Vaccines for the 2026 Bundibugyo Ebola disease outbreak: access gaps and recommendations

***Note on references**: to facilitate consultation, references are presented at the end of each section.*

Introduction

Ebola disease (EBOD) is a severe, often fatal haemorrhagic fever caused by several antigenically and biologically distinct orthoebolavirus species. Three have caused major human outbreaks: *Orthoebolavirus zairense* (EBOV, formerly Zaire ebolavirus), which causes Ebola virus disease (EVD); *O. sudanense* (SUDV), which causes Sudan virus disease (SVD); and *O. bundibugyoense* (BDBV), which causes Bundibugyo virus disease (BVD). BDBV is responsible for the current outbreak in the Democratic Republic of the Congo (DRC). The DRC is facing the largest and fastest-spreading Ebola disease outbreak in its recorded history, with more cases now being reported in other countries, including Kenya and Nigeria.

Over the past decade, the development of Ebola vaccines has focused primarily on EBOV. This led to the licensure of Ervebo (rVSVΔG-ZEBOV-GP) in 2019 and the establishment, in 2021, of a global stockpile of Ebola vaccines managed by the WHO-led International Coordinating Group (ICG) on Vaccine Provision. More recent investments have also advanced vaccine candidates against SUDV. In contrast, progress against BDBV has been limited. When the 2026 outbreak began, there were no BDBV-specific vaccine candidates available for clinical use or evaluation.

To respond to this gap, the research and development (R&D) community has pursued two parallel approaches: evaluating whether Ervebo confers any protection against BDBV and accelerating the development of BDBV-specific vaccines. With significant public funding now allocated to BDBV vaccine development, it is crucial that any resulting vaccine be accessible and affordable for populations affected by outbreaks, both now and in the future.

This technical brief examines, through an access lens, four vaccine candidates currently in clinical trials or expected to enter them soon, at different stages of clinical development: Ervebo, rVSVΔG-BDBV-GP, ChAdOx1-BDBV-GP and mRNA-1469. It identifies gaps in the current access landscape and makes recommendations to ensure that any safe and effective BDBV vaccine is equitably accessible to people and communities affected by the outbreak. This brief does not cover vaccine candidates still in preclinical development, including those being developed in Africa.

References for this section

1. Coalition for Epidemic Preparedness Innovations (CEPI). *From market failure to epidemic preparedness: the race for a Bundibugyo Ebola vaccine.* 4 June 2026. Available from: https://cepi.net/market-failure-epidemic-preparedness-race-bundibugyo-ebola-vaccine
2. MSF Access. *Principles for equitable access to medical tools for Ebola disease caused by Bundibugyo virus*. 8 June 2026. Available from: https://msfaccess.org/principles-equitable-access-medical-tools-ebola-disease-caused-bundibugyo-virus
3. World Health Organization. *Ebola disease caused by Bundibugyo virus - Democratic Republic of the Congo.* 8 October 2026. Available from: https://www.who.int/emergencies/disease-outbreak-news/item/2026-DON619
4. Africa Centres for Disease Control and Prevention (Africa CDC). *Bundibugyo Virus Disease (BVD) – Ebola Outbreak*. Available from: https://africacdc.org/bundibugyo-virus-disease-bvd-ebola-outbreak/

Global response to BDBV vaccines development and access

Many global institutions are collaborating on the development of BDBV vaccines. The Coalition for Epidemic Preparedness Innovations (CEPI) is leading rapid vaccine R&D by investing tens of millions of dollars to advance a multi-platform portfolio of BDBV-specific candidates into preclinical work, Phase 1 trials and at-risk manufacturing of clinical doses. Gavi, the Vaccine Alliance, has provided complementary "pull" financing, including up to US$50 million from its First Response Fund, of which up to US$40 million is earmarked to incentivise manufacturing scale-up.

In addition to being at the forefront of the operational response, the DRC Ministry of Health and the Institut National de Recherche Biomédicale (INRB) are co-leading locally relevant clinical studies. The World Health Organization (WHO), through its R&D Blueprint and Technical Advisory Group on Candidate Vaccine Prioritization (TAG-CVP), has convened expert reviews, prioritised vaccine candidates, issued a target product profile for BDBV vaccines and published emergency guidance on the use of Ervebo. Africa Centres for Disease Control and Prevention (Africa CDC) is co-leading continental preparedness and response planning, supporting trial readiness and advocating for African-led candidates and manufacturing. The ICG has released vaccines from the global Ervebo stockpile for immediate use in the DRC.

