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EMA starts rolling review of REGN-COV2 antibody combination (casirivimab / imdevimab)

EMA's human medicines committee (CHMP) has started a 'rolling review' of data on a medicine known as REGN-COV2 antibody combination (casirivimab / imdevimab), which is being co-developed by Regeneron Pharmaceuticals, Inc. and F. Hoffman-La Roche, Ltd (Roche) for the treatment and prevention of COVID-19.

The CHMP's decision to start the rolling review is based on preliminary results from a study that indicate a beneficial effect of the medicine in reducing the amount of virus in the blood (viral load) in non-hospitalised patients with COVID-19. However, EMA has not yet evaluated the full study and it is too early to draw any conclusions regarding the benefit-risk balance of the medicine.

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

The CHMP will evaluate all data on this medicine, including evidence from a study in hospitalised patients with COVID-19 and other clinical trials as they become available.

The rolling review will continue until enough evidence is available to support a formal marketing authorisation application.

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 shorter than a regular evaluation due to the time gained during the rolling review.

How is the medicine expected to work?

This medicine is made of casirivimab and imdevimab, two monoclonal antibodies. A monoclonal antibody is an antibody (a type of protein) that has been designed to recognise and attach to a specific structure (called an antigen). Casirivimab and imdevimab have been designed to attach to the spike protein of SARS-CoV-2 at two different sites. When the active substances are attached to the spike protein, the virus is unable to enter the body's cells.

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What is a rolling review?

A rolling review is one of the regulatory tools 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 the case of 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 should 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.