



## Johnson & Johnson Responds to Ebola Crisis With Commitment to Accelerate Vaccine Program in Collaboration With the US National Institutes of Health (NIH) and Provide Humanitarian Relief Aid

September 4, 2014

NEW BRUNSWICK, N.J., Sept. 4, 2014 /PRNewswire/ -- Johnson & Johnson (NYSE: JNJ) today announced it will fast-track the development of a promising new combination vaccine regimen against Ebola and broadly collaborate with its partners in global health to deliver immediate relief aid to address the current Ebola outbreak.

The accelerated vaccine program features a prime-boost regimen, in which one vector is used to prime and the other to boost the immune response. It consists of two vaccine components that are based on AdVac® technology from Crucell N.V. (part of the Janssen pharmaceutical companies of Johnson & Johnson, based in the Netherlands) and the MVA-BN® technology from Bavarian Nordic, (a biotech company, based in Denmark). The program has received direct funding and is also utilizing vaccine preclinical services from the National Institute of Allergy and Infectious Diseases (NIAID), part of National Institutes of Health (NIH). Crucell will bring this development program forward, in close collaboration with Bavarian Nordic and the NIAID, to allow for initiation of a clinical trial of this combined regimen in humans in early 2015.

The company's expedited vaccine development schedule is in response to the current Ebola outbreak in West Africa and is aligned with the [World Health Organization's Ebola Response Roadmap](#), including its call to fast-track access to treatment and vaccine options to address the Ebola virus outbreak.

Johnson & Johnson's multi-pronged approach, as part of their overall commitment to prevent disease in vulnerable populations, includes:

- an intensive review of known pathways in Ebola pathophysiology to determine whether previously tested medicines can be used to help patients survive an Ebola infection, and
- additional support to the non-profit organization Direct Relief International to facilitate the air transport of a variety of infection prevention products to Liberia and Sierra Leone.

"Patients are at the heart of everything we do. Our primary goal in this escalating Ebola epidemic is to assist governments in protecting health care workers, families and populations who are at high risk of being infected with Ebola as soon as possible in an effort to stop the disease from spreading further," said Paul Stoffels, M.D., Chief Scientific Officer of Johnson & Johnson. "With a strong heritage in collaborative partnerships and a proven track record in the rapid development and access of innovative products, we aim to ultimately eradicate deadly diseases like Ebola and save lives around the world."

Crucell and Bavarian Nordic are both currently developing preventive vaccines against filoviruses, including Ebola virus, with direct funding and vaccine preclinical services from NIAID. In addition, the two companies have developed a combination regimen that harnesses the potency of both vaccines and could be used to elicit protective immunity against the Zaïre species of the Ebola virus, which is responsible for the current outbreak in West Africa. The combination vaccine provided complete protection of vaccinated macaques against disease and death after exposure to a highly virulent wildtype Ebola Zaire strain.

Based on these promising results, Bavarian Nordic, Crucell and NIAID intend to advance this development program to allow for initiation of a human trial in early 2015.

The combination regimen uses proven vaccine technology platforms from both companies that have shown to be immunogenic and safe when used in humans for other applications: to date more than 1,000 humans have received Crucell's adeno-platform based vaccine in clinical trials, while Bavarian Nordic's MVA-BN platform is the basis of the smallpox vaccine registered in Canada and Europe and stockpiled in the rest of the world with a safety record of use in more than 7,300 humans. In addition to the clinical advantage of the combination regimen, the collaboration also allows for faster production with each company taking on the production of one element of the combination regimen.

Crucell has been exploring vaccines as well as other related programs targeting diseases with potential widespread social impact in partnership with the NIH since 2002. This new research collaboration for a monovalent vaccine targeting the Zaire strain of the Ebola virus is part of an ongoing development program for a multivalent vaccine against all filoviruses that cause disease in humans, including Ebola and Marburg viruses.

"In light of the current emergency in West Africa and given the evident, huge unmet medical need, we are stepping up our efforts and accelerating the Ebola program currently in pre-clinical development," said Johan Van Hoof, M.D., Global Head, Infectious Diseases and Vaccines, Janssen and Managing Director, Crucell. "We recognize the urgency of the situation and the need to collaborate with multiple partners to develop treatment and preventive solutions for Ebola."

The emergence of Ebola in West Africa has also strained the health care systems of Liberia, Sierra Leone and Guinea. The company's long tradition of disaster response has prompted support of Direct Relief International's efforts in this area. Johnson & Johnson is also participating in the ongoing efforts by public health authorities, including the Centres for Disease Control and the WHO, to mount a coordinated world response to address the immediate needs raised by the Ebola outbreaks.

### **About Ebola**

The Ebola virus belongs to a virus family called Filoviridae and can cause severe hemorrhagic fever in humans and nonhuman primates. Ebola has a mortality rate ranging from 50% to 90% according to the World Health Organization. The virus is highly prioritized by the U.S. Government, who has defined the virus as a "Category A" agent, due to its high mortality rate. Currently, no licensed vaccine, treatment or cure exists for this disease.

### **About Johnson & Johnson**

Caring for the world one person at a time inspires and unites the people of Johnson & Johnson. We embrace research and science - bringing innovative ideas, products and services to advance the health and well-being of people. Our approximately 126,000 employees at more than 270 Johnson & Johnson operating companies work with partners in health care to touch the lives of over a billion people every day, throughout the world.

### **About Crucell**

Crucell is part of the Janssen Pharmaceutical Companies of Johnson & Johnson, and is focused on research development and production of vaccines, proteins and antibodies that prevent and/or treat infectious diseases. Crucell is a major supplier of vaccines to UNICEF and the developing world. Crucell was the first manufacturer to launch a fully-liquid pentavalent vaccine named Quinvaxem®. With this innovation, Crucell has become a major partner in protecting children in developing countries against major infectious diseases. Crucell has a broad development pipeline, with several product candidates based on its unique AdVac® and/or PER.C6® production technology. Crucell licenses its PER.C6® technology and other technologies to the biopharmaceutical industry.

### **About Janssen**

At Janssen, we are dedicated to addressing and solving some of the most important unmet medical needs of our time in infectious diseases and vaccines, oncology, immunology, neuroscience, and cardiovascular and metabolic diseases. Driven by our commitment to patients, we develop innovative products, services and healthcare solutions to help people throughout the world.

*(This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995. 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 unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Crucell N.V. and/or Johnson & Johnson.*

*Risks and uncertainties include, but are not limited to, challenges and uncertainties inherent in product development, including the timeline for the potential availability of a vaccine against Ebola.*

*A further list and description 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, 2013, including in Exhibit 99 thereto, 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 statements as a result of new information or future events or developments.)*

SOURCE Johnson & Johnson

News Provided by Acquire Media