Several non-governmental organisations (NGOs), including Médecins Sans Frontières (MSF), are also contributing to the development of BDBV vaccines by conducting clinical trials and observational studies.

References for this section

1. Gavi, the Vaccine Alliance. *Gavi commits US$50 million to Bundibugyo ebolavirus vaccines and outbreak response*. 29 May 2026. Available from: https://www.gavi.org/news/media-room/gavi-commits-us-50-million-bundibugyo-ebolavirus-vaccines-and-outbreak-response
2. World Health Organization. *WHO target product profile for Bundibugyo virus disease vaccines*. 14 Jul 2026. Available from: https://www.who.int/publications/i/item/B09835
3. Coalition for Epidemic Preparedness Innovations (CEPI). *Ebola Bundibugyo*. Available from: https://cepi.net/ebola-bundibugyo

Vaccine trials

The absence of a licensed BDBV-specific vaccine has prompted clinical research during the current outbreak. Two main studies aim to generate evidence on the use of existing Ebola vaccines and BDBV-specific vaccine candidates: BRAVO, which is underway, and Tumaini, which is in preparation.

In September 2026, MSF and its epidemiological research centre, Epicentre, launched the BRAVO study in collaboration with the DRC Ministry of Health, Africa CDC, the INRB and scientific partners. This observational study aims to enrol 20,000 frontline workers in Ituri and North Kivu, provinces with particularly high rates of virus transmission, and will generate real-world evidence on whether Ervebo protects against disease and death caused by BDBV. While BDBV-specific vaccines are under development, BRAVO will help assess whether Ervebo could serve as an interim vaccination option during BDBV outbreaks.

Tumaini is a randomised, controlled, adaptive Phase 2/3 platform trial that will evaluate the efficacy, safety and immunogenicity of vaccines among individuals who have been in contact with Bundibugyo virus disease cases. Several vaccine candidates are expected to be evaluated, including Ervebo, ChAdOx1-BDBV-GP and mRNA-1469. The trial is sponsored by the University of Antwerp (Belgium) and the INRB (DRC). Many organisations, including MSF and Epicentre, are collaborating on its implementation. Financing is provided by CEPI, among others, while MSF is using the organisation's own funding and operational capacity to support the trial. The trial started in October 2026.

In parallel, Africa CDC and the DRC government have launched an Ervebo vaccination campaign, outside these studies, targeting both affected provinces and at-risk areas.

Snapshot of clinical research evaluating vaccines against BDBV

	BRAVO STUDY	TUMAINI TRIAL
SPONSORS AND PARTNERS	Sponsored by MSF and Epicentre, in collaboration with partners in DRC.	Led and sponsored by the Institut National de Recherche Biomédicale and the University of Antwerp, in collaboration with multiple partners including MSF (independent funding), with CEPI funding support.
TIMELINE	Launched in September 2026.	Launched in October 2026.
TARGET POPULATION	Up to 20,000 frontline workers.	Contacts of confirmed cases.
WHAT THE TRIAL WILL ASSESS	• Effectiveness of Ervebo against illness and death.	• Immune responses to BDBV-specific vaccine candidates; • Effectiveness of Ervebo and BDBV-specific candidates.
VACCINES CANDIDATES BEING EVALUATED	• **Being evaluated**: Ervebo	• **Being evaluated:** Ervebo • **Expected in November 2026:** ChAdOx1-BDBV-GP and mRNA-1469 • **Expected in 2027:** rVSVΔG-BDBV-GP

Table 1: Overview of the BRAVO study and Tumaini trial

References for this section

1. Africa Centres for Disease Control and Prevention (Africa CDC). *Africa CDC supports the immediate implementation of the DRC Government's decisions to control the 2026 Bundibugyo Ebola emergency*. 10 Aug 2026. Available from: https://africacdc.org/news-item/africa-cdc-supports-the-immediate-implementation-of-the-drc-governments-decisions-to-control-the-2026-bundibugyo-ebola-emergency/
2. Science. *'Mismatched' vaccine being rolled out against Ebola outbreak*. 11 Aug 2026. Available from: https://www.science.org/content/article/mismatched-vaccine-being-rolled-out-against-ebola-outbreak
3. Médecins Sans Frontières (MSF). *MSF launches Ebola disease vaccination study among DRC frontline workers*. 19 Sep 2026. Available from: https://www.msf.org/msf-launches-ebola-vaccination-study-among-drc-frontline-workers
4. Coalition for Epidemic Preparedness Innovations (CEPI). *Final preparations underway for pivotal Phase 2/3 Bundibugyo vaccine trial*. 12 Oct 2026. Available from: https://cepi.net/final-preparations-underway-pivotal-phase-23-bundibugyo-vaccine-trial

