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EMA issues advice on use of antibody combination (bamlanivimab / etesevimab)

EMA's human medicines committee (CHMP) has completed its review on the use of the monoclonal antibodies bamlanivimab and etesevimab 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 antibodies prior to marketing authorisation.

The Agency concluded that bamlanivimab and etesevimab can be used together to treat confirmed COVID-19 in patients who do not require supplemental oxygen and who are at high risk of their COVID-19 disease becoming severe. The Agency also looked at the use of bamlanivimab alone and concluded that, despite uncertainties around the benefits of monotherapy, it can be considered a treatment option.

The medicines are given by infusion (drip) into a vein and the proposed conditions of use are published on the EMA website.

EMA made its recommendations following a review of data including quality data, and data from a study[1] that looked into the effects of monotherapy and combination therapy in outpatients with COVID-19 who do not need supplemental oxygen. Although some uncertainties remain, particularly around the benefits of monotherapy, the results indicate that the combination reduced the viral load (amount of virus in the back of the nose and throat) more than placebo (a dummy treatment). The results also indicated that the combination and monotherapy led to fewer COVID-19-related medical visits.

In terms of safety, most side effects reported were mild or moderate; however, reactions related to the infusion (including allergic reactions) are likely and should be monitored for.

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

More about the medicines

Bamlanivimab and etesevimab are both monoclonal antibodies. A monoclonal antibody is a type of protein that has been designed to recognise and attach to a specific structure (called an antigen).

[1] https://jamanetwork.com/journals/jama/fullarticle/2775647

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Bamlanivimab and etesevimab have been designed to attach to the spike protein of SARS-CoV-2 at two different sites. When the medicines are attached to the spike protein, the virus is unable to enter the body's cells.

More about the procedure

The review of antibodies bamlanivimab and etesevimab 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 the antibodies bamlanivimab and etesevimab 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.