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EMA starts rolling review of sotrovimab (VIR-7831) for COVID-19

EMA's human medicines committee (CHMP) has started a 'rolling review' of data on sotrovimab (also known as VIR-7831 and GSK4182136), a monoclonal antibody developed by GlaxoSmithKline and Vir Biotechnology, Inc. 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 prevent hospitalisation or death in non-hospitalised patients with COVID-19. However, EMA has not yet received 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 laboratory and animal studies, in addition to data on the quality of the medicine.

EMA will evaluate all data on this medicine, including evidence from 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 EU 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.

A separate review of sotrovimab is already underway to provide EU-wide recommendations to support national authorities who may decide on the use of the medicine for COVID-19 prior to marketing authorisation.

How is the medicine expected to work?

Sotrovimab (also known as VIR-7831 and GSK4182136) is a monoclonal antibody with activity against COVID-19. A monoclonal antibody is a type of protein that attaches to a specific structure (called an antigen). Sotrovimab is 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 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.