

PRESS RELEASE



Issued: Friday 23 January 2015, London UK

Major milestone for GSK/NIH candidate Ebola vaccine as first doses shipped to Liberia for use in phase III clinical trial

- **Healthcare workers among those to be vaccinated in large-scale trial involving up to 30,000 people due to start in the coming weeks**

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GSK has announced that the first batch of its candidate Ebola vaccine is being shipped to West Africa and is expected to arrive in Liberia later today Friday 23 January. The shipment, containing an initial 300 vials of the candidate vaccine, is the first to arrive in one of the main Ebola affected countries and will be used to start the first large-scale efficacy trial of experimental Ebola vaccines in the coming weeks.

The candidate vaccine is currently being tested in five small phase I clinical trials in the UK, USA, Switzerland and Mali, involving around 200 healthy volunteers in total. Initial data from these trials show that the candidate vaccine has an acceptable safety profile, including in a West African population, and across the different doses evaluated. Based on the safety and immunological data available from these trials, GSK has selected the most appropriate dosage level to advance to the next phases of clinical testing. Results from the first of the phase 1 studies were published in November 2014 and results from the remaining phase 1 studies will be published in the coming months.

The selected dose will now be tested in a large phase III clinical trial led by the US National Institutes of Health (NIH) which is expected to involve up to 30,000 people, one third of whom will receive GSK's candidate Ebola vaccine. It will compare the candidate vaccine to a control vaccine to assess whether the immune response seen in phase 1 trials actually translates into meaningful protection against Ebola. This trial will begin in Liberia in the coming weeks, subject to regulatory approval, with further shipments of vaccines to follow.

Dr Moncef Slaoui, Chairman of Global Vaccines at GSK, said: "Shipping the vaccine today is a major achievement and shows that we remain on track with the accelerated development of our candidate Ebola vaccine. The initial phase I data we have seen are encouraging and give us confidence to progress to the next phases of clinical testing which will involve the vaccination of thousands of volunteers, including frontline healthcare workers. If the candidate vaccine is able to protect these people, as we hope it will, it could significantly contribute to efforts to bring this epidemic under control and prevent future outbreaks.

"It is important to remember that this vaccine is still in development and any potential future use in mass vaccination campaigns will depend on whether WHO, regulators and other stakeholders are satisfied that the vaccine candidate provides protection against Ebola without causing significant side effects and how quickly large quantities of vaccine can be made."

GSK is working closely with the World Health Organization (WHO) and Centers for Disease Control and Prevention (CDC) in the US to assist with the design and to potentially support trials in other affected countries – Sierra Leone and Guinea – in the coming months. In parallel, GSK plans to begin large phase II safety trials in non-affected West African countries.



The candidate Ebola vaccine shipped today was co-developed by the NIH's National Institute of Allergy and Infectious Diseases (NIAID) and Okairios, a biotechnology company acquired by GSK in 2013. It uses a type of chimpanzee cold virus, known as chimpanzee adenovirus type 3 (ChAd3), as a carrier to deliver benign genetic material from the Zaire strain of the Ebola virus, which is responsible for the current Ebola outbreak in West Africa. GSK has been working with the NIH to accelerate development in response to the current Ebola epidemic.

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