

**Press Contacts:**

Ernie Knewitz  
+1 (732) 524-6623  
+1 (917) 697-2318

Seema Kumar  
+1 (908) 405-1144

Ronan Collins (EU)  
+47 488 425 00

**Investor Contacts:**

Louise Mehrotra  
+1 (732) 524-6491

Lesley Fishman  
+1 (732) 524-3922

## **Johnson & Johnson Announces Start of Clinical Trial of Ebola Vaccine Regimen in Sierra Leone**

*First study of Janssen's prime-boost vaccine regimen in an Ebola outbreak country*

*Study being initiated on parallel track with multiple ongoing Phase I and II studies across U.S., Europe and Africa as part of accelerated development plan for vaccine regimen*

*Milestone reached just one year after Johnson & Johnson announced expanded commitment to combating Ebola*

**NEW BRUNSWICK, N.J., – October 9, 2015** – Johnson & Johnson (NYSE: JNJ) today announced the start of a safety and immunogenicity clinical trial in Sierra Leone of a preventive Ebola vaccine regimen in development at its Janssen Pharmaceutical Companies. Trial recruitment is underway, and the first volunteers have received their initial vaccine dose. This is the first study conducted of Janssen's Ebola prime-boost vaccine regimen in a West African country affected by the recent Ebola epidemic.

The new study, EBOVAC-Salone, will take place in Sierra Leone's Kambia district, where some of the country's most recent Ebola cases have been reported. The regimen being tested uses a combination of two vaccine components based on AdVac® technology from Crucell Holland B.V., one of the Janssen Pharmaceutical Companies, and MVA-BN® technology from Bavarian Nordic. Volunteers in the study will first be given the AdVac dose to prime their immune system, and then the MVA-BN dose is given two months later to boost their immune response, with the goal of potentially strengthening and optimizing the duration of the immunity.

"Never again can Ebola be allowed to cause the human suffering that the world has witnessed in West Africa and we remain committed as ever to help the international community get to combat this disease," said Paul Stoffels, M.D., Chief Scientific Officer and Worldwide Chairman, Pharmaceuticals, Johnson & Johnson. "One of the many lessons learned from the outbreak is we cannot let our guard down with Ebola, and we need to test every promising prevention tool. It is our hope that this study will help to confirm the value of this vaccine regimen in Ebola control efforts – not just for Sierra Leone, but for the world."

Since announcing its commitment to combat Ebola in October 2014, Johnson & Johnson has mobilized significant resources to advance the research and development of an Ebola vaccine regimen with the goal of addressing the urgent public health need of affected countries such as

Sierra Leone. With this goal in mind, in 2015 Janssen developed partnerships and consortia with other companies and research institutions, secured funding from European and U.S. public authorities, and launched multiple Phase I and II studies in rapid succession across the U.S., Europe and Africa. Additionally, Janssen in partnership with Bavarian Nordic, rapidly scaled up production of the vaccine regimen to more than 800,000 regimens, with the capacity to produce a total of 2 million regimens as needed.

Professor Peter Piot, M.D., Director of the London School of Hygiene & Tropical Medicine, which is one of the partners conducting the study, said: "We cannot afford to be complacent about Ebola. We urgently need a vaccine that offers long term protection of the population, including health workers and other care givers, in order to prevent a resurgence of the virus. To achieve this goal, it is vital to test a range of vaccine candidates, particularly in the areas affected by the epidemic where we are still seeing new cases emerging, and there is evidence that the infection may have longer-term effects among survivors. Prime-boost vaccination is an effective strategy for long-term prevention of several infectious diseases, and we believe it may have a key role to play in the fight against Ebola."

The EBOVAC-Salone study is notable in that it will evaluate the vaccine regimen's safety and immune response within the general population of Sierra Leone, including vulnerable groups such as adolescents, children, and people with HIV. In addition to the London School of Hygiene & Tropical Medicine which is coordinating the EBOVAC-Salone trial, Janssen is partnering with Sierra Leone's Ministry of Health and Sanitation, the College of Medicine and Allied Health Sciences, and two consortia of which Janssen is a member that are funded by Europe's Innovative Medicines Initiative (IMI): EBOVAC1 (Ebola Vaccine Development), which is conducting the study, and EBODAC (Ebola Vaccine Deployment, Acceptance & Compliance), which is developing a communication strategy and tools to promote the acceptance and uptake of the Ebola vaccine regimen.

From the outset, the EBOVAC-Salone team's goal has been to conduct a study that meets Sierra Leone's Ebola prevention needs, has the support of the Sierra Leonean people, and can play a sustaining role in helping to restore the country's health infrastructure following the Ebola outbreak. Significant investment has been made to build new facilities in Kambia to conduct the study, which will contribute substantially to the strengthening of the local health system. These include establishing the first Emergency Room at the Kambia District Hospital, and building a new vaccine storage facility on the hospital site. These efforts are complemented by the employment and training of doctors, nurses and other frontline healthcare workers who will gain valuable experience while contributing to the clinical study.

"Defeating this Ebola outbreak has been a long and difficult journey for everybody in Sierra Leone," said Professor Monty Jones, Special Adviser on Ebola to the President of Sierra Leone. Studying vaccines here in Sierra Leone will help us to secure our own future against the disease, and is also a proud contribution from Sierra Leone to the rest of the world."

