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Covid-19: UK approves monoclonal antibody sotrovimab for over 12s at high risk

Elisabeth Mahase

The UK's medicines regulator has approved a second monoclonal antibody, sotrovimab, for the treatment of people over 12 years with mild to moderate covid-19 who are at high risk of developing severe disease.[1]

The Medicines and Healthcare Products Regulatory Agency's decision was based on clinical trial data showing that a single dose of sotrovimab, which is given as an intravenous infusion over 30 minutes, reduced the risk of hospital admission and death by 79% in high risk adults with symptomatic covid-19.

The MHRA concluded from the trial findings that sotrovimab is most effective when taken during the early stages of infection and so is recommended for use within five days of symptoms starting. It has not yet been confirmed when or how the treatment will be rolled out in the NHS.

In August the UK approved its first monoclonal antibody treatment for covid-19, Ronapreve, a combination of casirivimab and imdevimab, after phase III trial data reported that the treatment reduced the risk of hospital admission or death by 70% in high risk patients who had not been admitted to hospital.[2]

Developed by GSK and Vir Biotechnology, sotrovimab is a single monoclonal antibody that works by binding to the SARS-CoV-2 spike protein, thereby preventing the virus from attaching to and entering human cells. It was given emergency use authorisation by the US Food and Drug Administration in May.[3]

Alongside the two monoclonal antibodies, the UK has approved the antiviral drug molnupiravir for the treatment of mild to moderate covid-19 in adults with at least one risk factor for severe illness.[4] Like molnupiravir, sotrovimab has been authorised for use in people with at least one risk factor for developing severe illness, such as obesity, being aged over 60 years, diabetes mellitus, and heart disease.

Munir Pirmohamed, chair of the Commission on Human Medicines, said, "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."

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