5 MARCH 2015 , GENEVA - Based on promising data from initial clinical trials in late 2014, WHO with the Health Ministry of Guinea, Médecins Sans Frontières (MSF), Epicentre and The Norwegian Institute of Public Health (NIPH), will launch a Phase III trial in Guinea on 7 March to test the VSV-EBOV vaccine for efficacy and effectiveness to prevent Ebola. The vaccine was developed by the Public Health Agency of Canada. A second vaccine will be tested in a sequential study, as supply becomes available.

“We have worked hard to reach this point,” said WHO Director-General, Dr Margaret Chan. “There has been massive mobilization on the part of the affected countries and all partners to accelerate the development and availability of proven interventions. If a vaccine is found effective, it will be the first preventive tool against Ebola in history.”

Vaccination will take place in areas of Basse Guinée, the region that currently has the highest number of cases in the country. The trial strategy adopted will be “ring vaccination”, based on the approach used to eradicate smallpox in the 1970s. This involves the identification of a newly diagnosed Ebola case – the “index case” – and the tracing of all his/her contacts. The contacts are vaccinated if they give their consent.

“The Ebola epidemic shows signs of receding but we cannot let down our guard until we reach zero cases,” said Assistant Director-General Marie-Paule Kieny, who leads the Ebola Research and Development effort at WHO. “An effective vaccine to control current flare-ups could be the game-changer to finally end this epidemic and an insurance policy for any future ones.”

The objectives of the trial are two-fold: to assess if the vaccine protects the contacts who were vaccinated and if vaccinating the contacts will create a buffer - or ring of protected individuals - around the index case to prevent further spread of the infection. Vaccination will also be proposed to front-line workers in the area where the trial will take place.

Canadian governmental institutions are supporting the trial through the provision of critical training and support to the African research teams conducting the trial, in addition to scientific advice.

In the last six months WHO has convened a series of emergency consultations with scientists, ethicists, regulators and policy makers to identify potential preventive and therapeutic products to help stem the epidemic. Canada's VSV and GSK cAd3 vaccines quickly emerged as promising tools due to prior successful studies on non-human primates.

"For more than a year we have been racing around the clock to stop the epidemic from spreading further," explains Bertrand Draguez, Medical Director at MSF.

"We need to ensure that we continue our efforts to identify infection cases and follow up on their contacts, and in parallel keep promoting R&D for treatments, diagnostics and vaccines. This epidemic remains unpredictable. We don't know when it will end, and that's why it remains crucial for us to keep focusing our efforts on developing a vaccine capable of protecting the population in this epidemic and any future ones. Frontline workers and the contacts of infected patients will be enrolled, if they consent, in the vaccine study."

"Participation of the community in the study areas in Guinea is vital to enable the successful assessment of this vaccine," stresses John-Arne Røttingen, NIPH, and chair of the study steering group. "The study process has ensured the inclusion of Guinean investigators since its inception, and is a response to a request from Guinean authorities."

Since September 2014, the two most advanced Ebola vaccines have been evaluated in about 15 countries in Africa, Europe and North America. The testing timelines were considerably accelerated through the simultaneous organization of multiple trials and emergency procedures to expedite data sharing and analysis between the investigators and manufacturers. The VSV-EBOV vaccine was selected for the planned trial based on a framework of parameters developed by the WHO Scientific and Technical Advisory Committee on Ebola Experimental interventions (STAC-EE). Criteria included acceptable safety profile, induction of appropriate immune responses, including neutralizing antibodies, and the timely availability of sufficient supplies of vaccine doses.

Further measures were taken to accelerate the testing process by organizing multi-country emergency assessments, joint ethical and regulatory reviews of trial protocols and clearing of regulatory hurdles. For the Guinea trial, the Guinea National Regulatory Authority with support from Health Canada jointly reviewed the trial protocol.

WHO, UNICEF, US Centers for Disease Control (CDC), the Bill and Melinda Gates Foundation and Gavi (the Global Vaccine Alliance) are collaborating with the affected countries to develop plans and strategies for large-scale introduction, should this be needed. The vaccines' manufacturers have assured that enough vaccine will be available in the coming months. Financial resources are in place to procure and make vaccines available to the Ebola affected countries. Million of doses will be funded by Gavi, whose Executive Board approved a US$ 300 million funding envelope in December 2014. There are also U$ 90 million earmarked to support the deployment of the vaccine(s).

http://www.who.int/mediacentre/news/releases/2015/ebola-vaccine-trial/en/