

PRESS RELEASE

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For Immediate Release

Uganda starts Ebola Vaccine Trial among Healthcare and Frontline Workers in Mbarara

Kampala, Uganda- A Ugandan-led team of Researchers in Uganda have started a two-year trial among healthcare and frontline workers to provide additional information and assess the immunogenicity and safety of the investigational Ebola vaccine Ad26.ZEBOV, MVA-BN-Filo, manufactured by Janssen Vaccines & Prevention B.V.. part of the Janssen Pharmaceutical companies of Johnson & Johnson (Janssen). The vaccine regimen is based on AdVac® technology from Janssen, and MVA-BN® technology from Bavarian Nordic A/S.

The trial team will also describe knowledge about Ebola virus disease and transmission, and the perception and attitudes about the vaccine and protection in a subset of participants.

The ZEBOVAC (**An open-label, single arm study to provide additional information on immunogenicity and safety of Ad26.ZEBOV/MVA-BN®-Filo**) trial, will be undertaken at Epicentre Mbarara, Mbarara University of Science and Technology in Western Uganda and sponsored by the London School of Hygiene & Tropical Medicine.

It will test the Johnson & Johnson (J&J) investigational Ebola vaccine regime which uses a 'prime-boost' approach where Ad26.ZEBOV is given as the first dose followed by MVA-BN-Filo 56 days later.

It aims to enroll 800 people including healthcare workers such as physicians, clinicians, nurses and pharmacists, and frontline workers such as cleaners, mortuary attendants and surveillance, ambulance and burial teams.

Other participants will include healthcare staff providing non-Ebola related care which places them in contact with patients at public and private health centres or clinics. Frontline workers, particularly healthcare workers, are at increased risk of contracting Ebola Virus Disease.

During the early phase of the 2014 outbreak in West Africa, a study in Guinea found that up to 38% of the Ebola patients were healthcare workers with hospital acquired infection transmissions likely in 12 of the 14 cases.

The Johnson & Johnson (J&J) investigational Ebola vaccine regimen has been tested in more than 6000 persons in Europe, United States and Africa, including Uganda and is safe. Although it has not been used in previous outbreaks, and thus demonstration of efficacy in humans is lacking, it has shown outstanding safety and immunogenicity in humans and is highly protective against Ebola challenge in non-human primates.

Uganda has kept Ebola infections to a minimum through active surveillance, preparedness and swift containment despite an ongoing Ebola outbreak declared in the neighboring DRC almost a year ago. In June 2019, Uganda registered its first Ebola case, a five-year-old boy who had previously travelled to the DRC for the burial of his grandfather who had succumbed to Ebola. The boy and two other cases are the only known fatalities in Uganda. In July, the World Health Organization (WHO) together with the Ministry of Health declared Uganda Ebola-free.

Professor Pontiano Kaleebu, Director of the MRC/UVRI & LSHTM Uganda Research Unit and trial Principle Investigator, said:

“A vaccine, alongside strong community engagement, strengthened diagnosis and real time sequencing, is key to controlling Ebola epidemics. Available vaccines have been used under study conditions as primary prevention or ring vaccination approaches, however currently there is no licensed Ebola vaccine for international use. Developing effective vaccines and treatments against Ebola are therefore global public health priorities. In this trial we hope to avail more information that will help us work towards having a licenced Ebola vaccine.”

ZEBOVAC is funded by Coalition for Epidemic Preparedness Innovations (CEPI) and is sponsored by the London School of Hygiene & Tropical Medicine. The vaccine regimen is provided in-kind by Janssen. Both local and international investigators from Medical Research

Council/Uganda Virus Research Institute & London School of Hygiene and Tropical Medicine (MRC/UVRI and LSHTM) Uganda Research Unit, Uganda Virus Research Institute, Epicentre-Mbarara & Paris, Mbarara University of Science & Technology (MUST) and of Ministry of Health, Uganda are collaborating on the trial. The study team is further supported by the Ministry of Health (Uganda) and the EBODAC consortium.

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Notes to the Editor

- This open-label single arm study uses a prime-boost approach where the first dose of the Ebola Vaccine, Ad26.ZEBOV (a recombinant, replication-defective adenovirus type 26-vectored vaccine that encodes Ebola Zaire glycoprotein, Mayinga variant) is given as the first dose followed by MVA-BN-Filo (a recombinant, replication-defective Vaccinia Ankara-vectored vaccine that encodes for glycoproteins for the three species of Ebola Zaire, Ebola Sudan, Marburg, and the nucleoprotein of Tai Forest virus), 56 days later.
- The trial has been approved by the UVRI Research Ethics Committee, Uganda National Council of Science and Technology (UNCST) and National Drug Authority (NDA). All participants will provide informed consent and must be above 18 years before enrolment in the study, in addition to meeting all the study's other criteria. Participants can also withdraw at any time during the study.

About the London School of Hygiene & Tropical Medicine (LSHTM)

The London School of Hygiene & Tropical Medicine (LSHTM) is a world-leading centre for research, postgraduate studies and continuing education in public and global health. LSHTM has a strong international presence with 3,000 staff and 4,000 students working in the UK and countries around the world, and an annual research income of £140 million. LSHTM is one of the highest-rated research institutions in the UK, is partnered with two MRC University Units in The Gambia and Uganda, and was named University of the Year in the Times Higher Education Awards 2016. 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. <http://www.lshtm.ac.uk>

About MRC/UVRI and LSHTM Uganda Research Unit

The Medical Research Council/ Uganda Virus Research Institute and London School of Hygiene and Tropical Medicine (MRC/UVRI & LSHTM) Uganda Research Unit is an internationally recognized center of excellence for research on HIV and Emerging Infections, Vaccines and Immunity and Chronic Diseases and Cancer. Through a multidisciplinary approach intersecting basic science, epidemiological research, social-behavioural research and the conduct of new intervention evaluation studies, the Unit contributes knowledge to evaluation of innovative health care options, treatment and prevention, and the development of health policy and practice in Africa and worldwide.

www.mrcuganda.org

About Epicentre

Epicentre's Uganda Research Centre conducts health related research aimed at influencing policy globally and relevant to Africa and Uganda in particular. Studies are conducted according to Good Clinical Practices and Good Clinical and Laboratory Practices quality standards. Epicenter has set close collaborations with the MUST, the Mbarara Regional Referral Hospital , the Ministry of Health and other stakeholders in research, academia and the health sector.

www.epicentre.msf.org

About the Uganda Virus Research Institute (UVRI)

The UVRI engages in health research pertaining to human infections and disease processes associated with or linked to viral aetiology and provides expert advice, enables partnerships and communication and serves as a center for training and education.

UVRI's mission is to conduct scientific investigation on viral disease and other diseases to contribute to knowledge, policy and practice and engage in capacity development for improved public health. www.uvri.go.ug