24 February 2021
EMA/114418/2021

EMA starts rolling review of Celltrion antibody regdanvimab for COVID-19

EMA's human medicines committee (CHMP) has started a 'rolling review' of data on the monoclonal antibody regdanvimab (also known as CT-P59), which is being developed by Celltrion, for the treatment of COVID-19.

The decision to start the rolling review is based on preliminary results from an ongoing study looking at the ability of the medicine to treat COVID-19. 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 medicine.

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

The EMA will evaluate all data on this medicine 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 quicker than a regular evaluation due to the time gained during the rolling review.

How is the medicine expected to work?

Regdanvimab is a monoclonal antibody 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). Regdanvimab has been designed to attach to the spike protein of SARS-CoV-2, the virus that causes COVID-19. When it attaches to the spike protein, the ability of the virus to enter the body's cells is reduced. This is expected to reduce the need for hospitalisation in patients with mild to moderate COVID-19.

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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.