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EMA starts review of VIR-7831 for treating patients with COVID-19

EMA is reviewing currently available data on the use of the monoclonal antibody VIR-7831 (also known as GSK4182136) in the treatment of patients with COVID-19. EMA is starting this review to support national authorities who may decide on the use of this medicine for COVID-19 prior to marketing authorisation.

The review will include data from a study comparing the effect of VIR-7831 with that of a dummy treatment (placebo) in patients with mild to moderate COVID-19 who were at high risk of progressing to more severe COVID-19. The preliminary results indicate that VIR-7831 reduced the risk of hospitalisation for more than 24 hours or death by 85% compared with placebo.

EMA's human medicines committee (CHMP) will look at how well the medicine prevents hospitalisation and death in non-hospitalised COVID-19 patients who do not require oxygen supplementation. The CHMP will also consider data on the medicine's quality and safety.

While a more comprehensive rolling review is anticipated to start ahead of a possible application for a marketing authorisation, this current review will provide EU-wide recommendations for national authorities who may take evidence-based decisions on the early use of the medicine.

EMA will communicate on the outcome of this review once it concludes.

More about the medicine

VIR-7831 (GSK4182136) is a monoclonal antibody with activity against SARS-CoV-2, the virus that causes COVID-19. A monoclonal antibody is a type of protein that attaches to a specific structure (called an antigen). VIR-7831 is designed to attach to the spike protein of SARS-CoV-2, limiting the ability of the virus to enter the body's cells. The medicine is expected to reduce the need for hospitalisation in patients with COVID-19.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

More about the procedure

EMA's Executive Director requested the review under Article 5(3) of Regulation 726/2004 following preliminary discussions with EMA's COVID-19 pandemic task force (COVID-ETF), which brings together experts from across the European medicines regulatory network.

The review is being carried out by EMA's Committee for Medicinal Products for Human Use (CHMP), which is responsible for questions concerning medicines for human use. The Committee will issue a scientific opinion within the shortest possible timeframe.