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EMA recommends authorisation of COVID-19 medicine Evusheld

EMA's human medicines committee (CHMP) has recommended granting a marketing authorisation for Evusheld, developed by AstraZeneca AB, for the prevention of COVID-19 in adults and adolescents from 12 years of age weighing at least 40 kg before potential exposure to the SARS-CoV-2 virus.

Evusheld is made of the active substances tixagevimab and cilgavimab, two monoclonal antibodies designed to attach to the spike protein of the SARS-CoV-2 virus (the virus that causes COVID-19) at two different sites. When the antibodies in Evusheld attach to the spike protein, the virus cannot enter the cells to multiply and is unable to cause COVID-19 infection.

In reaching its conclusion, the CHMP evaluated data from a study in over 5,000 people showing that Evusheld, given as two injections of 150 mg tixagevimab and 150 mg cilgavimab, reduced the risk of COVID-19 infection by 77%, with the duration of protection from the virus estimated to be at least six months. In the study, adults who had never had COVID-19 and had not received a COVID-19 vaccine or other preventative treatment received Evusheld or placebo (a dummy injection). Of the people given Evusheld, 0.2% (8 out of 3,441) had lab-confirmed breakthrough COVID-19 in the first six months after treatment, compared with 1.0% (17 out of 1,731) of the people who received placebo.

The safety profile of Evusheld was favourable and side effects were generally mild, with a small number of people reporting reactions at the injection site or hypersensitivity. The CHMP concluded that the medicine's benefits are greater than its risks in the approved use and will now send its recommendation to the European Commission for a rapid decision applicable in all EU Member States.

The study data were collected before the emergence of the Omicron variant that is currently driving COVID-19 infections worldwide. Laboratory studies show that the Omicron BA.1 variant may be less sensitive to tixagevimab and cilgavimab at 150 mg doses than the Omicron BA.2 variant. EMA will assess data in the coming weeks to evaluate whether an alternative dosing regimen could be appropriate for the prevention of COVID-19 resulting from emerging variants.

Where to find more information

The product information for Evusheld contains information for healthcare professionals, a package leaflet for members of the public and details of conditions of the medicine's authorisation.

An assessment report with details of EMA's evaluation of Evusheld and the full risk management plan will be published shortly. Clinical trial data submitted by the company in the application for marketing authorisation will be published on the Agency's clinical data website in due course.

More information will also be made available in an overview of the medicine in lay language, including a description of the medicine's benefits and risks and why EMA recommended its authorisation in the EU.

Assessment of Evusheld

During the assessment of Evusheld, the CHMP had the support of EMA's safety committee, PRAC, who assessed the risk management plan of Evusheld, and the COVID-19 EMA pandemic task force (COVID-ETF), a group that brings together experts from across the European medicines regulatory network to facilitate rapid and coordinated regulatory action on medicines and vaccines for COVID-19.

Evusheld was evaluated as part of 'OPEN', an initiative started in December 2020 with the aim of increasing international collaboration in the EU review of COVID-19 vaccines and therapeutics. More information can be found on EMA's governance during COVID-19 pandemic webpage.