REPUBLIC OF CYPRUS
MINISTRY OF HEALTH

Press Release

COVID-19: EMA recommends authorisation of antibody medicine Xevudy

EMA's human medicines committee (CHMP) has recommended authorising the monoclonal antibody Xevudy (sotrovimab) for the treatment of COVID-19. The applicant is GlaxoSmithKline Trading Services Limited, who developed the medicine together with Vir Biotechnology.

The Committee recommended authorising Xevudy 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 the disease becoming severe.

Xevudy is the third monoclonal antibody recommended in the EU for treating COVID-19 and its approval follows those of Regkirona and Ronapreve in November. Monoclonal antibodies are proteins designed to attach to a specific target, in this case the spike protein of SARS-CoV-2 (the virus that causes COVID-19), which the virus uses to enter human cells.

In reaching its conclusion, the CHMP evaluated data from a study involving 1,057 patients with COVID-19 showing that treatment with Xevudy significantly reduces hospitalisation and deaths in patients with at least one underlying condition putting them at risk of severe COVID-19. Following treatment with Xevudy, 1% of patients (6 out 528) were hospitalised for longer than 24 hours within 29 days of treatment compared with 6% of patients on placebo (30 out of 529), 2 of whom died.

The majority of patients in the study were infected with the original SARS-CoV-2 virus. Some patients were infected with variants including Alpha and Epsilon. Based on laboratory studies, Xevudy is also expected to be active against other variants (including Omicron).

The safety profile of Xevudy was favourable, with a small number of hypersensitivity (allergic) reactions and infusion-related reactions reported, and the CHMP concluded that the medicine's benefits are greater than its risks for the approved use.
The CHMP will now send its recommendations to the European Commission for a rapid decision applicable in all EU Member States.

While the evaluation of the marketing authorisation application was underway, the Committee gave advice to assist EU Member States in deciding on the early use of this medicine. This means the medicine was already available to some patients in the EU.

More information about the evaluation of the medicine and the approved product information is available on the medicine page on EMA's website.

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