



## News Release

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## Johnson & Johnson Announces European Commission Approval for Janssen's Preventive Ebola Vaccine

*This marks the first major regulatory approval of a vaccine developed by Janssen*

*The Ebola vaccine regimen leverages Janssen's AdVac® technology, plus Bavarian Nordic's established MVA-BN® technology*

*Janssen's AdVac® technology is also being used to develop a vaccine candidate to prevent COVID-19*

**NEW BRUNSWICK, N.J., 1 July 2020** – Johnson & Johnson today announced that the European Commission (EC) has granted Marketing Authorisation for its Janssen Pharmaceutical Companies' Ebola vaccine regimen for the prevention of Ebola Virus Disease. Enabled by this approval, Janssen is now collaborating with the World Health Organization (WHO) on vaccine pre-qualification, which should help accelerate registration of its preventive Ebola vaccine regimen in African countries and facilitate broader access to those most in need.

Two Marketing Authorisation Applications (MAAs) were submitted to the European Medicines Agency (EMA) for the vaccines composing the two-dose regimen, Zabdeno® (Ad26.ZEBOV) and Mvabea® (MVA-BN-Filo). Marketing Authorisation under exceptional circumstances has been granted following Accelerated Assessment of the MAAs and a positive opinion by the EMA's Committee for Medicinal Products for Human Use (CHMP). Janssen's Ebola vaccine regimen is indicated for active immunization for the prevention of Ebola Virus Disease caused by the *Zaire ebolavirus* species in individuals aged one year and above.

"The European approval of Janssen's Ebola vaccine regimen is a landmark moment – both for our Company and in the world's battle against the deadly Ebola virus. Building on our history, we are committed to bringing forward vaccines to help overcome the threat of some

of the world's most life-threatening infectious diseases," said Paul Stoffels, M.D., Vice Chairman of the Executive Committee and Chief Scientific Officer of Johnson & Johnson.

The worst Ebola outbreak to date was the West African epidemic, which caused nearly 30,000 cases and more than 11,000 deaths in 2014-2016.<sup>1</sup> The world's second worst Ebola outbreak on record began in the Democratic Republic of the Congo (DRC), in 2018. It has since caused more than 3,000 cases and over 2,000 deaths – a mortality rate of 65 percent.<sup>2</sup>

"The approval of our Ebola vaccine symbolizes the progress Janssen has made towards achieving our vision of delivering potentially transformational vaccines to communities most at risk of deadly infectious diseases. Not only is it the first vaccine to emerge from our vaccines pipeline, it is also the first approved vaccine to be developed using Janssen's AdVac<sup>®</sup> technology. The same technology is being used to develop vaccine candidates to protect against SARS-CoV-2, as well as Zika, RSV and HIV," said Mathai Mammen, M.D., Ph.D., Global Head, Janssen Research & Development, LLC.

Janssen's Ebola vaccine regimen is specifically designed to induce long-term immunity against the Ebola virus<sup>3,4</sup> in adults and children aged one year and above. As such, it will be used to support preventive vaccination in countries most at risk of outbreaks, as well as for other at-risk groups such as healthcare workers, biosafety level 4 (BSL4) laboratory workers, military personnel deployed in the affected regions, airport staff and visitors to high-risk countries.

The regimen includes Ad26.ZEBOV as the first dose, based on Janssen's AdVac<sup>®</sup> viral vector technology,<sup>5</sup> and MVA-BN-Filo as the second dose, based on Bavarian Nordic's MVA-BN<sup>®</sup> technology, administered approximately eight weeks later.<sup>6</sup>

"I am enormously grateful for the dedication from everyone who has been a part of this development, including our many global strategic partners for their extraordinary commitment to helping make this regimen a reality," said Johan Van Hoof, M.D., Managing Director, Janssen Vaccines and Prevention B.V. "The devastating 2014 outbreak of Ebola in West Africa grew exponentially, overwhelming healthcare systems. In less than six years, with the strength of global public-private collaborations, we have an approved Ebola vaccine which could help those most in need, with the ultimate goal of preventing outbreaks before they start."

