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EMA review of regdanvimab for COVID-19 to support national decisions on early use

EMA is conducting a review of Celltrion's monoclonal antibody regdanvimab (CT-P59) to support national authorities who may decide on the use of this medicine for COVID-19 prior to authorisation.

This review is in addition to the ongoing rolling review of regdanvimab for the treatment of confirmed COVID-19 in patients who do not require supplemental oxygen therapy and are at high risk for progressing to severe COVID-19 and/or hospitalisation.

EMA's human medicines committee (CHMP) will look at data on how well the medicine prevents COVID-19 from becoming severe or reduces hospitalisation and admission to intensive care units.

While the more comprehensive rolling review is ongoing ahead of a possible application for a marketing authorisation, this procedure will provide a shared EU expert opinion to national authorities who may take evidence-based decisions on early use of the medicine, e.g. in compassionate use programmes.

EMA will communicate on the outcome of this review once it concludes.

More about the medicine

Regdanvimab is a monoclonal antibody with activity against 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, the virus that causes COVID-19. 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

EMA's Executive Director requested the review under Article 5(3) of Regulation 726/2004 following preliminary discussions with EMA's COVID-19 pandemic task force (COVID-ETF), which brings together experts from across the European medicines regulatory network.

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The review is being carried out by EMA's Committee for Medicinal Products for Human Use (CHMP), which is responsible for questions concerning medicines for human use. The Committee will issue a scientific opinion within the shortest possible timeframe.

The review is being carried out alongside a rolling review ahead of possible application for authorisation if the data on efficacy, safety and quality are sufficient.