

Title	ERVEBO – A Health Technology Assessment
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Reference	link to full report in French https://www.has-sante.fr/jcms/p_3159879/fr/ervebo

Aim

Assessment of ERVEBO (live attenuated vaccine against Zaire ebolavirus) with a view to funding by the French national health insurance system, and of its clinical contribution compared to other strategies in the prevention of Ebola Virus Disease caused by the Zaire ebolavirus, for populations in which vaccination is recommended.

Conclusions of Transparency Committee

- Ebola Virus Disease is a serious, acute viral disease, often rapidly fatal in humans.
- ERVEBO is a preventive treatment.
- The vaccine efficacy/adverse effects ratio is high.
- There are no alternative vaccines or drugs.
- ERVEBO can be used according to its MA within the scope of current vaccination guidelines, and in combination with the recommended protective measures.
- ERVEBO is likely to have an impact of international reach on public health.

Given all these elements, the Committee deems that the clinical benefit of ERVEBO is substantial in the MA indication.

Considering:

- the demonstrated major efficacy of ERVEBO in the prevention of Ebola Virus Disease caused by Zaire ebolavirus, estimated to be 100%, 95% CI [63.5%; 100%], $p = 0.0471$ in the main study available,
- the response to the medical need brought in a generally fatal disease, as the first vaccine to have MA in France in this indication,

and despite:

- the uncertainties, in particular with respect to the duration of protection provided,
- the safety signals that will be the subject of additional monitoring in the context of national pharmacovigilance monitoring (arthralgia and arthritis, skin rash, transient decrease in white cells and risk of vaccine virus transmission),

ERVEBO is a vaccine with a new mechanism of action, having demonstrated superiority and a clinically relevant effect in terms of morbidity-mortality in a context of an inadequately met medical need for a serious disease, with a high level of evidence. ERVEBO therefore provides major clinical added value (CAVI) in the prevention of Ebola Virus Disease caused by Zaire ebolavirus recommended by current national guidelines.

Recommendations

The Transparency Committee issued its approval for the funding of ERVEBO by the French national health insurance system in the MA indication.

Methods

The assessment of ERVEBO was founded on evidence-based medicine with a critical analysis of the clinical data.

Written by

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