Inclusion of pregnant women and children in vaccination studies

As data from the current outbreak indicate high fatality risk of Bundibugyo virus disease among pregnant women and children, MSF has called for these groups to be actively included in all clinical research. Pregnant and breastfeeding women are eligible to participate in both BRAVO and Tumaini. Children are not included in BRAVO, which enrols only frontline workers. The orthoebolavirus current Tumaini protocol allocates children aged 1 to 12 years to a dedicated study arm evaluating Ervebo, which has a well-established safety profile in this age group.

Reference for this section

1. Russell N, Thomson J, Coldiron M, et al. An urgent opportunity to ensure children's access to oral post-exposure prophylaxis trials for Bundibugyo virus disease. *Lancet Child Adolesc Health*. 2026;10(11):780-781. doi: https://doi.org/10.1016/S2352-4642(26)00238-5

BDBV vaccine candidates and access considerations

Ervebo (rVSVΔG-ZEBOV-GP)

Ervebo (rVSVΔG-ZEBOV-GP) is currently the only licensed orthoebolavirus vaccine on the market. The other licensed vaccine regimen, Zabdeno/Mvabea, has been discontinued by its supplier due to commercial reasons. Ervebo was approved in 2019 to prevent disease caused by EBOV, following the demonstration of its safety and efficacy in the "*Ebola ça suffit*" ring vaccination trial in Guinea in 2015.

Emerging evidence suggests that Ervebo may provide some cross-protection against BDBV. Animal studies have shown improved survival among vaccinated animals, while analyses of blood samples from previously vaccinated individuals have detected antibodies against BDBV, although at lower levels than against EBOV.

Additionally, more than 365,000 individuals, including tens of thousands of frontline workers, were vaccinated with Ervebo in the eastern DRC (North Kivu and Ituri) between 2018 and 2024. This allows researchers to assess whether past vaccination with Ervebo confers some protection against BDBV during the current outbreak. Retrospective studies are underway, and anecdotal evidence suggests possible protection against death.

Following a meeting in July 2026, the WHO TAG-CVP recommended that Ervebo be evaluated against BDBV in a Phase 3 trial. Currently, it is being assessed through the BRAVO observational study and the Tumaini Phase 3 trial, while also being used under a compassionate-use framework in vaccination campaigns led by Africa CDC and the DRC government in affected provinces and at-risk areas.

- **IP, licensing and regulatory status**

The rVSVΔG-ZEBOV-GP vaccine was originally developed by the Public Health Agency of Canada (PHAC). The broad patent, filed by the Canadian Government, covered vaccines against viral haemorrhagic fevers using recombinant vesicular stomatitis virus (rVSV) as a vector. Patent protection was sought and obtained in several high-income jurisdictions, including the United States, Canada, Australia and the European Union. The patent reportedly expired in 2023 in major jurisdictions.

In 2010, Ervebo was licensed to BioProtection Systems (BPS) for potential payments of up to CA$205,000 per licensed product, including royalties on sales. Following the acquisition of BPS by NewLink Genetics, no progress was made towards initiating a Phase 1 clinical trial. In 2014, at the outset of the major Ebola outbreak in West Africa, NewLink agreed to sublicense rVSVΔG-ZEBOV-GP to the U.S. corporation Merck and Co. (MSD) for US$50 million, while the extent of its own technical development contribution remains unclear. PHAC retained the right to license the technology to third parties outside the EBOV field. Accordingly, MSD may not hold exclusive rights to the development of an rVSV-based vaccine against BDBV.

- **Funding**

The rVSVΔG-ZEBOV-GP benefited substantially from public funding during early development and even after the vaccine was licensed to private companies in Canada. Between 2014 and 2016, during the West African Ebola outbreak, U.S. government sources provided US$119,355,036 to support the vaccine development. Although the amount invested by MSD and other private actors has not been disclosed, a significant amount of the vaccine R&D costs was covered by public sector grants, particularly those funded by the U.S. government.

More recently, some studies evaluating whether individuals vaccinated with Ervebo develop an immune response against BDBV have been financed through a US$4.17 million grant from CEPI.

