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EMA ends rolling review of the antibodies bamlanivimab and etesevimab for COVID-19 following withdrawal by Lilly

EMA has ended the rolling review of bamlanivimab and etesevimab, two antibodies for the treatment of COVID-19 developed by Elli Lilly Netherlands BV, after the company informed the Agency that it was withdrawing from the process.

Since March 2021, EMA's human medicines committee (CHMP) has been reviewing data on these medicines as part of a rolling review. During this process the company submitted data as they became available in order to speed up the evaluation of an eventual marketing authorisation application. In March 2021, EMA also issued advice for treating COVID-19 based on data from a clinical study. This advice supported the use of the antibodies at national level before a marketing authorisation.

At the time of the company's withdrawal, EMA had received non-clinical (laboratory) data, data from clinical studies, data on the quality and manufacturing process of the antibodies and the risk management plan (RMP).

Although EMA was speeding up its review of the data, some questions about the medicines' quality remained to be satisfactorily addressed.

The withdrawal was a decision by the company and the reasons can be found in the company's letter of withdrawal. This means that EMA is no longer reviewing data on these antibodies and will not conclude this review. The company retains the right to request another rolling review or submit a marketing authorisation application in the future.

The withdrawal has no consequences on the previous advice issued in March and patients may continue to receive the medicines based on national arrangements.

EMA will continue to expedite its review of data on COVID-19 vaccines and treatments during this ongoing pandemic. EMA is working closely with developers, providing advice early in the development process and reviewing data on a rolling review basis when appropriate.

More information on the withdrawal can be found in the questions and answers document.

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More about the medicines

Bamlanivimab and etesevimab are both monoclonal antibodies. A monoclonal antibody is a type of protein that has been designed to recognise and attach to a specific structure (called an antigen). Bamlanivimab and etesevimab have been designed to attach to the spike protein of SARS-CoV-2, the virus causing COVID-19, at two different sites. When the medicines are attached to the spike protein, the virus is unable to enter the body's cells.

More about rolling reviews

A rolling review is a regulatory tool that EMA uses to speed up the assessment of a promising medicine or vaccine during a public health emergency, such as the COVID-19 pandemic. Normally, all data on a medicine's or vaccine's effectiveness, safety and quality and all required documents must be ready at the start of the evaluation in a formal application for marketing authorisation. In the case of a rolling review, the CHMP reviews data as they become available from ongoing studies. Data are assessed during so-called 'rolling review cycles' – there is no pre-defined number of cycles, as the process is driven by the data becoming available. Once sufficient data are available, the company can submit a formal application for marketing authorisation. By reviewing the data as they become available, the CHMP can reach an opinion on the medicine's authorisation sooner.

Throughout the pandemic, EMA and its scientific committees are supported by the COVID-19 EMA pandemic task force (COVID-ETF). This group brings together experts from across the European medicines regulatory network to advise on the development, authorisation and safety monitoring of medicines and vaccines for COVID-19 and facilitate quick and coordinated regulatory action.