Janssen supported vaccination initiatives in the DRC and neighboring Rwanda, with the goal of preventing Ebola's geographic spread beyond the outbreak zone. When considering both clinical studies and vaccination initiatives, approximately 60,000 people have been vaccinated with Janssen's preventive Ebola vaccine regimen to date.<sup>7</sup> Janssen-sponsored Phase 1 studies have been reported in peer-reviewed journals including *JAMA*<sup>3,8</sup> and the *Journal of Infectious Diseases*,<sup>9,10</sup> and Phase 1, 2 and 3 data were presented at the 2019 European Congress of Clinical Microbiology & Infectious Disease (ECCMID).<sup>4,6,11</sup> These studies indicate that the vaccine regimen is well tolerated, inducing robust and durable immune responses to the *Zaire ebolavirus* species. The evaluation of the protective effect of the vaccine regimen was demonstrated through the bridging of clinical immunogenicity results to efficacy and immunogenicity data obtained in non-human primates (NHP).<sup>12</sup>

In May 2019, the WHO's Strategic Advisory Group of Experts (SAGE) on immunization recommended the use of the Janssen Ebola vaccine regimen as part of efforts to contain the DRC outbreak<sup>13</sup> and more than 50,000 people in the DRC<sup>14</sup> and Rwanda<sup>15</sup> have been vaccinated to date through this initiative alone.<sup>7</sup>

Johnson & Johnson has made a significant investment in the Ebola vaccine regimen since its decision to accelerate the development program in 2014 in response to the Ebola crisis in West Africa. The Company is grateful to its global strategic partners who have helped to support and co-fund these efforts, including Bavarian Nordic A/S, the Biomedical Advanced Research and Development Authority (BARDA), part of the Office of the Assistant Secretary for Preparedness and Response at the U.S. Department of Health and Human Services (HHS), the Innovative Medicines Initiative (IMI) funded through the EU Horizon 2020 program, and the National Institutes of Health (NIH) at the U.S. Department of Health and Human Services (HHS).

### **Regulatory Submissions & Status**

Today's European Commission Marketing Authorisation decision follows the positive opinion in May 2020 from the CHMP of the EMA<sup>16</sup> and the granting of an Accelerated Assessment for Janssen's investigational preventive Ebola vaccine regimen MAAs by the CHMP in September 2019.<sup>17</sup> The MAAs are supported by data from eleven Phase 1, 2 and 3 clinical studies<sup>18</sup> evaluating the safety and immunogenicity (ability to induce an immune response) of the vaccine regimen in more than 6,500 adults and children aged one year and above across the U.S., Europe and Africa,<sup>18</sup> preclinical studies, and immunobridging analyses comparing the results of clinical and preclinical efficacy studies.

Discussions with the U.S. Food and Drug Administration (FDA) have taken place to define the required data set for filing US licensure.

### **About Janssen's Ebola Vaccine Regimen**

The Janssen preventive Ebola vaccine regimen, Ad26.ZEBOV and 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.

Janssen's 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, College of Medicine and Allied Health Sciences (COMAHS, University of Sierra Leone), Grameen Foundation, Inserm, Inserm Transfert, London School of Hygiene & Tropical Medicine (LSHTM), Wellcome Trust, Coalition for Epidemic Preparedness Innovations (CEPI), Uganda Virus Research Institute (UVRI), University of Antwerp, University of Oxford,

Université de Kinshasa (UNIKIN), Vibalogics GmbH, Walter Reed Army Institute of Research (WRAIR), World Vision Ireland, The Ministry of Health and Sanitation Sierra Leone, Republic of Rwanda Ministry of Health and the Democratic Republic of the Congo Ministry of Public Health and all the people who participated in clinical trials during the Ebola epidemic in West Africa and the DRC.

### **About the Janssen Pharmaceutical Companies**

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.

Janssen Research & Development, LLC and Janssen Vaccines and Prevention B.V. are members of the Janssen Pharmaceutical Companies of Johnson & Johnson.

Learn more at [www.janssen.com](http://www.janssen.com). Follow us at @JanssenGlobal

### **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](http://www.jnj.com). Follow us at @JNJNews.

### **Notice to Investors Concerning Forward-Looking Statements**

*This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding the EC approval of our 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 December 29, 2019, 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](http://www.sec.gov), [www.jnj.com](http://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.*

## **References**

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