- **Manufacturing, storage and supply**

MSD manufactures Ervebo at commercial scale at its plant in Germany. A global emergency stockpile of the vaccine was established in 2021 under the ICG, which decides on allocations. The stockpile is financed by Gavi, with a target size of 500,000 doses. As of 5 October 2026, it contained 336,260 doses of Ervebo. In addition, some high-income countries also hold national stockpiles; in the United States, for example, Ervebo is not commercially marketed but is held in the Strategic National Stockpile. Both MSF and the DRC government have obtained doses of Ervebo from the ICG stockpile for vaccination studies and for the current outbreak response activities, respectively. Doses have also been sent to the sponsors of the Tumaini trial.

Ervebo must be stored frozen between -80°C and -60°C to maintain its shelf life. Once thawed, it can be kept at 2°C to 8°C for up to 14 days. Although the DRC has built up ultra-cold chain capacity during

previous Ebola outbreaks, these requirements may still pose challenges for transport and last-mile delivery.

In 2023, MSD and SK Bioscience signed a contract manufacturing agreement to produce a next-generation EBOV vaccine candidate. Building on Ervebo, MSD, SK Bioscience and Hilleman Laboratories, a Singapore-based not-for-profit organisation, are developing a next-generation vaccine intended to increase manufacturing productivity and thermostability. According to MSD, these improvements may help increase the global vaccine supply, improve vaccine affordability and help expand access. This project has received US$30 million in funding from CEPI in January 2026. MSD has also stated that it will "explore options for making the updated vaccine available to public-sector buyers in low- and middle-income countries at a significantly more affordable price than the current vaccine, reflecting the anticipated reduction in production costs and subject to regulatory review."

- **Pricing**

Gavi pays approximately US$99 per dose to MSD under a global health agreement for the ICG-managed global health emergency stockpile. No commercial price has been publicly disclosed.

References for this section

1. Herder M, Graham JE, Gold R. From discovery to delivery: public sector development of the rVSV-ZEBOV Ebola vaccine. *J Law Biosci*. 2020;7(1):lsz019. doi: https://doi.org/10.1093/jlb/lsz019
2. Médecins Sans Frontières Access Campaign. *The devil is in the details: a new stockpile for Ebola vaccines*. 14 Jan 2021. Available from: https://msf-access.medium.com/the-devil-is-in-the-details-a-new-stockpile-for-ebola-vaccines-a3c003be2a65
3. SK bioscience. *SK bioscience announces contract manufacturing agreement with MSD for next-generation Zaire Ebola vaccine candidate*. 8 May 2023. Available from: https://www.skbioscience.com/en/news/news_01_01?mode=2&id=208
4. Coalition for Epidemic Preparedness Innovations (CEPI). *CEPI backs updated Zaire ebolavirus vaccine that aims to improve vaccine affordability and accessibility*. 20 Jan 2026. Available from: https://cepi.net/cepi-backs-updated-zaire-ebolavirus-vaccine-aims-improve-vaccine-affordability-and-accessibility
5. World Health Organization. *WHO Public Assessment Report (WHOPAR) for Ervebo (Ebola Zaire Vaccine [rVSVΔG-ZEBOV-GP, live])*. Updated 18 May 2026. Available from: https://extranet.who.int/prequal/sites/default/files/vwa_vaccine/FVP-P-383_Ebola_1dose_Merck_WHOPAR-2026.pdf
6. World Health Organization. *WHO emergency guidance on the use of licensed Ebola virus vaccine during Bundibugyo virus disease outbreaks*. 28 May 2026. Available from: https://www.who.int/publications/i/item/B09772
7. World Health Organization. *Third meeting of the WHO Technical Advisory Group on candidate vaccine prioritization (TAG-CVP) for Bundibugyo virus disease outbreak response: meeting report*. 7 Aug 2026. Available from: https://www.who.int/publications/i/item/B09865
8. Coalition for Epidemic Preparedness Innovations (CEPI). *New studies test whether existing Ebola vaccines can generate immune responses to Bundibugyo ebolavirus*. 19 Aug 2026. Available from: https://cepi.net/new-studies-test-whether-existing-ebola-vaccines-can-generate-immune-responses-bundibugyo

rVSVΔG-BDBV-GP

Several BDBV-specific vaccine candidates based on the recombinant vesicular stomatitis virus (rVSV) platform, the same platform used for Ervebo, are in development. One of these candidates, rVSVΔG-BDBV-GP, was originally developed at the University of Texas Medical Branch (UTMB) and is now being advanced by the International AIDS Vaccine Initiative (IAVI). The candidate showed promising results in animal studies as early as 2013, when a single dose protected all vaccinated non-human primates against subsequent BDBV challenge.

