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EMA reviewing data on monoclonal antibody use for COVID-19

EMA's human medicines committee (CHMP) is reviewing available data on the use of the monoclonal antibodies casirivimab, imdevimab, bamlanivimab and etesevimab to treat patients with COVID-19 who do not require oxygen supplementation and who are at high risk of progressing to severe COVID-19. The committee will carry out two separate reviews, one for the casirivimab/imdevimab combination and another for bamlanivimab/etesevimab.

EMA is reviewing the data to provide a harmonised scientific opinion at EU level to support national decision making on the possible use of the antibodies before a formal authorisation is issued. Earlier this week, EMA already started a rolling review of the antibody combination casirivimab and imdevimab.

The reviews have been started in view of recent studies[1,2] that looked into the effects of the combinations casirivimab/imdevimab and bamlanivimab/etesevimab in outpatients with COVID-19 who do not need supplemental oxygen. Preliminary results for both studies indicate that the combinations reduced the viral load (amount of virus in the back of the nose and throat) more than placebo (a dummy treatment) and led to fewer COVID-19-related medical visits and hospitalisations.

The Committee will also look at the use of bamlanivimab alone based on a study[3] which indicated that bamlanivimab monotherapy can reduce viral load and provide clinical benefit.

EMA will communicate further when it has reviewed all the data.

More about the medicine

Casirivimab, imdevimab, bamlanivimab and etesevimab are monoclonal antibodies with activity against COVID-19. A monoclonal antibody is an antibody (a type of protein) that has been designed to recognise and attach to a specific structure (called an antigen).

[1] https://www.nejm.org/doi/full/10.1056/NEJMoa2035002
[2] https://jamanetwork.com/journals/jama/fullarticle/2775647
[3] https://www.nejm.org/doi/pdf/10.1056/NEJMoa2029849?articleTools=true

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These four monoclonal antibodies are designed to attach to the spike protein of SARS-CoV-2 at different sites. When they attach to the spike protein, the virus is unable to enter the body's cells. The antibodies attach to different parts of the protein and using them in combination (casirivimab with imdevimab and bamlanivimab with etesevimab) may have a greater effect than using them alone.

More about the procedure

The CHMP is conducting two separate reviews (one for the casirivimab/imdevimab combination and another for bamlanivimab/etesevimab). EMA's Executive Director requested both reviews under Article 5(3) of Regulation 726/2004 following preliminary discussions 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 reviews are being carried out by EMA's Committee for Medicinal Products for Human Use (CHMP), responsible for questions concerning medicines for human use, which will issue a scientific opinion within the shortest possible timeframe. The scientific opinions are then published for EU Member States who may consider them when making decisions on the use of these medicines at national level before formal marketing authorisations are issued.