Press release

First oral antiviral for COVID-19, Lagevrio (molnupiravir), approved by MHRA

The antiviral was found to be safe and effective following a stringent review of the available evidence.

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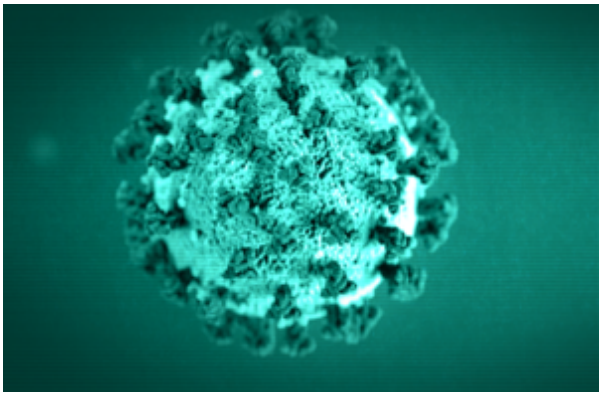

The antiviral Lagevrio (molnupiravir) is safe and effective at reducing the risk of hospitalisation and death in people with mild to moderate COVID-19 who are at increased risk of developing severe disease, the Medicines and Healthcare products Regulatory Agency (MHRA) announced today.

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 first oral antiviral for the treatment of COVID-19 to be approved.

Developed by Ridgeback Biotherapeutics and Merck Sharp & Dohme (MSD), Lagevrio works by interfering with the virus' replication. This prevents it from multiplying, keeping virus levels low in the body and therefore reducing the severity of the disease.

Based on the clinical trial data, Lagevrio is most effective when taken during the early stages of infection and so the MHRA recommends its use as soon as possible following a positive COVID-19 test and within five days of symptoms onset

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

Health and Social Care Secretary Sajid Javid said:

"Today is a historic day for our country, as the UK is now the first country in the world to approve an antiviral that can be taken at home for COVID-19. This will be a gamechanger for the most vulnerable and the immunosuppressed, who will soon be able to receive the ground-breaking treatment.

“The UK is leading the way to research, develop and roll out the most exciting, cutting-edge treatments, and my thanks goes to the expert teams at the MHRA and MSD for this triumph, as well as the Antivirals Taskforce who have procured the treatment.

“We are working at pace across the government and with the NHS to set out plans to deploy molnupiravir to patients through a national study as soon as possible

“This antiviral will be an excellent addition to our armoury against COVID-19, and it remains vital everyone comes forward for their life-saving COVID-19 vaccine - particularly those eligible for a booster - to ensure as many people as possible are protected over the coming months.”

Dr June Raine, MHRA Chief Executive, said:

“Following a rigorous review of the data by our expert scientists and clinicians, we are satisfied that Lagevrio (molnupiravir) is safe and effective for those at risk of developing severe COVID-19 disease and have granted its approval.

“Lagevrio is another therapeutic to add to our armoury against COVID-19. It is also the world’s first approved antiviral for this disease that can be taken by mouth rather than administered intravenously. This is important, because it means it can be administered outside of a hospital setting, before COVID-19 has progressed to a severe stage.

“With no compromises on quality, safety and effectiveness, the public can trust that the MHRA has conducted a robust and thorough assessment of the 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 endorses the MHRA’s regulatory approval of Lagevrio.

“In clinical trials, Lagevrio was found to be effective in reducing the risk of hospitalisation or death for at-risk non-hospitalised adults with mild to moderate COVID-19 by 50%.

“Based on this and other data that has been carefully reviewed by the Commission and its expert group, it is clear Lagevrio is another safe and effective treatment to help us in our fight against COVID-19.”

Lagevrio 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.