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EMA issues advice on use of sotrovimab (VIR-7831) for treating COVID-19

EMA's human medicines committee (CHMP) has completed its review on the use of the monoclonal antibody sotrovimab (also known as VIR-7831 and GSK4182136) to treat patients with COVID-19. This review was undertaken to provide a harmonised scientific opinion at EU level to support national decision-making on the possible use of the antibody prior to marketing authorisation.

The Agency concluded that sotrovimab can be used to treat confirmed COVID-19 in adults and adolescents (aged 12 years and above and weighing at least 40 kg) who do not require supplemental oxygen therapy and who are at risk of progressing to severe COVID-19.

The medicine is given by infusion (drip) into a vein and the proposed conditions of use are available.

EMA made its recommendations following a review of data, including data on quality and from a study into the effects of sotrovimab in adult outpatients with mild COVID-19 symptoms who do not need supplemental oxygen. A planned interim analysis of this study indicated that sotrovimab reduced the risk of hospitalisation for more than 24 hours or death by 85% compared with placebo: hospitalisation for more than 24 hours or death occurred in 1% (3 out of 291) of patients who received sotrovimab and 7% (21 out of 292) of those who received placebo.

In terms of safety, most side effects reported were mild or moderate. Reactions related to the infusion (including allergic reactions) cannot be excluded and healthcare professionals should monitor patients for these reactions.

EMA's recommendations can now be used to support national advice on the possible use of this monoclonal antibody before a marketing authorisation is issued.

While the current evaluation has concluded, a rolling review of sotrovimab, which started on 7 May, is ongoing. Once finalised, the rolling review will be the basis for an EU marketing authorisation application for this medicine.

More about the medicine

Sotrovimab (also known as VIR-7831 and 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

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to a specific structure (called an antigen). Sotrovimab is designed to attach to the spike protein of SARS-CoV-2, limiting the ability of the virus to enter the body's cells.

More about the procedure

The review of sotrovimab was started at the request of the EMA Executive Director under Article 5(3) of Regulation 726/2004 following preliminary discussion with the COVID-19 EMA pandemic task force (COVID-ETF), which 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.

The review of sotrovimab was carried out by EMA's Committee for Medicinal Products for Human Use (CHMP), responsible for questions concerning medicines for human use, which has now issued its scientific opinion. The CHMP's scientific opinion can be taken into account by EU member states and EMA when evaluating this medicine for the treatment of COVID-19.