MHRA approves Xevudy (sotrovimab), a COVID-19 treatment found to cut hospitalisation and death by 79%

Another COVID-19 treatment, Xevudy (sotrovimab), has today been approved by the Medicines and Healthcare products Regulatory Agency (MHRA) after it was found to be safe and effective at reducing the risk of hospitalisation and death in people with mild to moderate COVID-19 infection who are at an increased risk of developing severe disease.

This follows a rigorous review of its safety, quality and effectiveness by the UK regulator and the government's independent expert scientific advisory body, the Commission on Human Medicines, making it the second monoclonal antibody therapeutic to be approved following Ronapreve.

Developed by GSK and Vir Biotechnology, sotrovimab is a single monoclonal antibody. The drug works by binding to the spike protein on the outside of the COVID-19 virus. This in turn prevents the virus from attaching to and entering human cells, so that it cannot replicate in the body.

In a clinical trial, a single dose of the monoclonal antibody was found to reduce the risk of hospitalisation and death by 79% in high-risk adults with symptomatic COVID-19 infection.

Based on the clinical trial data, sotrovimab is most effective when taken during the early stages of infection and so the MHRA recommends its use as soon as possible and within five days of symptom onset.

Like molnupiravir, it has been authorised for use in people who have mild to moderate COVID-19 infection and at least one risk factor for developing severe illness. Such risk factors include obesity, older age (>60 years), diabetes mellitus, or heart disease.

Unlike molnupiravir, sotrovimab is administered by intravenous infusion over 30 minutes. It is approved for individuals aged 12 and above who weigh more than 40kg.

It is too early to know whether the omicron variant has any impact on sotrovimab's effectiveness but the MHRA will work with the company to establish this.

Dr June Raine, MHRA Chief Executive said:

"I am pleased to say that we now have another safe and effective COVID-19 treatment, Xevudy (sotrovimab), for those at risk of developing severe illness.

"This is yet another therapeutic that has been shown to be effective at protecting those most vulnerable to COVID-19, and signals another significant

step forward in our fight against this devastating disease.

“With no compromises on quality, safety and effectiveness, the public can trust that the MHRA have conducted a robust and thorough assessment of all the available data.”

Professor Sir Munir Pirmohamed, Chair of the Commission on Human Medicines, said:

“The Commission on Human Medicines and its COVID-19 Therapeutics Expert Working Group has independently reviewed the data and agrees with the MHRA’s regulatory approval of Xevudy (sotrovimab).

“When administered in the early stages of infection, sotrovimab was found to be effective at reducing the risk of hospitalisation and death in high-risk individuals with symptomatic COVID-19. Based on the data reviewed by the Commission and its expert group, it is clear sotrovimab is another safe and effective treatment to help us in our fight against COVID-19.”

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

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

Notes to editors

- 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.
- 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.
- 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.
- The MHRA’s Conditional Marketing Authorisation for sotrovimab is valid in Great Britain only. An emergency use authorisation has been granted for Northern Ireland to ensure access across the whole of the United Kingdom. Both authorisations were made on the basis of the same rigorous evaluation.
- More information can be found in the product information