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Questions and answers on end of rolling review for antibodies bamlanivimab and etesevimab for COVID-19

EMA has ended the rolling review of bamlanivimab and etesevimab, two antibodies developed by Eli Lilly Netherlands BV, after the company informed the Agency that it was withdrawing from the process. The rolling review started on 11 March 2021; the company withdrew on 29 October 2021.

What are bamlanivimab and etesevimab and how are they expected to work?

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.

What is a rolling review?

A rolling review is a regulatory tool that EMA uses to speed up the assessment of a promising medicine 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, EMA's human medicines committee (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.

How far had the rolling review process got when the company withdrew?

The company withdrew from the process shortly after the start of the sixth rolling review cycle, which included data from ongoing clinical studies, further data on the quality and manufacturing process of these antibodies and an updated version of its proposed risk management plan (RMP), which contains important information about the medicines' safety and how to minimise any potential risks.

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In the previous rolling review cycles, the company had provided non-clinical (laboratory) data, initial data on the quality of the antibodies, the initial RMP and preliminary clinical data from studies in adults.

As the Agency was still evaluating the data provided by the company, it had not yet made any recommendations. At the time of withdrawal some questions about the medicines' quality still remained to be satisfactorily addressed.

What were the reasons given by the company for withdrawing?

In its letter notifying the Agency of the withdrawal, the company stated that it withdrew because the CHMP required validation data which could only be generated by producing new batches of active substance which was not required based on the company's supply forecasts.

Does this withdrawal affect patients in clinical trials and previous advice given (under article 5(3))?

The company informed the Agency that there are currently no clinical trials with bamlanivimab and etesevimab ongoing in the EU.

In March 2021 EMA issued advice to support the use of the antibodies bamlanivimab and etesevimab for treating COVID-19. The advice was to be used at national level before a marketing authorisation is issued. The withdrawal has no consequences on the previous advice issued and patients may continue to receive the antibodies based on national arrangements.