Despite these encouraging results, the candidate remained at the preclinical stage for more than a decade. The only subsequent study, conducted in 2023, evaluated its use as post-exposure prophylaxis. When the outbreak began in 2026, no clinical-grade doses were available and no Phase 1 trial had been conducted. As a result, rVSVΔG-BDBV-GP will not be among the first BDBV-specific vaccine candidates evaluated in the Tumaini trial.

- **IP, licensing and regulatory status**

The underlying rVSVΔG vector platform was originally developed and patented by PHAC. PHAC subsequently granted IAVI a non-exclusive licence to develop multiple rVSV-based haemorrhagic fever candidates, including Lassa fever, Marburg virus disease and Sudan Ebola virus disease. The intellectual property (IP) related to the platform is distinct from that associated with the BDBV-specific vaccine construct. While IAVI holds a licence to use the rVSVΔG vector platform, the BDBV-specific vaccine candidate was developed by the University of Texas Medical Branch (UTMB), building on earlier work by the National Institute for Allergy and Infectious Diseases (NIAID). In June 2026, IAVI entered into an agreement with UTMB to advance the development of rVSVΔG-BDBV-GP.

Researchers at UTMB and NIAID have disclosed the existence of IP related to this technology. However, the scope and status of any BDBV-specific IP remain unclear, and additional patent applications may be filed as vaccine development progresses.

There is no publicly available information on the exact terms and conditions of IP licensing among UTMB, NIAID and IAVI, making it difficult to assess the implications for downstream access, including in high-risk countries.

Finally, another U.S.-based company, Public Health Vaccines, has also developed a BDBV-specific vaccine using the rVSVΔG vector, although the candidate is less advanced than IAVI's.

- **Funding**

Before 2026, limited information is publicly known about the funding for the development of rVSVΔG-BDBV-GP. In 2026, CEPI awarded two consecutive grants to accelerate its development: US$3.2 million was awarded to IAVI in June and US$8.5 million was awarded to Hilleman Laboratories in July.

- **Manufacturing, storage and supply**

To accelerate the release of clinical trial doses, IAVI and CEPI are collaborating with Hilleman Laboratories, which is already involved in other projects to streamline the manufacturing of Ervebo. CEPI has stated that this collaboration aims to support the rapid and affordable supply of rVSVΔG-BDBV-GP in outbreak-affected countries. However, clinical trial doses are not expected to be available before the end of 2026.

It remains unclear which company will ultimately manufacture rVSVΔG-BDBV-GP and hold the licence for this vaccine. While there are currently no plans to produce rVSVΔG-BDBV-GP in Africa in the short term, IAVI has developed a plan to transfer the production of all its rVSVΔG-vectored vaccines to the Institute Pasteur de Dakar.

Like Ervebo, rVSVΔG-BDBV-GP is expected to require ultra-cold-chain storage (Ervebo must be stored between -80°C and -60°C). As previously noted, Hilleman Laboratories has been working with MSD to develop a thermostable second-generation version of Ervebo that could be stored at 2°C to 8°C. It remains unclear whether these improvements will also be applied to rVSVΔG-BDBV-GP.

- **Pricing**

No price has been published yet, as the vaccine candidate is still in clinical development.

References for this section

1. IAVI. *IAVI and IPD sign agreement formalizing collaboration to advance vaccine development, manufacturing, and access in Africa*. 13 Dec 2024. Available from: https://www.iavi.org/press-release/iavi-and-ipd-sign-agreement-formalizing-collaboration-to-advance-vaccine-development-manufacturing-and-access-in-africa/
2. World Health Organization. *WHO Technical Advisory Group on Candidate Vaccine Prioritization (TAG-CVP): meeting report*. 28 May 2026. Available from: https://www.who.int/publications/i/item/B09771
3. IAVI. IAVI to advance vaccine candidate for Bundibyo virus, receives funding from CEPI. 1 Jun 2026. Available from: https://www.iavi.org/press-release/iavi-vaccine-candidate-bundibugyo-virus-cepi-funding/
4. Coalition for Epidemic Preparedness Innovations (CEPI). *CEPI awards Public Health Vaccines US$1.9m to accelerate Bundibugyo ebolavirus vaccine*. 8 Jun 2026. Available from: https://cepi.net/cepi-awards-public-health-vaccines-us19m-accelerate-bundibugyo-ebolavirus-vaccine
5. Coalition for Epidemic Preparedness Innovations (CEPI). *Hilleman Laboratories to develop and produce CEPI-backed Bundibugyo ebolavirus vaccine doses for clinical trials*. 29 Jul 2026. Available from: https://cepi.net/hilleman-laboratories-develop-and-produce-cepi-backed-bundibugyo-ebolavirus-vaccine-doses-clinical

