Evusheld approved to prevent COVID-19 in people whose immune response is poor

A new medicine, Evusheld (tixagevimab/cilgavimab), has today been authorised for COVID-19 prevention by the Medicines and Healthcare products Regulatory Agency (MHRA) after meeting the UK regulatory standards of safety, quality and effectiveness.

The decision to grant approval for this treatment was endorsed by the government's independent expert scientific advisory body, the Commission on Human Medicines, after carefully reviewing the evidence.

Developed by AstraZeneca, Evusheld is a combination of two long-acting antibodies that works by binding to the spike protein on the outside of the SARS-CoV-2 virus, the virus that causes COVID-19. This in turn prevents the virus from attaching to and entering human cells.

Evusheld is authorised to be used before being exposed to the risk of COVID-19 infection in order to prevent disease (known as 'pre-exposure prophylaxis').

For most people, the best way to prevent infection is vaccination. Evusheld has been approved for use in adults who are unlikely to mount an immune response from COVID-19 vaccination or for whom vaccination is not recommended.

Recipients should not be currently infected with or had recent known exposure to a person infected with the COVID-19 virus.

A single dose of the two medicines, tixagevimab and cilgavimab, should be given as two injections into a muscle by a healthcare professional.

In a clinical trial in adults, Evusheld was found to reduce the risk of developing symptomatic COVID-19 by 77%, with protection from the virus continuing for at least 6 months following a single dose.

There is not yet enough data to know how effective Evusheld is against Omicron or the duration of its effect against this variant, and the MHRA will work with the company to establish this.

Dr June Raine, MHRA Chief Executive said:

"After a careful review of the data, I am pleased to confirm that we have authorised another medicine to help protect against the effects of COVID-19.

"Evusheld is a "pre-exposure prophylaxis" treatment, meaning it is taken to prevent COVID-19 before the risk of acquiring infection. One dose has been found to provide long-lasting protection against this disease for up to 6

months.

“While the COVID-19 vaccines continue to be the first-line defence against COVID-19, we know that some people may not respond adequately to these vaccines and for a small number of individuals COVID-19 vaccines may not be recommended for other reasons, such as a previous allergic reaction to one of the vaccine ingredients.

“For these people, Evusheld could provide effective protection against COVID-19.”

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 Evusheld.

“We have carefully reviewed data on the medicine’s safety, quality and effectiveness and are satisfied it meets the expected standards.

“The recommended dosage is 300 mg of Evusheld but a higher dose of 600 mg may be more appropriate for some COVID-19 variants. All this is outlined in the Summary of Product Characteristics.

“Pre-exposure prophylaxis with Evusheld is not a substitute for vaccination in individuals for whom COVID-19 vaccination is recommended.”

Notes to Editors

1. The Medicines and Healthcare products Regulatory Agency is responsible for regulating 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 an executive agency of the Department of Health and Social Care.
3. The Commission on Human Medicines (CHM) advises ministers and the MHRA 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.