The EBOVAC-Salone study is being initiated on a parallel track with multiple ongoing Phase I and II studies that are being conducted across the U.S., Europe and Africa as part of the accelerated development plan for the Ebola vaccine regimen. First-in-human Phase I clinical studies of the prime-boost vaccine regimen began in the United Kingdom and United States in January 2015, followed by several sites in Africa. In May 2015, Johnson & Johnson presented promising preliminary data from the UK Phase I study to the U.S. Food and Drug Administration

(FDA). A Phase II study, being carried out in the UK and France, started in July 2015, and a second multi-site Phase II study will shortly commence in several West and East African countries in outside epidemic areas. These Phase II studies are being coordinated by Institut National de la Sante et de la Recherche Medicale (Inserm), another consortium partner with Janssen.

To date, there is no licensed vaccine, treatment or cure for the Ebola virus. The Ebola outbreak in West Africa began in March 2014 and has put the health care systems of Sierra Leone, Liberia and Guinea under tremendous pressure. As of October 2015, over 28,400 people have been infected with the virus across the three countries, and over 11,300 have died – including more than 500 healthcare workers. In Sierra Leone specifically, nearly 14,000 cases of Ebola have been reported and nearly 4,000 people have died.<sup>i</sup>

### **About the EBOVAC-Salome Study**

‘EBOVAC-Salome’ is a clinical trial to assess the safety and immunogenicity of an Ebola prime-boost vaccine regimen among adults, adolescents and children in Sierra Leone who volunteer to participate. Volunteers are planned to enroll in the study at different stages over the course of several months. In stage 1 of the study, approximately 40 adults aged 18 years or older will be vaccinated to gain information about the safety and immunogenicity (immune response) of the prime-boost regimen. In stage 2, a larger group of approximately 400 individuals will be vaccinated to further evaluate the safety and immunogenicity of the vaccine regimen across different age groups. In this stage, adolescents and children will be included. Additional stages are being finalized in consultation with the Sierra Leonean authorities and international health agencies. Further details of the study are posted on [clinicaltrials.gov](http://clinicaltrials.gov).

In January 2015, Europe’s Innovative Medicines Initiative (IMI) awarded a consortia of leading global research institutions and non-government organizations working in conjunction with the Janssen Pharmaceutical Companies grants totaling more than €100 million from the Ebola+ programme to support the development, manufacturing and deployment of the vaccine regimen. Janssen’s EBOVAC1 and EBODAC consortia partners also include the University of Oxford, Inserm, Grameen Foundation and World Vision of Ireland. The Innovative Medicines Initiative 2 Joint Undertaking is under grant agreement EBOVAC1 (grant nr. 115854) and EBODAC (grant nr. 115847), part of the Ebola+ program launched in response to the Ebola virus disease outbreak. This IMI2 Joint Undertaking receives support from the European Union’s Horizon 2020 research and innovation programme and European Federation of Pharmaceutical Industries and Associations (EFPIA).

### **About the Ebola Vaccine Regimen**

Janssen’s investigational Ebola vaccine regimen was discovered in a collaborative research program with the National Institutes of Health (NIH). This program received direct funding and preclinical services from the National Institute of Allergy and Infectious Diseases (NIAID), part of NIH, under Contract Numbers HHSN272200800056C, and HHSN272201000006I and HHSN272201200003I, respectively. The MVA-BN-Filo material used in phase 1 studies was produced under NIAID/Fisher BioServices contract #FBS-004-009 and NIH contract HHSN272200800044C.

In September 2015, Crucell Holland B.V., one of the Janssen Pharmaceutical Companies, was awarded \$28.5 million from The Biomedical Advanced Research and Development Authority

(BARDA), part of the U.S. Department of Health and Human Services, to help accelerate the development of the prime-boost vaccine regimen.

### **About Johnson's & Johnson's Commitment on Ebola**

In addition to accelerating development of the vaccine regimen, Johnson & Johnson engaged in a range of philanthropic efforts to support organizations leading Ebola prevention and control efforts including Direct Relief International, Partners in Health, AmeriCares, IntraHealth and Project HOPE. The company also supports ongoing efforts by public health authorities, including the U.S. Centers for Disease Control and Prevention (CDC) and the World Health Organization (WHO), to mount a coordinated world response to address the immediate needs raised by the Ebola outbreak. As part of its commitment to support nurses, Johnson & Johnson gave an educational grant to Nurse.com to make available to every nurse in the U.S. continuing education resources about Ebola.

### **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 127,000 employees at more than 265 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 Holland B.V. is one of the Janssen Pharmaceutical Companies of Johnson & Johnson, and is focused on research, development and production of vaccines that prevent and/or treat infectious diseases. Crucell has a broad development pipeline, with several product candidates based on its unique AdVac<sup>®</sup> and PER.C6<sup>®</sup> production technology.

### **About the Janssen Pharmaceutical Companies of Johnson & Johnson**

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.

### **Cautions Concerning Forward-Looking Statements**

*(This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995, including regarding development of an Ebola vaccine. 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 development, including the uncertainties of clinical success and the timeline for the availability of a potential vaccine against Ebola; technological advances and new products attained by competitors; the challenges and risks involved in large-scale production of a vaccine; and the uncertainty of the level of demand for 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 undertake to update any forward-looking statements as a result of new information or future events or developments.)*

# # #

---

<sup>i</sup> WHO Ebola Situation Reports. Accessed October 1, 2015. <http://apps.who.int/ebola/ebola-situation-reports>