ChAdOx1-BDBV-GP

ChAdOx1-BDBV-GP is a BDBV-specific adenovirus-vectored vaccine candidate developed by the University of Oxford in collaboration with the Serum Institute of India (SII). It is currently being evaluated in a Phase 1 clinical trial involving healthy volunteers, while animal studies are assessing its efficacy against BDBV.

It remains unclear whether ChAdOx1-BDBV-GP will be suitable as a single-dose vaccine or whether two doses will be required. The ChAdOx1-vectored vaccine for COVID-19, known under the brand names CoviShield and Vaxzevria, was approved as a two-dose vaccine. Additionally, a ChAdOx1 vaccine candidate against EBOV provided only moderate protection after a single dose in a non-human primate study.

Assuming the animal studies and Phase 1 trial are successful, ChAdOx1-BDBV-GP is expected to be evaluated in the Tumaini vaccine trial shortly.

- **IP, licensing and regulatory status**

The vaccine candidate is based on the University of Oxford's ChAdOx1 platform. The vector platform is protected by at least one patent filed by Oxford University Innovation (formerly Isis Innovation), with an expiry date around 2032. No publicly available patent filings have been disclosed specifically for ChAdOx1-BDBV-GP.

There is no publicly available information on the terms and conditions of the licensing agreement between the University of Oxford and SII.

- **Funding**

The ChAdOx1 vector technology was developed prior to the COVID-19 pandemic and benefited from substantial public investment. Records from the University of Oxford indicate that more than £104 million (close to US$140 million) of funding was invested in the platform during and after the COVID-19 pandemic, with more than 97% funding provided by public and philanthropic sectors. Following the BDBV outbreak, CEPI awarded an US$8.6 million grant to SII and the University of Oxford to accelerate the release of clinical trial doses of ChAdOx1-BDBV-GP.

- **Manufacturing, storage and supply**

During the COVID-19 pandemic, SII gained experience in producing ChAdOx1 vaccines at scale. Clinical-trial doses of ChAdOx1-BDBV-GP are already available and, as of September 2026, 620,000 doses had been stockpiled.

Cold-chain requirements are generally less demanding for ChAdOx1-vectored vaccines than for rVSV-vectored vaccines. ChAdOx1-BDBV-GP is therefore expected to be stored and transported using a conventional cold chain at 2°C to 8°C.

- **Pricing**

No price has been published yet, as the vaccine candidate is still in clinical development.

References for this section

1. Cross S, Rho Y, Reddy H, Pepperrell T, Rodgers F, Osborne R, et al. Who funded the research behind the Oxford–AstraZeneca COVID-19 vaccine? *BMJ Glob Health*. 2021;6(12):e007321. doi: https://doi.org/10.1136/bmjgh-2021-007321
2. World Health Organization. *WHO Technical Advisory Group on Candidate Vaccine Prioritization (TAG-CVP): meeting report*. 28 May 2026. Available from: https://www.who.int/publications/i/item/B09771
3. Coalition for Epidemic Preparedness Innovations (CEPI). *CEPI-backed Bundibugyo ebolavirus vaccine trial launched by Oxford*. 12 Jul 2026. Available from: https://cepi.net/cepi-backed-bundibugyo-ebolavirus-vaccine-trial-launched-oxford

mRNA-1469

mRNA-1469 is a BDBV-specific mRNA vaccine candidate being developed by Moderna. It is currently being evaluated in a Phase 1 clinical trial involving healthy volunteers. Animal studies are also being conducted to evaluate its efficacy against BDBV.

It remains unclear whether mRNA-1469 will be suitable as a single-dose vaccine or whether it will require two doses.

If the animal studies and Phase 1 trial are successful, mRNA-1469 is expected to be evaluated in the Tumaini vaccine trial shortly.

- **IP, licensing and regulatory status**

The U.S.-based corporation Moderna retains full control over the development of mRNA-1469. No IP licensing or technology transfer arrangements specific to this vaccine or other orthoebolavirus mRNA vaccine candidates have been announced.

