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EMA receives application for marketing authorisation for Regkirona (regdanvimab) for treating patients with COVID-19

EMA has started evaluating an application for marketing authorisation for the monoclonal antibody Regkirona (regdanvimab, also known as CT-P59) to treat adults with COVID-19 who do not require supplemental oxygen therapy and who are at increased risk of progressing to severe COVID-19. The applicant is Celltrion Healthcare Hungary Kft.

EMA will assess the benefits and risks of Regkirona under a reduced timeline and could issue an opinion within two months, depending on the robustness of the data submitted and whether further information is required to support the evaluation.

Such a short timeframe is only possible because EMA's human medicines committee (CHMP) has already reviewed some data on the medicine during a rolling review. During this phase, CHMP assessed data from laboratory studies and animal studies, as well as data on the quality of the medicine. In addition, CHMP assessed data from a study into the effects of Regkirona in adult outpatients with mild to moderate COVID-19 symptoms who do not need supplemental oxygen.[1]

In parallel, EMA's safety committee (PRAC) completed the preliminary assessment of the risk management plan (RMP) proposed by the company, which outlines measures to identify, characterise and minimise the medicine's risks.

Furthermore, EMA's committee for medicines for children (PDCO) has issued its opinion on the company's paediatric investigation plan (PIP), which describes how the medicine should be developed and studied for use in children, in accordance with the accelerated timelines for COVID-19 medicines, and an EMA decision has been adopted.

Should the additional data now submitted with the marketing authorisation application be sufficient for CHMP to conclude that the benefits of Regkirona outweigh its risks for the treatment of COVID-19, EMA will liaise closely with the European Commission to fast track the decision granting marketing authorisation in all EU and EEA Member States.

EMA will communicate at the time of CHMP's opinion.

[1] Based on an interim analysis of this study EMA issued advice on use of regdanvimab for treating COVID-19 in March 2021.

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How is the medicine expected to work?

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 COVID-19.