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EMA starts rolling review of Eli Lilly antibodies bamlanivimab and etesemivab for COVID-19

EMA's human medicines committee (CHMP) has started a 'rolling review' of data on the antibodies bamlanivimab and etesemivab which are being developed by Eli Lilly to be used in combination for the treatment of COVID-19. The review will also look at bamlanivimab used alone.

The decision to start the rolling review is based on preliminary results from two studies, one looking at the ability of the medicines to treat COVID-19 when combined, the other one when bamlanivimab is used alone. However, EMA has not yet evaluated the full dataset and it is too early to draw any conclusions regarding the benefit-risk balance of the medicines.

EMA has started evaluating the first batch of data, which come from animal studies (non-clinical data).

EMA will evaluate all data on these medicines, including evidence from clinical trials as they become available. The rolling review will continue until enough evidence is available to support formal marketing authorisation applications.

EMA will assess the medicine's compliance with the usual standards for effectiveness, safety and quality. While the overall review timeline cannot be forecast yet, the process should be quicker than a regular evaluation due to the time gained during the rolling review.

How are the medicines expected to work?

Bamlanivimab and etesemivab are two monoclonal antibodies with activity against COVID-19. A monoclonal antibody is a type of protein that has been designed to attach to a specific structure (called an antigen). Bamlanivimab and etesemivab have been designed to attach to the spike protein of SARS-CoV-2 at two different sites. When they attach to the spike protein, the virus cannot enter the body's cells. Because the antibodies attach to different parts of the protein, using them in combination may have a greater effect than using either alone.

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What is a rolling review?

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. Normally, all data on a medicine's effectiveness, safety and quality and all required documents must be submitted at the start of the evaluation in a formal application for marketing authorisation. In a rolling review, EMA's human medicines committee (CHMP) reviews data as they become available from ongoing studies, before a formal application is submitted. Once the CHMP decides that sufficient data are available, the formal application can be submitted by the company. By reviewing the data as they become available, the CHMP can reach its opinion sooner on whether or not the medicine or vaccine can be authorised.

During the rolling review, and 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.