the placebo group.

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[1] A **conditional recommendation** is one for which the WHO Guideline Development Group concluded that the desirable effects of adhering to the recommendation probably outweigh the undesirable effects but the Guideline Development Group is not confident about these trade-offs.