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EMA starts rolling review of Evusheld (tixagevimab and cilgavimab)

EMA's human medicines committee (CHMP) has started a rolling review of Evusheld (also known as AZD7442), a combination of two monoclonal antibodies (tixagevimab and cilgavimab), which is being developed by AstraZeneca AB for the prevention of COVID-19 in adults.

The CHMP's decision to start the rolling review is based on preliminary results from clinical studies, which suggest that the medicine may help protect against the disease. EMA has started evaluating data from laboratory and animal studies (non-clinical data).

EMA will evaluate more data on the quality, safety and effectiveness of the medicine as they become available. The rolling review will continue until enough evidence is available for the company to submit a formal marketing authorisation application.

EMA will assess the compliance of Evusheld with the usual EU standards for effectiveness, safety and quality. While EMA cannot predict the overall timelines, it should take less time than normal to evaluate an eventual application because of the work done during the rolling review.

EMA will communicate further when a marketing authorisation application for the medicine has been submitted.

How is the medicine expected to work?

This medicine is made of tixagevimab and cilgavimab, two 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). Tixagevimab and cilgavimab have been designed to attach to the spike protein of SARS-CoV-2 (the virus that causes COVID-19) at two different parts. By attaching to the spike protein, the medicine is expected to stop the virus from entering the body's cells and causing infection. Because the antibodies attach to different parts of the protein, using them in combination may be more effective 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 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. Once the CHMP decides that sufficient data are available, the company can submit a formal application. By reviewing the data as they become available, the CHMP can come to an opinion on the medicine's authorisation sooner.

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.