



### **Company Overview**

GeoVax Labs, Inc. is a clinical-stage biotechnology company developing immunotherapies and vaccines against cancer and infectious diseases using a novel vector vaccine platform [Modified Vaccinia Ankara-Virus Like Particle (MVA-VLP)]. GeoVax's recombinant MVA vector expresses target proteins on highly immunogenic VLPs in the person being vaccinated resulting in induction of durable immune responses while providing the safety characteristics of the replication-defective MVA vector. Important attributes of GeoVax vaccines include single dose, no adjuvant, durable immunity, extensive safety and cost-effective manufacturing.

Our technology and expertise have been broadly validated through development programs focused on preventive vaccines against hemorrhagic fever viruses (Ebola, Marburg, and Lassa fever), Zika virus and malaria; preventive and therapeutic vaccines against HIV; a therapeutic vaccine for chronic hepatitis B virus infections; and preventive and therapeutic vaccines for multiple solid tumor cancers. Several of our programs have received substantial federal support (>\$50M to date) from the NIH and Department of Defense (DOD).

During 2018, GeoVax was recognized as the winner of the "Best Biotech" and as a finalist for the "Best Prophylactic Vaccine" at the Vaccine Industry Excellence (VIE) Awards, and as a finalist for "Pipelines of Promise" at Buzz of BIO. GeoVax was also selected as a finalist for the "Best New Vaccine Technology Platform" as well as the "Best Therapeutic Vaccine" at the 2019 VIE Awards.

# Key Highlights

- Unique, proprietary vaccine platform with an extensive, clinically-proven safety profile and significant advantages vs competitive vaccine technologies.
- Immuno-oncology program showing promising early data; potential for multiple cancer indications and partnering opportunities.
- Clinical program underway in HIV with NIH funding support; Phase 2a completed.
- Preclinical single-dose 100% protection demonstrated with Zika, Ebola, Marburg, and Lassa fever vaccines; studies underway in malaria and hepatitis B (immunotherapy).
- Multiple well-recognized corporate, academic and government collaborators.

# **Technology** Pipeline



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### **OTCQB: GOVX**

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# **Technology Platform**

GeoVax's MVA-VLP vector vaccine platform combines the safety of a replication-defective live vector (MVA) with the immunogenicity of VLPs and the durability of immune responses elicited by vaccinia vectors. Upon vaccination, MVA-VLPs mimic a natural infection in which target proteins are displayed on the surface of the VLPs produced by the vaccine. The VLP-displayed proteins stimulate both humoral and cellular arms of the immune system to recognize, prevent, and control target infections/diseases. The MVA vector has been optimized for retention of vaccine inserts during manufacture and we have a strong international patent portfolio that continues to expand in conjunction with our ongoing vaccine and immunotherapy developments.

## Cancer Immunotherapy

We are using our MVA-VLP vaccine platform to express abnormal, aberrantly glycosylated forms of the cell surface-associated Mucin 1 (MUC1) protein that is associated with a wide range of cancers, including breast, colon, ovarian, prostate, pancreatic, and lung. We are collaborating with a leading expert in cancer immunotherapy at the University of Pittsburgh for assistance in selection and testing of vaccine candidates. We are also collaborating with ViaMune, Inc. and have shown that our MVA-VLP-MUC1 vaccine in combination with their synthetic MUC1 vaccine significantly reduced tumor burden in a transgenic human MUC1 therapeutic mouse model. Additionally, we have expanded our oncology program to target other cancer antigens through a collaboration with Vaxeal Holding, SA, and Virometix AG, two Swiss biotech companies specializing in immuno-therapy-based cancer vaccines, Emory University for HPV-associated head and neck cancers, and Leidos, Inc. for combination with novel peptide checkpoint inhibitors developed by Leidos. Each of these oncology programs have the potential to yield multiple vaccine candidates against various types of cancers. Our MUC1 vaccine can be ready for Phase 1 human trials in Q4 2020. Our clinical approach will use standard-of-care (SOC) treatments, vaccination, and immune checkpoint inhibitors (CPI) to unleash a patient's immune system to fight their cancer.

