REPUBLIC OF CYPRUS
MINISTRY OF HEALTH

EMA reviewing data on sabizabulin for COVID-19

EMA's Emergency Task Force (ETF) has started a review of data on the use of sabizabulin for treating COVID-19.

The review will look at all available data, including data from a study involving hospitalised patients with moderate-to-severe COVID-19 who are at high risk of acute respiratory distress syndrome and death.[1] The results of this study indicate that sabizabulin treatment could reduce the number of deaths in these patients compared with placebo (a dummy treatment).

Although the developer, Veru, has not yet applied to EMA for a marketing authorisation or a rolling review, the review (based on data from the company) will assist EU Member States who may consider allowing use of the medicine before a possible authorisation.

The review is the first to be triggered under Article 18 of the new EU regulation (Reg 2022/123) that expanded the role of EMA during public health emergencies. The ETF will conduct this review and send recommendations to the Agency's human medicines committee (CHMP), which will issue the Agency's opinion.

EMA will communicate on the outcome of the review when it concludes.

More about the medicine

Sabizabulin works by disrupting microtubules, which form part of the internal skeleton in cells. These microtubules play a role in helping SARS-CoV-2 (the virus that causes COVID-19) enter and leave cells. By binding to parts of the microtubules, sabizabulin is expected to interfere with the life cycle of the virus and limit its replication and spread.

Sabizabulin is also expected to supress some inflammatory reactions that occur following infection with SARS-CoV-2, including reactions that can lead to acute respiratory distress syndrome and death.

More about the procedure

The review of sabizabulin was started on 27 July 2022 under Article 18 of Regulation 2022/123, following a request from Germany. EMA's Emergency Task Force (ETF) will conduct the review in accordance with Article 18 (3) and send recommendations to EMA's Committee for Medicinal Products for Human Use (CHMP), which will issue the Agency's opinion.

EU Member States may then consider the opinion if they intend to permit use of the medicine before a possible authorisation.

The review of sabizabulin will be the first review conducted under Article 18 (3 and 4) of Regulation 2022/123. For public health emergencies, such Article 18 reviews will replace those previously conducted under Article 5 (3) of Regulation 726/2004.

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