Other mRNA vaccine platforms are also being developed. The Global mRNA Technology Transfer Programme, established by the Medicines Patent Pool, is building mRNA vaccine-production capacity in

middle-income countries. Some programme participants have announced plans to develop mRNA vaccine candidates against BDBV. However, these candidates are at a much earlier stage of development than mRNA-1469 and are therefore beyond the scope of this brief.

- **Funding**

Moderna's vaccine programme for orthoebolaviruses and other emerging infectious diseases predates the current BDBV outbreak. In 2026, CEPI significantly increased its funding to Moderna by providing US$50 million to support the development of mRNA-1469. This funding will cover preclinical activities, a Phase 1 clinical trial and manufacturing.

- **Manufacturing, storage and supply**

The mRNA platform offers the potential advantage of rapid production. However, manufacturing of Moderna's vaccine products remains concentrated in a limited number of facilities. Moderna's plans to establish manufacturing facilities in Kenya have not yet materialised.

The company has announced that it will supply at least 500,000 doses of mRNA-1469 to low- and middle-income countries under 'access pricing'. However, no further details on this pricing model have been made publicly available.

mRNA vaccines usually require storage at frozen temperatures. Although the thermostability profile of RNA-1469 vaccine is not yet known, it will probably need to be stored at -20°C or even lower temperatures.

- **Pricing**

No price has been published yet, as the vaccine candidate remains in clinical development.

References for this section

1. Coalition for Epidemic Preparedness Innovations (CEPI). *Moderna's Bundibugyo ebolavirus vaccine candidate enters first human trial, backed by CEPI*. 3 Aug 2026. Available from: https://cepi.net/modernas-bundibugyo-ebolavirus-vaccine-candidate-enters-first-human-trial-backed-cepi
2. TechTimes. *Moderna's mRNA Ebola Vaccine Enters Human Trials: Platform Speed Meets Cold-Chain Wall in Ituri*. 4 Aug 2026. Available from: https://www.techtimes.com/articles/323044/20260804/modernas-mrna-ebola-vaccine-enters-human-trials-platform-speed-meets-cold-chain-wall-ituri.htm

Conclusions and access priorities

Urgently prioritise Ervebo supply for outbreak response: Ongoing manufacturing constraints could further limit the availability of Ervebo at a time when vaccine doses are urgently needed to interrupt transmission in countries facing active outbreaks.

→ MSF calls on MSD to allocate all Ervebo doses released in the coming months to the ICG/UNICEF stockpile to support evaluation and use in the DRC and other countries experiencing ongoing transmission.

→ MSF also calls on high-income countries to refrain from stockpiling or reserving doses beyond their immediate public health needs, so that limited supplies reach countries facing active outbreaks.

Strengthen transparency and accountability: Little information is publicly available on post-trial access**,** including pricing, supply and licence agreements. Given the significant public funding invested in their development, funders and governments must require enforceable access conditions. MSF calls on funders to attach transparent and enforceable access conditions to public funding of BDBV vaccine candidates, so that any successful candidate is affordable and accessible. These conditions should cover pricing (not-for-profit or cost-plus), registration of products in the region, transparency on R&D and manufacturing costs, licensing, technology transfer and supply.

- → MSF further calls on funders to include march-in-rights clauses in their funding contracts in case the license holder does not comply with the required access terms. Funders should also publish the access terms agreed with grantees.
- → MSF calls on developers to disclose IP licensing terms, and not to apply for or enforce IP in countries where clinical trials are conducted or that face high risks of filovirus outbreaks.

Ensure affordability and equitable access: The only Ebola vaccine currently available is priced at US$99 per dose. This very high price should not be repeated for future BDBV vaccines but avoiding this outcome requires deliberate action from manufacturers, research institutes and funders.

- → MSF calls on CEPI and other funders to require future manufacturers to commit to affordable, transparent and sustainable pricing, informed by public disclosure of R&D and manufacturing costs. Governments that support CEPI should also include these requirements a condition of their funding contributions to ensure that successful vaccine candidates are accessible through global stockpiles and direct procurement by outbreak-affected countries and humanitarian organisations.
- → MSF calls on procurement agencies to establish clear affordability and pricing transparency requirements in procurement agreements with existing vaccine manufacturers, such as MSD for Ervebo, and future BDBV vaccine manufacturers, to ensure improved access for countries at risk of outbreaks and humanitarian organisations.

