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J&J starts clinical trial of Ebola vaccine in Sierra Leone

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Johnson & Johnson (J&J) has 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 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 helping the international community combat this disease," said Dr Paul Stoffels, chief scientific officer and worldwide chairman, Pharmaceuticals, J&J. He added, "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."

Professor Peter Piot, director of the London School of Hygiene and 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.

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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 health care workers who will gain valuable experience while contributing to the clinical study.

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 US, 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 US Food and Drug Administration (US 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 nearly 11,300 have died - including more than 500 health care workers. In Sierra Leone specifically, nearly 14,000 cases of Ebola have been reported and nearly 4,000 people have died.

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