17 October 2019
EMA/CHMP/557387/2019
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Ervebo

Ebola Zaire Vaccine (rVSVΔG-ZEBOV-GP, live)

On 17 October 2019, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a conditional marketing authorisation[2] for the medicinal product Ervebo, intended for prophylaxis against Zaire Ebola virus disease (EVD). Ervebo was reviewed under EMA's accelerated assessment programme. The applicant for this medicinal product is Merck Sharp & Dohme B.V.

Ervebo will be available as solution for injection. The active substance of Ervebo consists of a live attenuated recombinant Vesicular Stomatitis Virus (rVSV) with a deletion of the VSV envelope glycoprotein replaced with the Zaire Ebolavirus (ZEBOV) surface glycoprotein. Ervebo is a viral vaccine (ATC code J07BX02) that provides active immunisation against Zaire Ebolavirus by inducing an immune response that helps protect against the disease.

The benefits with Ervebo are its ability to prevent laboratory confirmed EVD based on clinical efficacy data gathered in individuals at risk of infection during an Ebola outbreak in West Africa. The most common side effects are injection-site reactions (pain, swelling and erythema), headache, pyrexia, myalgia, fatigue and arthralgia.

The full indication is: "Ervebo is indicated for active immunization of individuals 18 years of age or older to protect against Ebola Virus Disease (EVD) caused by Zaire Ebolavirus. The use of Ervebo should be in accordance with official recommendations".

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

[2] A conditional marketing authorisation is granted to a medicinal product that fulfils an unmet medical need when the benefit to public health of immediate availability outweighs the risk inherent in the fact that additional data are still required. The marketing authorisation holder is likely to provide comprehensive data at a later stage.

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