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EMA receives application for conditional authorisation of first COVID-19 treatment in the EU

EMA has now received an application for conditional marketing authorisation (CMA) of the antiviral medicine remdesivir for the treatment of COVID-19 and has formally started its evaluation. The assessment of the benefits and risks of remdesivir is being performed under a reduced timeline and an opinion could be issued within weeks, depending on the robustness of the data submitted and whether further information is required to support the evaluation.

Such a short timeframe will only be possible because some data have already been assessed during the first cycle of the rolling review, which started on 30 April and was concluded on 15 May. During this first phase, EMA scientific committees and working parties operated in synergy to complete their assessment of the dossier significantly earlier compared with a regular evaluation procedure, while still ensuring a robust evaluation of the available data.

During the rolling review, EMA's human medicines committee (CHMP) assessed data on quality and manufacturing, preliminary data from several clinical studies and supporting data from compassionate use programmes. At the conclusion of the first cycle of the rolling review, the CHMP invited the company to submit further data together with an application for a conditional marketing authorisation.

In parallel, EMA's safety committee (PRAC) completed the initial assessment of the preliminary risk management plan (RMP) proposed by the company, which outlines measures to identify, characterise and minimise the medicine's risks. The PRAC will continue to evaluate the safety data for remdesivir in an expedited manner to promptly identify and address potential safety concerns with the medicine.

Furthermore, EMA's committee for medicines for children (PDCO) rapidly issued its opinion on the company's paediatric investigation plan (PIP), which describes how the medicine should be developed and studied for use in children, in accordance with the accelerated timelines for COVID-19 products, and an EMA decision was adopted.

Should the additional data now submitted with the CMA application be sufficient to allow CHMP to conclude that the benefits of remdesivir outweigh its risks in the treatment of COVID-19, EMA will liaise closely with the European Commission to support fast-tracking of the decision-making process and granting of a marketing authorisation by the European Commission valid in all EU[1] and EEA Member States.

[1] As of 1 February 2020, the United Kingdom is no longer an EU Member State. However, EU law still applies to the UK during the transition period.

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

Although remdesivir is not yet authorised for marketing in the European Union, it is available to patients through clinical trials and compassionate use programmes, through which patients can get access to unauthorised medicines.

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

More about the procedure

Further information on how EMA fast-tracks its regulatory procedures so that marketing authorisations of safe, effective and high-quality COVID-19 related medicines can be granted as soon as possible is available here:

www.ema.europa.eu/en/news/covid-19-how-ema-fast-tracks-development-support-approval-medicines-vaccines

www.ema.europa.eu/en/documents/leaflet/infographic-fast-track-procedures-treatments-vaccines-covid-19_en.pdf