Selected NHS patients to access coronavirus treatment remdesivir

- Innovative medicine with promising results in clinical trials to be made available to selected UK COVID-19 patients
- Government working in collaboration with manufacturer Gilead Sciences to supply remdesivir treatment to NHS
- Large international study including UK research centres has reported that remdesivir can shorten recovery time from COVID-19

Selected NHS coronavirus patients will soon be able to access a treatment to speed up their recovery.

Thanks to the joined-up efforts of the UK government, the devolved administrations, pharmaceutical company Gilead Sciences, the NHS, and the Medicines and Healthcare products Regulatory Agency (MHRA), the anti-viral drug remdesivir will be made available to patients meeting certain clinical criteria to support their recovery in hospital.

The drug is currently undergoing clinical trials around the world, including in the UK, with early data showing it can shorten the time to recovery by about 4 days.

The Early Access to Medicines Scheme (EAMS) and scientific opinion from MHRA supports remdesivir to be used by selected NHS patients. For the time being and due to limited supplies, treatment will be prioritised for patients who have the greatest likelihood of deriving the most benefit.

Minister for Innovation Lord Bethell said:

> This shows fantastic progress. As we navigate this unprecedented period, we must be on the front foot of the latest medical advancements, while always ensuring patient safety remains a top priority
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> The latest, expert scientific advice is at the heart of every decision we make, and we will continue to monitor remdesivir's success in clinical trials across the country to ensure the best results for UK patients.

Allocation of the drug will be based on expert clinical advice and will take into consideration the situation where it is most likely to provide the greatest benefit.

The UK government continues to work closely with its partners across the devolved administrations, the health system and industry to ensure UK patients have the greatest possible chance of getting the latest, ground-breaking treatments as quickly as possible.

Dr June Raine, MHRA Chief Executive, said:

> We are committed to ensuring that patients can have fast access to promising new treatments for COVID-19.
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> We will continue to work closely with the Department of Health and Social Care and other healthcare partners on protecting public health in the UK by prioritising our essential work on clinical trials, access to medicines, and the development of vaccines.

Hilary Hutton-Squire, Vice President and General Manager, Gilead Sciences UK and Ireland said:

> We are delighted that the MHRA and the Commission on Human Medicines (CHM) have decided to issue remdesivir a positive Scientific Opinion within the Early Access to Medicines Scheme (EAMS).
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> This decision reflects Gilead’s commitment to rapidly respond to the COVID-19 pandemic.
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> Treatment options in response to this global public health emergency are urgently needed and we are grateful to the UK government and the MHRA for their continued support and collaboration to make this medicine available to those patients who are most likely to benefit from it. We will continue to work closely with the government to supply remdesivir across the UK.

- Similar arrangements have already been made with other countries, including an emergency authorisation from the FDA in the US and MHLW/PMDA in Japan.
- EAMS aims to give patients with life threatening or seriously debilitating conditions access to medicines that do not yet have a marketing authorisation, when there is a clear medical need.
- Under the scheme, MHRA will give a scientific opinion on the benefit/risk balance of the medicine, based on the data available. This opinion does not replace the normal licensing procedures for medicines but supports clinicians and patients to make a decision on whether to use the medicine before its licence is approved.
- MHRA and the Commission on Human Medicines (CHM) considered the emerging results of an Active COVID-19 Treatment Trial (ACTT) study, and other studies conducted by Gilead. The data was sufficient to meet the criteria for an EAMS scientific opinion, and the benefits were determined to outweigh the risks.
- The scientific opinion describes the risks and benefits of the medicine based on data gathered from the patients who will benefit from the medicine. The opinion supports the prescriber and patient to make a decision on whether to use the medicine before its licence is approved.

- Find out more about the National Institute for Health Research's (NIHR) national process to prioritise COVID-19 research. See details on the process and the new single point of entry for prioritising COVID-19 studies.
- The drug will be used in adults and adolescents hospitalised with severe COVID-19 infection who meet clinical criteria suggesting they have the greatest likelihood of benefiting.
- The arrangements for allocation across the NHS is in place to distribute the medicine. NHS England will manage this allocation in collaboration with all 4 nations.
- Supply of the drug through this arrangement will be separate to the clinical trials currently occurring in the UK and around the world.