REPUBLIC OF CYPRUS
MINISTRY OF HEALTH

Press release

COVID-19: EMA recommends authorisation of two monoclonal antibody medicines

EMA's human medicines committee (CHMP) has recommended authorising Ronapreve (casirivimab/imdevimab) and Regkirona (regdanvimab) for COVID-19.

The Committee recommended authorising Ronapreve for treating COVID-19 in adults and adolescents (from 12 years of age and weighing at least 40 kilograms) who do not require supplemental oxygen and who are at increased risk of their disease becoming severe.

Ronapreve can also be used for preventing COVID-19 in people aged 12 years and older weighing at least 40 kilograms. The company that applied for authorisation of Ronapreve was Roche Registration GmbH.

With regard to Regkirona, the Committee recommended authorising the medicine for treating adults with COVID-19 who do not require supplemental oxygen and who are also at increased risk of their disease becoming severe. The applicant for Regkirona was Celltrion Healthcare Hungary Kft.

The CHMP will now send its recommendations for both medicines to the European Commission for rapid legally binding decisions.

First monoclonal antibodies recommended for marketing authorisation

Ronapreve and Regkirona are the first monoclonal antibody medicines to receive a positive opinion from the CHMP for COVID-19 and join the list of COVID-19 products that have received a positive opinion since Veklury (remdesivir) was recommended for authorisation in June 2020.

Monoclonal antibodies are proteins designed to attach to a specific target, in this case the spike protein of SARS-CoV-2, which the virus uses to enter human cells.

In reaching its conclusion, the CHMP evaluated data from studies showing that treatment with Ronapreve or Regkirona significantly reduces hospitalisation and deaths in COVID-19 patients at risk of severe COVID-19. Another study showed that Ronapreve reduces the chance of having COVID-19 if a household member is infected with SARS-CoV-2, the virus that causes COVID-19.

While the evaluation of the marketing authorisation applications for these medicines was underway, the Committee gave advice to assist EU Member States in deciding on the early use of these medicines. This means the medicines were already available to some patients in the EU.

Study data for Ronapreve

A main study involving patients with COVID-19 who did not require oxygen and were at increased risk of their illness becoming severe showed that treatment with Ronapreve at the approved dose led to fewer hospitalisations or deaths when compared with placebo (dummy treatment). Overall, 0.9% of patients treated with Ronapreve (11 out of 1,192 patients) were hospitalised or died within 29 days of treatment compared with 3.4% of patients on placebo (40 out of 1,193 patients).

Another main study looked at the benefits of Ronapreve for prevention of COVID-19 in people who had close contact with an infected household member but did not have COVID-19 symptoms. With Ronapreve, 29% (29 out of 100) of people tested positive and developed symptoms within 14 days of their positive test results compared with 42.3% (44 out of 104 people) of people who received a placebo.

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Study data for Regkirona

A main study in patients with COVID-19 showed that Regkirona treatment led to fewer patients requiring hospitalisations or oxygen therapy or dying when compared with placebo. Among the patients at increased risk of their illness becoming severe, 3.1% of patients treated with Regkirona (14 out 446) were hospitalised, required supplemental oxygen or died within 28 days of treatment compared with 11.1% of patients on placebo (48 out of 434).

The safety profile of both medicines was favourable with a small number of infusion-related reactions, and the CHMP concluded that the medicines' benefits are greater than their risks for their approved uses.

More information about the evaluation of both medicines and their approved product information is available on the medicine pages for both medicines on EMA's website.

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Ministry of Health
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