



Johnson & Johnson Joins World Health Organization in Efforts to Prevent Spread of Ebola in West Africa

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Up to 200,000 Johnson & Johnson Ebola vaccine regimens will be made available as part of a WHO early access clinical program now underway in Sierra Leone

Company's Ebola vaccine regimen also receives Prequalification from the WHO

The Johnson & Johnson vaccine regimen is designed to be used proactively to induce immunity against Ebola in adults and children

NEW BRUNSWICK, N.J., May 13, 2021 /PRNewswire/ -- Johnson & Johnson (NYSE: JNJ) (the Company) today announced the World Health Organization (WHO) and the government of Sierra Leone have begun administering the Company's Ebola vaccine regimen as part of a WHO early access clinical program aimed at preventing further spread of Ebola in West Africa. The vaccine regimen, developed by the Janssen Pharmaceutical Companies of Johnson & Johnson (Janssen) in collaboration with Bavarian Nordic A/S, is being donated to the WHO by Janssen for the purposes of the early access clinical program. Johnson & Johnson also announced that its Ebola vaccine regimen has received Prequalification from the WHO, which will help accelerate its registration in countries where Ebola is a persistent public health threat and facilitate broader access to people at risk of exposure to this virus.

Health authorities in Guinea officially declared a new Ebola outbreak in February 2021 after the West African country experienced its first cases of disease since the end of the 2014-2016 Ebola outbreak – which was the worst on record. Preliminary data obtained through genetic sequencing suggest that the new outbreak was caused by the same virus strain also responsible for the 2014-2016 outbreak and was likely reintroduced by a survivor. The continuation of the outbreak, which has caused at least 23 cases and 12 deaths, and the persistence of Ebola virus in human and animal hosts underscores the importance of proactive vaccination efforts to prevent the further spread of the virus and to be prepared for potential new outbreaks in the future.

"Johnson & Johnson's vision is to help prevent Ebola outbreaks before they start. WHO Prequalification of our vaccine regimen and the deployment to West Africa are important steps forward in reaching this goal and an important milestone for epidemic preparedness," said Paul Stoffels, M.D., Vice Chairman of the Executive Committee and Chief Scientific Officer of Johnson & Johnson. "By working closely with the WHO and national governments, we will be able to quickly support efforts to protect populations at risk and help end this latest outbreak. This proactive approach is essential if we are to solve the growing threat of infectious diseases, including Ebola."

Johnson & Johnson is grateful to its global strategic partners who have helped to support and co-fund the Ebola vaccine regimen, including Bavarian Nordic A/S, the Biomedical Advanced Research and Development Authority (BARDA) and the National Institutes of Health (NIH) at the U.S. Department of Health and Human Services (HHS), and the Innovative Medicines Initiative (IMI) funded through the EU Horizon 2020 program.

WHO Early Access Clinical Program

Administration of the Johnson & Johnson Ebola vaccine regimen in West Africa will be directed by the WHO and national governments in accordance with the protocol for the early access clinical program, which incorporates [interim 2019 recommendations](#) from the WHO's Strategic Advisory Group of Experts on Immunization (SAGE). The goal of the initiative is to establish a protective geographic barrier against the spread of Ebola beyond Guinea, beginning in the neighboring nation of Sierra Leone. The program administered its first doses of the Johnson & Johnson Ebola vaccine regimen this week in Sierra Leone's Kambia District, and is expected to expand to additional countries in the region as local preparations are completed.

The early access clinical program plans to administer the vaccine to up to 200,000 individuals beginning with health workers, other frontline workers and others at increased risk of exposure to the Ebola virus (adults and adolescents 14 years and above on a case-by-case basis or depending on national regulations). Pregnant women and HIV-positive adults who are otherwise healthy are permitted to enroll in the program.

Sierra Leone has prior experience administering the Johnson & Johnson Ebola vaccine. In 2015, during the West African epidemic, the country's Ministry of Health and the College of Medicine and Allied Health Sciences (COMAHS) at the University of Sierra Leone collaborated with Johnson & Johnson on the first clinical study of the vaccine in an Ebola-affected country ("EBOVAC-Salone"), which took place in Sierra Leone's Kambia district.

