



## **PRESS RELEASE**

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## **NBA APPROVES ANOTHER HIV PREVENTION VACCINE TRIAL**

LUSAKA, ZAMBIA-The National Biosafety Authority (NBA) has approved another HIV vaccine clinical trial for the prevention of HIV-1 infection in women.

The phase two trial which will involve about 500 participants will be conducted in Lusaka and Ndola by the Centre for Infectious Disease Research in Zambia (CIDRZ) and the Zambia Emory HIV Research Project (ZEHRP).

Last year the Authority approved one research trial involving HIV vaccine (by CIDRZ on the safety and immunogenicity of HVTN 120/ALVAC which is being conducted in Lusaka) and a Malaria research involving use of modified bacteria to control malaria (by Macha Research Trust, which is still at confined stage, in Choma).

The NBA Board met last week (Friday) and among others approved the CIDRZ and ZEHRP controlled phase 2B clinical research trial which will be conducted over a period of three years.

The study will enroll 2600 healthy, HIV -1 uninfected female volunteers aged between 18- 35 years across sites in Zambia, South Africa, Mozambique, Zimbabwe and Malawi. Zambia will have three sites, two in Lusaka (Matero clinic and ZEHRP Lusaka) and one in Ndola (ZEHRP).

The Scientific Advisory Committee (SAC) of the NBA made a recommendation to the NBA Board to consider the approval of the new HIV trials after a risk assessment was done on the genetic modifications involving the transformation of the organism and the applicants meeting the required set standards.

NBA Chief Executive Officer (CEO) Mr Lackson Tonga said the trial will involve the release of a heterologous prime/ boost vaccine regime for the HVTN 705/ALVAC, a phase 2b clinical trial to evaluate the efficacy of the genetically modified vaccine in healthy HIV- 1 uninfected female participants. “The permit is valid for three years beginning May this year,” Mr Tonga said.

The Scientific Advisory Committee (SAC) considered the CIDRZ/ZEHRP application to conduct research on HIV vaccine. The committee was satisfied after further reviewing the application and found it to have met the expected safety threshold and other requirements from collaborating partners such as Zambia Medicines Regulatory Authority, National Health Research Authority (NHRA) and the relevant ethics committees.

“As per our mandate which include regulating the research and development of any products that may/do contain genetically modified organisms, we are happy that institutions are coming forth to obtain research permits. This is cardinal as we need to know that any form of modification on microorganisms research does not pose as a threat to human, animals and the environment,” he said.

“For us risk assessment is critical and we will not allow any research whose risk assessment has not been done in products involving genetically modified organisms to be conducted in the country. The same goes for products that may be made from genetically modified organisms or contain genetically modified organisms on the market whose risk assessment we do not know.”

**-Ends-**

### **About NBA**

NBA was established under the Biosafety Act No. 10 of 2007. Through the Act the NBA regulates the research, development, application, importation, export, transit, contained use, release or placing on the market of any GMO whether intended for use as a pharmaceutical, food, feed or processing, or a product of a GMO also to ensure that any activity involving the use or a product of GMO prevents any socio-economic impact or harm to human, animal health and the environment in the country.

Some of the functions of the NBA include processing notifications and applications of GMOs or products of GMOs into the country, in accordance with the requirements of the Biosafety Act, promoting public awareness and education concerning the activities regulated under the Act such as risk assessment, risk management and authorization processes; keeping any GMO or any product of a genetically modified organism under review and to ban its handling or release in Zambia. NBA furthermore, establishes and maintains a database of GMOs and their products as well as making available such information to the public.

For more information about NBA visit: [www.nbazambia.org.zm](http://www.nbazambia.org.zm) you can also follow us on Facebook: NBA-Zambia and twitter: @NBA\_Zambia

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