**REPUBLIC OF CYPRUS**
**MINISTRY OF HEALTH**

**Press release**

# EMA issues advice on use of regdanvimab for treating COVID-19

EMA's human medicines committee (CHMP) has completed its review on the use of the monoclonal antibody regdanvimab (also known as CT-P59) 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 regdanvimab can be used for the treatment of confirmed COVID-19 in adult patients who do not require supplemental oxygen therapy 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 a review of data from an ongoing study looking into the effects of regdanvimab in adult outpatients with COVID-19 symptoms described as mild to moderate who do not need supplemental oxygen. Results from the first part of the study indicate that regdanvimab may lower the rate of hospitalisation. However, the results were not robust enough to reach a firm conclusion on the medicine's benefits at this point in time. 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.

Despite the uncertainties, the CHMP concluded that regdanvimab can be considered a treatment option for patients at high risk of progressing to severe COVID-19, based on a reasonable likelihood that the medicine may provide clinical benefit, and a low likelihood of harm.

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 regdanvimab, which started on 24 February, is currently ongoing. Once finalised, the rolling review will be the basis for an EU marketing authorisation application for this medicine.

**More about the medicine**

Regdanvimab 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 has been designed to attach to a specific structure (called an antigen). Regdanvimab has been designed to attach to the spike protein of SARS-CoV-2. When it attaches to the spike protein, the ability of the virus to enter the body's cells is reduced. This is expected to reduce the need for hospitalisation in patients with mild to moderate COVID-19.

**More about the procedure**

The review of regdanvimab 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 regdanvimab 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.

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Ministry of Health

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