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Global Public-Private Partnership Announces Publication of Positive Phase 1 Data for Ebola Vaccine Regimen in *JAMA*

First published clinical data show prime-boost Ebola vaccine regimen produced an antibody response in 100 percent of healthy volunteers that was sustained 8 months following immunization

An Ebola vaccine is still urgently needed to address the problem of Ebola persistence in affected countries and to prevent future outbreaks

Partners involved in the clinical program for the Ebola vaccine regimen include the Janssen Pharmaceutical Companies of Johnson & Johnson, the London School of Hygiene & Tropical Medicine, the University of Oxford, Inserm, Bavarian Nordic and Europe's Innovative Medicines Initiative

LONDON, UNITED KINGDOM – April 19, 2016 – A public-private partnership of some of the world's leading health organizations today announced that data from a Phase 1 study of a preventive Ebola vaccine regimen have been published in *JAMA*: *The Journal of the American Medical Association*. The results, the first published on the vaccine regimen, suggest that the regimen was well-tolerated by healthy volunteers and immunogenic (produced an immune response). Among the findings, 100 percent of participants in the study achieved an initial antibody response to Ebola, and this response was sustained 8 months following immunization. The study was led by the Oxford Vaccine Group at the University of Oxford Department of Paediatrics and took place in the United Kingdom.

The Ebola vaccine regimen is being developed by the Janssen Pharmaceutical Companies of Johnson & Johnson, in collaboration with Bavarian Nordic. The regimen was first discovered in a collaborative research program with the U.S. National Institutes of Health (NIH). Clinical studies have been supported by grants awarded by Europe's Innovative Medicines Initiative (IMI) to a consortium of leading global research institutions working with Janssen, which includes the London School of Hygiene & Tropical Medicine, the University of Oxford and Inserm, the French National Institute of Health and Medical Research.

“The Ebola crisis in West Africa left a huge human cost, we continue to see flare-ups of this disease, and the world needs to be far better prepared for the next major outbreak,” said Paul Stoffels, M.D., Chief Scientific Officer and Worldwide Chairman, Pharmaceuticals, Johnson & Johnson. “This study suggests that Janssen’s investigational prime-boost vaccine regimen, if approved by regulators, could be an important tool in global strategies to help prevent another Ebola epidemic.”

The Phase 1 study tested a vaccine regimen containing two components based on, respectively, AdVac® technology from Crucell Holland B.V., one of the Janssen Pharmaceutical Companies, and MVA-BN® technology from Bavarian Nordic A/S. Healthy volunteers were given one vaccine dose to prime their immune system, and then the alternative vaccine to boost their immune response, with the goal of evaluating the duration of immunity. Prime-boost vaccination is an established approach for the prevention of several infectious diseases.

“Recent evidence highlighting the persistence of the Ebola virus in bodily fluids, and the potential for sexual transmission from Ebola survivors, reinforce the importance of finding a robust and durable vaccine for this disease,” said Dr. Matthew Snape of the Oxford Vaccine Group and the study’s lead author. “These results show that an initial immune response with AdVac immunization is enhanced by MVA-BN boosting, generating sustained immunity that has the potential to provide durable protection from Ebola in at-risk populations.”

In the study, most participants were randomized in a blinded fashion to receive either vaccine or placebo, while some individuals were in an open-label group receiving vaccine. Among the randomized participants, 97 percent generated antibodies specific to Ebola four weeks after a priming dose with AdVac. Additionally, more than half of AdVac recipients developed Ebola-specific T cells, a key marker of cellular immunity. Validating the prime-boost concept, these immune responses were enhanced by administration of the MVA-BN booster dose, with 100 percent of participants generating Ebola-specific antibodies at 21 days post-boost, and 79-100 percent showing T cell responses depending on the dosing interval.

Notably, 8 months following prime vaccination, 100 percent of individuals in the study maintained Ebola-specific antibodies, while vaccine-induced T cell responses persisted in 77-80 percent of those receiving the AdVac/MVA-BN regimen.

In terms of safety, injection site pain was the most common reported adverse event, and was transient and generally of mild-to-moderate severity. Among randomized participants, fever was reported in 5 percent of AdVac recipients compared to 4.2 percent of those receiving placebo. In the open-label group, 27 percent of participants reported fever. All episodes of fever resolved within 24 to 48 hours. No serious vaccine-related adverse events were observed.

“Forty years after the discovery of Ebola, the world still needs an approved vaccine for this disease,” said Dr. Peter Piot, Director, London School of Hygiene & Tropical Medicine. “A durable prime-boost vaccine could be a vital asset in efforts to proactively protect the general population in countries that are vulnerable to Ebola outbreaks. And in light of the persistent challenges that we are seeing with the Ebola virus, durability has become a particularly important goal for vulnerable populations such as health workers and the families of Ebola survivors.”

“First of all, this study provides important validation for the concept of a prime-boost vaccination strategy against this disease,” said Yves Levy, CEO, Inserm. “Additionally, these data indicate that the vaccine regimen can induce two types of immune response – antibody-based and cellular – which together may have the potential to confer long-term protection against Ebola. These results are highly significant findings in the fight against Ebola in which Inserm has been involved since the very beginning.”

“We are delighted to see such positive results produced by a consortium supported with grants from the Ebola+ programme,” said Ruxandra Draghia-Akli, Director, Health Directorate, European Commission, and member of the IMI Governing Board. “These and the many other Ebola studies underway with the European Commission and IMI support show that cooperation research and public-private partnerships can be formed with great speed to develop innovative solutions for today’s most pressing global health threats. Only by joining forces as an international community can we prevent, control, and end pandemics.”

