REPUBLIC OF CYPRUS
MINISTRY OF HEALTH

Press release

EMA issues advice on use of REGN-COV2 antibody combination (casirivimab / imdevimab)

EMA's Human Medicines Committee (CHMP) has completed its review on the use of the monoclonal antibodies casirivimab and imdevimab 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 the combination also known as REGN-COV2 can be used for the treatment of confirmed COVID-19 in patients who do not require supplemental oxygen and who are at high 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 here.

EMA made its recommendations following review of data including quality data and a study that looked into the effects of the combination in outpatients with COVID-19 who do not need supplemental oxygen. Preliminary 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) and 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) have been seen 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.

In parallel, a rolling review of the combination of antibodies casirivimab and imdevimab, which started on 1st February, is currently ongoing. Once finalised it will be the basis for an EU marketing authorisation for this combination.

More about the medicine

This medicine is made of casirivimab and imdevimab, two monoclonal antibodies. 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). Casirivimab and imdevimab have been designed to attach to the spike protein of SARS-CoV-2 at two different sites. When the active substances are attached to the spike protein, the virus is unable to enter the body's cells.

More about the procedure

The review of REGN-COV2 antibody combination (casirivimab / imdevimab) 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 article 5(3) review for the antibodies bamlanivimab and etesevimab, which started on 4th February at the same time as the review on the monoclonal antibodies casirivimab and imdevimab, is ongoing.

The review of REGN-COV2 antibody combination (casirivimab / imdevimab) 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.

Ministry of Health

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