

Goal achieved: 120 volunteers vaccinated for the Ebola vaccine trial at the Lausanne University Hospital (CHUV/PMU) in Lausanne, Switzerland.

120 volunteers have received a candidate Ebola vaccine in the past month at the Clinical Trial Unit of the Lausanne University Hospital (CHUV) & the Polyclinique Médicale Universitaire (PMU) in Switzerland. Volunteers, investigators and sponsors were eager to swiftly contribute to the global fight against the Ebola epidemic and its devastating consequences in the affected areas.

Additional information:

Prof. Blaise Genton
Chief physician Infectious Diseases
Blaise.Genton@chuv.ch
+41 79 556 58 68

Communications Unit
Darcy Christen
Darcy.Christen@chuv.ch
+41 79 556 60 00

Useful links

CHUV
www.chuv.ch

Polyclinique médicale universitaire
www.pmu-lausanne.ch

GSK
www.gsk.com

The Ebola vaccine has been developed by GSK and the US National Institutes of Health (NIH). The first ongoing trials in humans have been fast-tracked in response to the current Ebola outbreak and are providing valuable information about the safety of the experimental vaccine, ahead of the next stage of trials in West Africa.

‘The safety data looked satisfactory so far,’ says Professor Blaise Genton, who is leading the Lausanne trial. ‘Overall, subjects have local reactions similar to those observed after routine vaccination. General symptoms such as fever might be slightly more frequent, though no serious adverse event has been observed so far’. The first immunogenicity results will be available before the end of December. The whole set of safety and immunogenicity results for the 120 subjects followed for 28 days will be available end of January 2015.

The vaccine is made of a single Ebola virus protein, which belongs to the Zaire strain circulating in West Africa, built in a chimpanzee adenovirus vector. As it does not contain infectious Ebola virus material, it cannot cause a person who is vaccinated to become infected with Ebola but should generate immune responses aimed at protecting subjects when exposed to the Ebola virus.

Pre-clinical research by the NIH and Okairo, a biotechnology company acquired last year by GSK, has indicated that the vaccine provides promising protection in non-human primates exposed to Ebola without significant adverse effects.

Similar phase I studies are being conducted in the US, UK, and Mali. Safety and immunogenicity data collected from these and those of the Lausanne trial on a total of about 280 subjects should provide sufficient safety data to proceed for larger trials in Africa, which could start as early January 2015 according to the World Health Organization. Immunogenicity data will help to select the optimal dose to use. These studies will be conducted among subjects most at risk of Ebola in order to investigate whether the experimental vaccine protects against the disease, and how well it does so.

The Lausanne study is part of a large Horizon 2010 grant awarded by the European Commission. The funding for the study comes from the Swiss government directly. The Lausanne study had received the authorization to start the study from the Ethics Committee and the Swiss federal drug agency (Swissmedic) earlier this fall.

Notes to editors

- * Safety trials with small groups of healthy volunteers are required to ensure that the vaccine does not cause unforeseen side effects, and that it generates a good immune response to Ebola in humans. This is necessary before the vaccine can be rolled out to larger at-risk populations, even on an experimental basis.
- * 120 healthy volunteers are receiving the GSK/NIH Ebola vaccine in the Lausanne trial. The volunteers receive the vaccine in the upper arm after standard clinical observations are made and blood samples taken.
- * The volunteers fill in a diary to record any reactions to the vaccination. They are asked to return to the trial centre the day after the vaccination – and also 7, 14, 28 days, 3 months and 6 months later – for a review of how they are and to give further blood samples.
- * The researchers hope to publish initial data on vaccine safety and the early immune responses to the vaccine in February. But with volunteers providing blood samples for 6 months after their vaccination, the trial still has a long way to run beyond those initial data.
- * The Lausanne and VRC research teams are currently working to analyze the blood samples from volunteers to understand the immune responses the vaccine generates. A number of assays and tests are done to measure and characterize the antibody and T cell responses the body produces in the weeks and months following vaccination.
- * The NIAID/GSK Ebola vaccine candidate, is based on a novel technology platform developed by Okairos and uses an attenuated strain of chimpanzee cold virus, called chimp adenovirus type 3 (ChAd3). The adenovirus acts as a carrier, or vector, to deliver benign genetic material derived from the Ebola virus Zaire species that has caused the current Ebola outbreak in West Africa. The genetic material contained in the investigational vaccine cannot cause a vaccinated individual to become infected with Ebola. The vaccine candidate delivers the Ebola genetic material to human cells but does not replicate further. Rather, it allows the vaccine recipient's cells to express a protein, and that protein prompts an immune response in the person.

Photos are available upon request.