"We are moving with urgency and purpose to bring all of our available resources to help prevent the spread of this latest Ebola outbreak in Guinea," said Ruxandra Draghia-Akli, M.D., Ph.D., Global Head, Global Public Health Research & Development, Johnson & Johnson. "We believe that, through the preventive use of Ebola vaccines, the global health community can help protect vulnerable communities living under the threat of this disease."

WHO Prequalification

The Johnson & Johnson Ebola vaccine regimen, Zabdeno® (Ad26.ZEBOV) and Mvabea® (MVA-BN-Filo), was granted WHO Prequalification in April 2021. This follows [Marketing Authorisation](#) for the vaccine which was granted by the European Commission in July 2020 for the active immunization for the prevention of Ebola Virus Disease caused by the *Zaire ebolavirus* species in individuals aged one year and above. Both WHO Prequalification and the European Commission authorization were supported by a multi-country clinical program, including 15 clinical studies sponsored by Janssen across three continents. Discussions are ongoing with the U.S. Food and Drug Administration regarding the approval of the vaccine regimen in the U.S.

WHO Prequalification is often a prerequisite for national registrations of new vaccines and medicines in developing countries. Johnson & Johnson now looks forward to collaborating with the WHO's African Vaccine Regulatory Forum (AVAREF) to progress national registrations of the Company's Ebola vaccine regimen. The Company's Ebola vaccine regimen is designed to be used proactively to induce immunity against Ebola virus disease in adults and children.

Johnson & Johnson's Commitment to Ebola & Pandemic Preparedness

Johnson & Johnson is one of the few innovative healthcare companies in the world today that is actively advancing science across multiple disease areas with the aim of strengthening public health.

We accelerated the development of our Ebola vaccine regimen in 2014 in response to the worst Ebola outbreak on record, which took place in West Africa from 2014-2016 and caused more than 11,000 deaths. In 2019, in response to the second-worst outbreak which took place 2018-2020 in the Democratic Republic of the Congo (DRC), Johnson & Johnson announced it would provide its Ebola vaccine regimen to assist immunization efforts in the affected region and in [neighboring Rwanda](#) through the UMURINZI vaccination campaign. This marked the first widespread deployment of Ebola vaccines in an outbreak setting.

The Rwandan Ministry of Health continues to administer the vaccine regimen through the UMURINZI campaign, which recently achieved the milestone of reaching 200,000 individuals who are at risk of exposure to Ebola. To date, more than 225,000 individuals participating in clinical trials and vaccination initiatives have received at least the first dose of the Johnson & Johnson Ebola vaccine regimen, including 180,000 who have been fully vaccinated.

Johnson & Johnson Ebola Vaccine Regimen

The European Commission-approved Johnson & Johnson preventive Ebola vaccine regimen, Zabdeno[®] (Ad26.ZEBOV) and Mvabea[®] (MVA-BN-Filo), utilizes a non-replicating viral vector strategy in which viruses – in this case adenovirus serotype 26 (Ad26) and Modified Vaccinia Virus Ankara (MVA) – are genetically modified so that they cannot replicate in human cells. In addition, these vectors carry the genetic code of several Ebola virus proteins in order to trigger an immune response. The Ebola vaccine regimen was developed and is manufactured using Janssen's proprietary [AdVac[®] technology](#).

Johnson & Johnson's Ebola vaccine regimen originates from a collaborative research program with the NIH and received direct funding and preclinical services from the National Institute of Allergy and Infectious Diseases, part of NIH, under Contract Number HHSN272200800056C. Further funding for the Ebola vaccine regimen has been provided in part with federal funds from the Office of the Assistant Secretary for Preparedness and Response, BARDA under Contract Numbers HHSO100201700013C and HHSO100201500008C.

