REPUBLIC OF CYPRUS
MINISTRY OF HEALTH

Press release

EMA receives application for marketing authorisation for ronapreve (casirivimab / imdevimab) for treatment and prevention of COVID-19

EMA has started evaluating an application for marketing authorisation for the monoclonal antibody combination ronapreve (casirivimab / imdevimab). The applicant is Roche Registration GmbH.

Ronapreve, co-developed by Regeneron Pharmaceuticals Inc. and Roche Registration GmbH, is intended for the treatment of COVID-19 in adults and adolescents from 12 years of age who do not require supplemental oxygen therapy and who are at increased risk of progressing to severe COVID 19, and for the prevention of COVID-19 in adults and adolescents aged 12 years and older.

EMA will assess the benefits and risks of ronapreve 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 data on the medicine during a rolling review. During this phase, CHMP assessed data from laboratory and animal studies, as well as data on the quality of the medicine. In addition, the CHMP assessed clinical data, including data from a clinical trial investigating the effectiveness of ronapreve in preventing hospitalisation in adult outpatients with confirmed COVID-19 who did not need supplemental oxygen. CHMP also assessed data from a second clinical study looking at the effectiveness of the medicine in preventing COVID-19 in adults and children at risk of infection with

SARS-CoV-2 (the virus that causes COVID-19) from a household member with diagnosed COVID-19.

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) issued its opinion on the company's paediatric investigation plans (PIPs) for casirivimab and imdevimab, which describe how the medicines should be developed and studied for use in children, in accordance with the accelerated timelines for COVID-19 medicines.

Should the additional data submitted with the marketing authorisation application be sufficient for CHMP to conclude that the benefits of ronapreve outweigh its risks in the treatment and prevention 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 further at the time of the CHMP's opinion.

How is the medicine expected to work:

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.

Ronapreve is intended to be given by infusion (drip) into a vein, or by injection under the skin.

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