28 May 2020
EMA/CHMP/138136/2020
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Mvabea

Ebola vaccine (MVA-BN-Filo [recombinant])

On 28 May 2020, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Mvabea, intended for prophylaxis against *Zaire ebolavirus* disease (EVD). Mvabea was reviewed under EMA's accelerated assessment programme. The applicant for this medicinal product is Janssen-Cilag International N.V.

Mvabea will be available as a suspension for injection. The active substance of Mvabea is based on the multivalent, recombinant, non-replicating modified vaccinia Ankara-Bavarian Nordic (MVA-BN) virus strain and encodes the *Zaire ebolavirus* Mayinga variant glycoprotein (GP), *Sudan ebolavirus* Gulu variant GP, *Taï Forest ebolavirus* nucleoprotein, *Marburg marburgvirus* Musoke variant GP. Mvabea is a viral vaccine, (ATC code: J07BX02) that provides, as part of the Zabdeno, Mvabea vaccine regimen,active immunisation for prevention of *Zaire ebolavirus* disease by inducing an immune response that protects against the disease.

The benefits with Mvabea are its ability to contribute to the generation of a protective response against the virus that causes *Zaire ebolavirus* disease. The most common side effects in adults are injection-site reactions (pain, warmth and swelling), fatigue, myalgia and arthralgia. The most common side effects in children are injection-site pain and fatigue.

The full indication is:

> Mvabea, as part of the Zabdeno, Mvabea vaccine regimen, is indicated for active immunisation for prevention of disease caused by Ebola virus (*Zaire ebolavirus* species) in individuals ≥ 1 year of age. The use of the vaccine regimen 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

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