The IMI provided funding through the IMI Ebola+ Programme to support a number of consortia that initiated multiple clinical trials and other vaccine development activities. The consortia funded by the Innovative Medicines Initiative 2 (IMI2) Joint Undertaking are EBOVAC1 (grant nr. 115854), EBOVAC2 (grant nr. 115861), EBOVAC3 (grant nr. 800176), EBOMAN (grant nr. 115850) and EBODAC (grant nr. 115847). This Joint Undertaking receives support from the EU's Horizon 2020 Framework Programme for Research and Innovation and the European Federation of Pharmaceutical Industries and Associations (EFPIA).

Johnson & Johnson also acknowledges its many strategic partners in the ongoing global clinical program for the vaccine regimen, including Bavarian Nordic A/S, Centre Muraz, Coalition for Epidemic Preparedness Innovations (CEPI), College of Medicine and Allied Health Sciences (COMAHS, University of Sierra Leone), Democratic Republic of the Congo Ministry of Public Health, Republic of Rwanda Ministry of Health and Rwanda Biomedical Center, Emory University's Project San Francisco (Kigali) / Center for Family Health Research, Emory University, Epicentre, Grameen Foundation, Inserm, Inserm Transfert, Institut National de Recherche Biomédicale (INRB), London School of Hygiene & Tropical Medicine (LSHTM), Médecins Sans Frontières (MSF), Rinda Ubuzima, Sierra Leone Ministry of Health and Sanitation, Uganda Virus Research Institute (UVRI), Université de Kinshasa (UNIKIN), University of Antwerp, University of Oxford, Walter Reed Army Institute of Research (WRAIR), World Health Organization, World Vision Ireland, Wellcome Trust, Vibalogics, and all the people who have participated in the Ebola vaccine clinical trials.

Learn more at www.JNJ.com/Ebola.

About Johnson & Johnson

At Johnson & Johnson, we believe good health is the foundation of vibrant lives, thriving communities and forward progress. That's why for more than 130 years, we have aimed to keep people well at every age and every stage of life. Today, as the world's largest and most broadly-based healthcare company, we are committed to using our reach and size for good. We strive to improve access and affordability, create healthier communities, and put a healthy mind, body and environment within reach of everyone, everywhere. We are blending our heart, science and ingenuity to profoundly change the trajectory of health for humanity. Learn more at www.jnj.com. Follow us at [@JNJNews](#).

About the Janssen Pharmaceutical Companies of Johnson & Johnson

At Janssen, we're creating a future where disease is a thing of the past. We're the Pharmaceutical Companies of Johnson & Johnson, working tirelessly to make that future a reality for patients everywhere by fighting sickness with science, improving access with ingenuity, and healing hopelessness with heart. We focus on areas of medicine where we can make the biggest difference: Cardiovascular & Metabolism, Immunology, Infectious Diseases & Vaccines, Neuroscience, Oncology, and Pulmonary Hypertension. Learn more at www.janssen.com. Follow us at [@JanssenGlobal](#).

Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding a program related to the Johnson & Johnson Ebola Vaccine Regimen. The reader is cautioned not to rely on these forward-looking statements. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or known or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of the Janssen Pharmaceutical Companies, and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges and uncertainties inherent in product research and development, including the uncertainty of clinical success and of obtaining regulatory approvals; uncertainty of commercial success; manufacturing difficulties and delays; competition, including technological advances, new products and patents attained by competitors; challenges to patents; product efficacy or safety concerns resulting in product recalls or regulatory action; changes in behavior and spending patterns of purchasers of health care products and services; changes to applicable laws and regulations, including global health care reforms; and trends toward health care cost containment. A further list and descriptions of these risks, uncertainties and other factors can be found in Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended January 3, 2021, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in the company's most recently filed Quarterly Report on Form 10-Q, and the company's subsequent filings with the Securities and Exchange Commission. Copies of these filings are available online at www.sec.gov, www.jnj.com or on request from Johnson & Johnson. None of the Janssen Pharmaceutical Companies nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.



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