By John Odyek

UGANDAN FIRM FILES US EBOLA VACCINE PATENT

Dei BioPharma has filed a utility patent application with the United States Patent and Trademark Office for a new vaccine platform designed to protect against several of the Ebola viruses responsible for major outbreaks in humans.

The patent application covers a Messenger Ribonucleic Acid (mRNA) vaccine that targets the main Ebola viruses linked to past epidemics, including Zaire Ebolavirus, which caused the 2014–2016 West Africa outbreak, Sudan Ebolavirus and Bundibugyo Ebolavirus.

Other members of the Ebola virus family, such as Taï Forest, Reston and Bombali are referenced as part of ongoing scientific efforts to prepare for future outbreaks.

A utility patent protects the functional aspects of a new or improved invention, covering how it works, what it is made of or how it is used. It provides inventors with exclusive rights to make, use, or sell the invention for up to 20 years according to international law and practice.

Dr Matthias Magoola, the founder of Dei BioPharma, said on Saturday the patent describes specially designed Ebola virus proteins delivered through lipid nanoparticles, the same type of carrier technology used in modern mRNA vaccines. The application covers methods for vaccine production, formulation and administration that are intended to support rapid deployment during outbreaks.

The filing contains 24 claims covering vaccine design, mRNA delivery systems, lipid nanoparticle formulations, manufacturing processes, dosage schedules and potential use during outbreaks, including protection of frontline health workers and people at high risk of exposure.

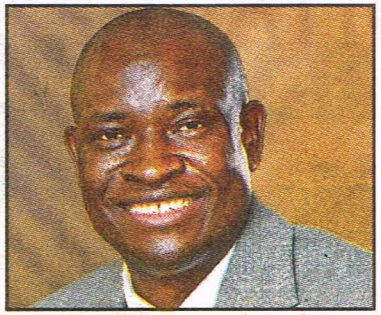
"For decades, Ebola virus preparedness has been approached as a challenge requiring separate vaccines for separate viral threats, our innovation challenges that paradigm by using rational antigen engineering to pursue broad protection against the most consequential outbreak-causing Ebolaviruses. This has the potential to transform Ebola preparedness globally, especially for African nations where these viruses pose the greatest threat," Magoola said.

The patent filing comes at a time of renewed attention to Ebola preparedness following a World Health Organisation (WHO) declaration that the current Bundibugyo Ebola virus disease outbreak in Uganda and the DR Congo constitutes a public health emergency of international concern. WHO has reported that no licensed vaccine or specific treatment currently exists for Bundibugyo virus disease.

Existing approved Ebola vaccines, including ERVEBO, are licensed to prevent disease caused by Zaire ebolavirus. Health authorities state that the vaccine does not protect against other Ebola virus species.

SEEKING TO ADDRESS GAP

Magoola said its new platform seeks to address that gap by targeting common features shared by the major Ebola viruses responsible for outbreaks. The company uses two design approaches. One identifies genetic features common across different Ebola viruses, while the other combines selected natural genetic segments from different strains to widen protection while maintaining the structure of the virus proteins.



Dr Matthias Magoola

The resulting mRNA is packaged in lipid nanoparticles that help deliver the vaccine into the body's cells. According to the company, this technology can support large-scale manufacturing and distribution using established vaccine supply systems.

Magoola said they are preparing for Phase One human clinical trials and are pursuing a regulatory pathway that could allow conditional approval within four to five years from the start of development.

Most major Ebola outbreaks have occurred in sub-Saharan Africa, where contact between humans and infected wildlife can trigger new infections. The 2014–2016 outbreak in Guinea, Liberia and Sierra Leone remains the largest on record, with more than 28,600 reported cases and 11,325 deaths, according to WHO.

Magoola said previous responses to Ebola outbreaks have often been constrained by limited vaccine supplies and protection restricted to specific virus strains. According to him, Africa needs vaccine platforms developed and manufactured within the region to respond quickly to threats such as Zaire, Sudan and Bundibugyo Ebolaviruses.

The company said the project is part of its wider vaccine research programme, which includes mRNA and protein-based vaccines for Ebola-related viruses and other emerging infectious diseases that can spread from animals to humans.

Under its current five-year development plan, Dei BioPharma intends to submit an Investigational New Drug application to the US Food and Drug Administration before beginning Phase One trials in healthy volunteers. These studies will focus on safety, side effects and determining the most effective dosage.

Phase Two trials are expected to involve larger and more diverse groups of participants, while Phase Three studies would assess immune responses and vaccine effectiveness. The company said it would seek accelerated regulatory review if clinical results are favourable.

To prepare for future deployment, Dei BioPharma is engaging manufacturing partners for clinical and commercial production. The company estimates that annual production capacity could reach between five million and ten million doses after approval.

According to the firm, the vaccine formulation is designed to remain stable for up to 24 months at minus 20 degrees Celsius and between six and 12 months when stored at standard refrigerator temperatures of 2 to 8 degrees Celsius.

The company said it is discussing future procurement, stockpiling and distribution arrangements with international and regional health organisations, including the World Health Organisation, the Coalition for Epidemic Preparedness Innovations (CEPI), Gavi, the Vaccine Alliance, and ministries of health across Africa.

Magoola said Dei BioPharma intends to adopt equitable pricing during outbreaks and use its manufacturing facility in Matugga, near Kampala, to strengthen regional vaccine supply.

"This is not only a scientific milestone. It is a step towards African technological self-determination in epidemic preparedness. Africa must not only receive vaccines during crises; Africa must help design, manufacture and deploy them," Magoola said.

Find more details on our website:
Newvision.co.ug