The Oxford study provides the first set of data from a total of 10 clinical studies that are being conducted on a parallel track across the U.S., Europe and Africa in support of potential eventual registration for the Ebola vaccine regimen. The first study of the vaccine regimen in a West African country affected by the recent Ebola outbreak began in Sierra Leone in October 2015.

The Ebola outbreak in West Africa began in March 2014 and put the health care systems of Sierra Leone, Liberia and Guinea under tremendous pressure. More than 28,600 individuals were infected with the virus across the three countries, and more than 11,300 people died – including more than 500 healthcare workers.[i] Unfortunately, flare-ups of the disease continue in the region, most recently in Guinea and Liberia, due to the persistence of the Ebola virus among survivors.[ii] Healthcare and frontline workers are most at risk in an Ebola outbreak and would benefit greatly from a durable vaccine.[iii]

About the Phase 1 Study
This first-in-human Phase 1 study was a single-center, randomized, placebo-controlled, observer-blind trial to assess the safety and immunogenicity of an Ebola prime-boost vaccine regimen among healthy adults. A total of 87 volunteers aged from 18 to 50 enrolled in the United Kingdom from December 2014. Of these, 72 were randomized into four groups of 18 receiving either Ad26.ZEBOV (AdVac) or MVA-BN-Filo (MVA-BN) as prime. Participants then received a boosting dose with the alternative vaccine 28 or 56 days later. Within each group individuals were randomized 5:1 to receive study vaccines vs. placebo. An open label group of 15 participants received AdVac boosted by MVA-BN 14 days later. Follow-up on study participants through 8 months was completed in October 2015 and an additional follow-up analysis through 12 months is ongoing. Further details of the study are posted on clinicaltrials.gov.

About the Ebola Vaccine Regimen
Janssen’s investigational Ebola vaccine regimen was developed 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 January 2015, Europe's Innovative Medicines Initiative (IMI) awarded 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. The results of the Phase 1 data published in *JAMA* are generated under grant agreement EBOVAC1 (grant nr. 115854). The 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). Additionally, the NIHR Oxford Biomedical Research Centre provides support to the Oxford Vaccines Group, which conducted the Phase 1 study.

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.

Janssen in partnership with Bavarian Nordic rapidly scaled up production of the vaccine regimen and now has approximately 2,000,000 regimens available, with the capacity to produce several million regimens if needed.

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 127,100 employees at more than 250 Johnson & Johnson operating companies work with partners in health care to touch the lives of over a billion people every day, throughout the world.

Our Commitment to Global Public Health

For 130 years, Johnson & Johnson has been committed to improving the health of individuals, families and communities around the world, including the most vulnerable populations. Today, our vibrant, entrepreneurial and committed employees bring business acumen and their collaborative spirit to help solve some of the most complex global health problems. By harnessing our collective breadth and scale, and our employees' passion and purpose, we strive to advance health care and positively impact the lives of all people.

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® and PER.C6® 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 health care solutions to help people throughout the world.

About the Oxford Vaccine Group
The Oxford Vaccine Group is an independent multi-disciplinary clinical trials and epidemiology group based at the Centre for Clinical Vaccinology and Tropical Medicine, University of Oxford. OVG works towards the goal of developing new and improved vaccines for the prevention of infection in adults and children. Current research includes vaccines for chickenpox, salmonella typhi, flu, RSV and Ebola. www.ovg.ox.ac.uk

About the London School of Hygiene & Tropical Medicine
The London School of Hygiene & Tropical Medicine is a world-leading centre for research and postgraduate education in public and global health, with more than 4,000 students and 1,000 staff working in over 100 countries. The School is one of the highest-rated research institutions in the UK, and among the world's leading schools in public and global health. Our mission is to improve health and health equity in the UK and worldwide; working in partnership to achieve excellence in public and global health research, education and translation of knowledge into policy and practice. www.lshtm.ac.uk

About Inserm
Founded in 1964, the French National Institute of Health and Medical Research (Inserm) is a public science and technology institute, jointly supervised by the French ministry of education, higher education and research and the ministry of social affairs, health and women's rights. Ranked as the number one academic research institution in biomedical research in the European Union, Inserm supports more than 300 laboratories across France. In total, the teams include nearly 13,000 researchers, engineers, technicians and administrative staff. The mission of these scientists is to study all diseases, from the most common to the rarest, through their work in biological, medical and public health research. www.inserm.fr

About the European Commission and Ebola research
Joining forces with industry to combat Ebola – €215 million of research funding for Ebola and related viruses has been mobilised by the Innovative Medicines Initiative (IMI), a partnership between the European Commission and the pharmaceutical industry in Europe. €114 million comes from Horizon 2020, and the remaining €101 million from the pharmaceutical companies involved in the projects. Work on these projects began already in January 2015, involving the clinical development of new vaccines against Ebola, as well as vaccine production and the development of fast diagnostic tests. The IMI2 Ebola+ programme continues to further strengthen research on Ebola. In addition, the European Commission has launched many other important research actions on Ebola.

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[i] WHO Ebola Situation Reports. Accessed March 31, 2016. http://apps.who.int/ebola/ebola-situation-reports
[ii] WHO Update from the Field. Liberia and Guinea step up coordination to stem new cases of Ebola. April 7, 2016. Accessed April 11, 2016. http://who.int/csr/disease/ebola/liberia-guinea-flareups-update/en/
[iii] Wellcome Trust. *Plotting the Course of Ebola Vaccines: Challenges and Unanswered Questions*. March 2016.