18 October 2019 | Geneva - The World Health Organization (WHO) welcomes the European Medicines Agency (EMA) announcement recommending a conditional marketing authorization for the rVSV-ZEBOV-GP vaccine, which has been shown to be effective in protecting people from the Ebola virus.

Today's announcement by EMA, the European agency responsible for the scientific evaluation of medicines developed by pharmaceutical companies, is a key step before the European Commission decision on licensing. In parallel, WHO will move towards prequalification of the vaccine.

"The conditional authorization of the world's first Ebola vaccine is a triumph for public health, and a testimony to the unprecedented collaboration between scores of experts worldwide," said Dr Tedros Adhanom Ghebreyesus, WHO Director-General. "My deepest gratitude is to the studies' volunteers, researchers, health workers in Guinea, other countries and the Democratic Republic of the Congo who have put themselves at risk to ensure people are protected with this vaccine."

In the past five years, WHO has convened experts to review the evidence on various Ebola vaccine candidates, informed policy recommendations, and mobilized a multilateral coalition to accelerate clinical evaluations. The EMA review was unique in that WHO and African regulators actively participated through an innovative cooperative arrangement put in place by WHO, which will help accelerate registration for the countries most at risk.

A randomized trial for the vaccine began during the West Africa Ebola outbreak in 2015. When no other organization was positioned to run a trial in Guinea during the complex emergency, the government of Guinea and WHO took the unusual step to lead the trial.

A global coalition of funders and researchers provided the critical support required. Funders included the Canadian Government (through the Public Health Agency of Canada, Canadian Institutes of Health Research, International Development Research Centre, Global Affairs Canada); the Norwegian Ministry of Foreign Affairs (through the Research Council of Norway's GLOBVAC programme); the Wellcome Trust; the UK government through the Department for International Development; and Médecins Sans Frontières.

The trial was successfully run using an innovative ring vaccination design. In the 1970s, this ring strategy helped to eradicate smallpox, but this was the first time that an experimental vaccine was evaluated this way.

WHO celebrates the commitment and sacrifices made by so many over the last five years, an international effort that led to this landmark moment in public health. The difficult and

painstaking work was undertaken by a global team of researchers, health workers, partners, regulators, governments and field workers from logisticians to vaccinators, and finally, local communities. Together they overcame many obstacles. WHO also recognizes the Canadian government contribution to the early development of this vaccine.

Anticipating that in coming years there will be higher Ebola vaccine demand during and between outbreaks, WHO is working with Gavi, UNICEF and other partners to develop a Global Ebola Vaccines Security Plan, as increased supply capacity and multiple manufacturers will be needed in the short- to medium-term to meet this demand and ensure vaccine security.

There are 8 vaccines undergoing clinical evaluation. WHO continues to work with partners towards an internationally coordinated governing mechanism to ensure access according to risk criteria, and manage supply and stockpiles, especially as supply will remain limited until a full manufacturing capacity is established or other vaccines are licensed.

A roadmap aiming to accelerate prequalification and coordinate actions and contributions to the licensing and roll-out of the rVSV-ZEBOV-GP vaccine in African countries has been developed.

This announcement will not have an immediate effect on how the vaccine is accessed or administered in the Democratic Republic of the Congo, as licensing has not yet occurred, and licensed doses will only be available mid-2020. The vaccine will continue to be used in the country under a research protocol (also known as “expanded access” or “compassionate use”), and with the ring vaccination strategy.

In the current Ebola outbreak in the Democratic Republic of the Congo, more than 236,000 people have been vaccinated with rVSV ZEBOV GP donated by Merck to WHO, including more than 60,000 health and frontline workers in the Democratic Republic of the Congo and in Uganda, South Sudan, Rwanda and Burundi.

“This vaccine has already saved many lives in the current Ebola outbreak, and the decision by European regulator will help it to eventually save many more,” said Dr Tedros, WHO Director-General. “I am proud of the role WHO has played, from supporting the research, to conducting the trial in Guinea in 2015.”