Accelerate the development of thermostable vaccines: Most of the vaccine candidates require complex cold chains, which may affect their deployment during outbreaks.

- → MSF calls on vaccine developers and funders to evaluate and incorporate existing technologies to improve thermostability of BDBV vaccines to enhance the usability of BDBV vaccines, with the aim of enabling storage at 2°C to 8°C, as is the case for most other vaccines.

Ensure sustained funding beyond outbreaks: The current BDBV outbreak has triggered a significant increase in funding for BDBV vaccine development. However, sustained funding for EDV and VHF research is also needed between outbreaks.

- → MSF calls on CEPI, other R&D funders and governments to ensure continued funding for EVD and VHF vaccines outside outbreak periods to advance research, strengthen preparedness for future outbreaks and improve product availability.

Enhance regional R&D and manufacturing capacity: Regional R&D and vaccine manufacturing capacity remains limited in Africa, leaving outbreak-affected countries dependent on external manufacturers.

→ MSF calls on developers and funders to strengthen partnerships with regional research institutions and support geographically diversified manufacturing capacity of EVD vaccines, including through licensing and technology transfers with qualified manufacturers in Africa, with provisions to ensure timely supply during outbreaks.

From reactive response to equitable access

The BDBV vaccines access gaps identified in this brief, including limited transparency around intellectual property and licensing arrangements, uncertainties related to pricing, manufacturing and supply, and the absence of clear and enforceable access commitments, reflect broader systemic challenges in ensuring timely and equitable access to medical tools needed for Ebola disease caused by BDBV. These challenges are closely linked to how research, development and deployment are prioritised, financed and governed.

In our statement, *Principles for equitable access to medical tools for Ebola disease caused by Bundibugyo virus,* MSF Access calls for a framework to strengthen access conditions and ensure preparedness is embedded throughout R&D and deployment processes.

At a glance: potential BDBV vaccine candidates

	MSD **ERVEBO**	IAVI **rVSVΔG-BDBV-GP**	Oxford/SII **ChAdOx1-BDBV-GP**	Moderna **mRNA-1469**
CLINICAL RESEARCH FOR BDBV	**Tumaini trial**: Phase 2/3 to start in November **BRAVO study** (launched)	Phase 1 not started.	**Tumaini trial**: Phase 2/3 to start in November	**Tumaini trial**: Phase 2/3 to start in November
PUBLIC AND PHILANTHROPIC INVESTMENT	**$$$** Extensive public funding for early development, over **US$119** million from the US government.	**$**$$ **US$11.7** million from CEPI for vaccine development and manufacturing readiness.	**$**$$ **US$8.6** million from CEPI, building on a largely publicly and philanthropically funded Oxford vaccine platform.	**$$**$ **US$50** million from CEPI for preclinical development, Phase 1 trials and manufacturing.
REGULATORY STATUS	Licensed for EBOV prevention only.	Investigational.	Investigational.	Investigational.
EXPECTED REGIMEN	**1** dose	**1** dose (most likely)	**1** or **2** doses (TBD)	**1** or **2** doses (TBD)
COLD-CHAIN REQUIREMENTS	❄❄❄ **-70°C** Ultra-cold chain	❄❄❄ **-70°C** Ultra-cold chain anticipated	❄❄❄ **2-8°C** Conventional cold chain anticipated	❄❄❄ **-20°C** Frozen storage anticipated
INTELLECTUAL PROPERTY	Patent reportedly expired in 2023 in major jurisdictions.	Patent scope and status unclear.	No BDBV-specific patents publicly identified.	No BDBV-specific patents publicly identified.
AVAILABILITY / STOCKPILE STATUS	**Stockpile**: 336.260 doses in ICG. Significant number of believed to be in USG national stockpile. Exact number unknown.	**Not available**: No dose expected before Dec 2026.	**Available**: 620,000 doses	**Availability unknown** **Target**: 500,000 doses
PRICING COMMITMENTS	**$$$** US$99/dose Potential price reductions if manufacturing is streamlined.	❌ No price announced Commitment to "*affordable supply in outbreak-affected countries*".	❌ No price announced Commitment to "*affordable supply to affected countries*".	❌ No price announced Commitment to "*access pricing*".
REGIONAL MANUFACTURING IN AFRICA	No announced plans.	Potential collaboration with IPD and IAVI. Status unclear.	No announced plans.	No announced plans. No further update on Moderna's collaboration with Kenya.

Table 2: Overview of BDBV vaccine candidates and access considerations