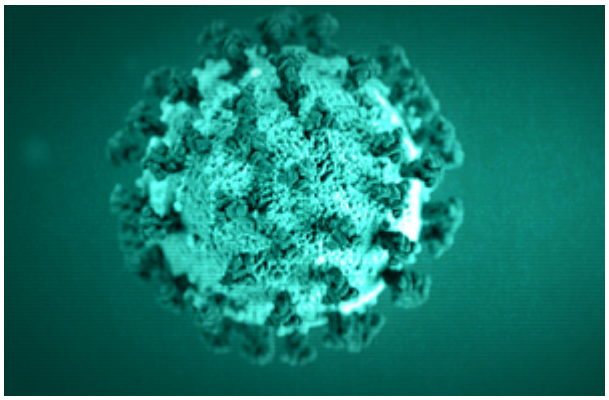
First monoclonal antibody treatment for COVID-19 approved for use in the UK

Press release

The Medicines and Healthcare products Regulatory Agency (MHRA) has today given approval for the first monoclonal antibody treatment for the prevention and treatment of COVID-19 in the UK.



Following on from a thorough review of the evidence carried out by the MHRA, and recommendation by the Commission on Human Medicines (CHM), the government's independent expert scientific advisory body, the MHRA has approved Ronapreve as the first monoclonal antibody combination product indicated for use in the prevention and treatment of acute COVID-19 infection for the UK.

Developed by Regeneron/Roche, the drug is administered either by injection or infusion and acts at the lining of the respiratory system where it binds tightly to the coronavirus and prevents it from gaining access to the cells of the respiratory system. Clinical trial data assessed by a dedicated team of MHRA scientists and clinicians has shown that Ronapreve may be used to prevent infection, promote resolution of symptoms of acute COVID-19 infection and can reduce the likelihood of being admitted to hospital due to COVID-19.

Health and Social Care Secretary Sajid Javid said:

> The UK is considered a world leader in identifying and rolling out life-saving treatments for COVID-19, once they have been proven safe and effective in our government-backed clinical trials.
>
> This is fantastic news from the independent medicines regulator and means the UK has approved its first therapeutic designed specifically for COVID-19.

> This treatment will be a significant addition to our armoury to tackle COVID-19 – in addition to our world-renowned vaccination programme and life-saving therapeutics dexamethasone and tocilizumab. “We are now working at pace with the NHS and expert clinicians to ensure this treatment can be rolled out to NHS patients as soon as possible.

Interim Chief Quality & Access Officer, Dr Samantha Atkinson said:

> We are pleased to announce the approval of another therapeutic treatment that can be used for to help save lives and protect against COVID-19.
>
> Ronapreve is the first of its kind for the treatment of COVID-19, and after a meticulous assessment of the data by our expert scientists and clinicians, we are satisfied that this treatment is safe and effective.
>
> With no compromises on quality, safety and efficacy, the public can trust that the MHRA have conducted a robust and thorough assessment of all the available data.

See Information for Healthcare Professionals, and Information for UK recipients

Notes to editors

1. The Medicines and Healthcare products Regulatory Agency is responsible for protecting and improving the health of millions of people every day through the effective regulation of all medicines and medical devices in the UK by ensuring they work and are acceptably safe. All our work is underpinned by robust and fact-based judgements to ensure that the benefits justify any risks.

2. The MHRA is a centre of the Medicines and Healthcare products Regulatory Agency which also includes the National Institute for Biological Standards and Control (NIBSC) and the Clinical Practice Research Datalink (CPRD). MHRA is an executive agency of the Department of Health and Social Care.

3. The Commission on Human Medicines (CHM) advises ministers on the safety, efficacy and quality of medicinal products. The CHM is an advisory non-departmental public body, sponsored by the Department of Health and

Social Care.

4. The regulatory process known as a ‘rolling review’ has been used throughout the pandemic to rapidly assess promising medicines during a public health emergency in the shortest time possible. The MHRA team clinicians carried out a rigorous, scientific and detailed review of all the available data, starting in January 2021. And looked at the laboratory pre-clinical studies, clinical trials, manufacturing and quality controls and also considered the conditions for its safe supply and distribution.

5. Ronapreve is not intended to be used as a substitute for vaccination against COVID-19.

6. Rogeneron/Roche conducted clinical trials before widespread vaccination and before the emergence of variants of the coronavirus. Interpretation of serology results (the meanings of ‘seropositive’ and ‘seronegative’) is now more complex in the presence of widespread vaccination and variants of the coronavirus; it would be for the attending healthcare professional to make an informed decision on use of the current product with knowledge of (i) the vaccination status of the patient, (ii) local prevalence of variant forms of the coronavirus and (iii) the technical aspects of serology tests offered by laboratories.

7. The company has submitted interim clinical trial reports and the MHRA will receive final study reports in coming months along with the company’s study report of the RECOVERY trial conducted by Oxford University.

8. The government and the NHS will confirm how this COVID-19 treatment will be deployed to patients in due course.

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