# Hepatitis B Virus (HBV) Therapeutic Vaccine

An estimated 240 million people are chronically infected with HBV -- 780,000 of which die each year, despite the availability of an effective prophylactic vaccine since 1982. Numerous HBV therapeutic vaccine candidates have been evaluated in clinical trials, but none have sufficiently activated both antibody and the cellular responses required for complete viral clearance, specifically, strong IgG1, IgG3 and CD4+ and CD8+ T cell responses. Clinical data from our HIV vaccine trials demonstrated that our MVA-VLP-HIV vaccine elicited strong IgG1, IgG3 and CD4+/CD8+T cell responses, more so than shown by previous HBV therapeutic vaccine candidates. We have constructed vaccine candidates containing multiple protective antigens from the HBV genotype D (causing more severe disease) (MVA-VLP-HBV) which are currently being tested in mice in our collaborator's laboratories. Our HBV therapeutic vaccine strategy combines novel multivalent MVA-VLP-HBV antigens in combination with SOC and CPI, to work towards a high cure rate.

## HIV/AIDS Vaccine Program

Our most clinically advanced program is a prophylactic vaccine for the Clade B HIV, the subtype of HIV prevalent in the Americas, Australia, Japan and Western Europe. This program has successfully completed Phase 1 and Phase 2a human clinical trials and continues to advance toward pivotal human trials with support from the NIH. We are also developing an HIV vaccine targeting Clade C HIV, the subtype of HIV most prevalent in Africa.

Our HIV vaccine may also prove useful as a necessary component of a combination therapy to provide a cure for HIV infection. We have entered a collaboration with American Gene Technologies International, Inc. (AGT) to test this concept in combination with AGT's gene therapy technology. Clinical trials are expected to commence in 2019. In addition, we anticipate that our HIV vaccine will participate in additional "functional cure" initiatives that are currently in the planning stage.

## Hemorrhagic Fever Vaccines

We have demonstrated 100% single-dose protection in preclinical lethal challenge models for our Ebola, Marburg, and Lassa fever vaccines and are developing vaccines against other highly lethal hemorrhagic viruses with pandemic potential. We were recently awarded a grant from the US Army to fund advanced preclinical testing and GMP manufacturing for our Lassa fever vaccine. Our Ebola vaccine has completed efficacy testing in non-human primates and is ready for GMP manufacture and Phase 1 human trials.

## Zika Vaccine

We have achieved 100% protection of mice when vaccinated with a single dose of our Zika vaccine and exposed to a lethal challenge of the Zika virus injected directly into the brain. Our Zika vaccine is based on the NS1 protein of Zika which is not associated with Antibody Dependent Enhancement (ADE) of infection, a safety concern for other Zika vaccines under development. Moreover, an NS1 based vaccine has the potential advantage of blocking transmission of Zika from humans to its mosquito vectors. Our Zika vaccine has completed efficacy testing in non-human primates and is ready for GMP manufacture and Phase 1 human trials.

# Malaria Vaccine

Globally, malaria causes 214 million infections and 438,000 deaths annually. Despite decades of vaccine research, vaccine candidates have failed to induce substantial protection (e.g. >50%). Most of these vaccines are based on truncated proteins or VLP proteins targeting a limited number of antigens derived from only one stage of the malaria parasite's life cycle. Our MVA-VLP multi-antigen malaria vaccine candidates are designed to induce a Th1 biased immune response with durable functional antibodies (IgG1 and IgG3) and CD4+ and CD8+ T cell responses, all hallmarks of an ideal malaria vaccine. We are collaborating with the Burnet Institute, a leading infectious disease research institute in Australia, as well as with Leidos, Inc. (under a contract from USAID Malaria Vaccine Development Program) for the development of a vaccine to prevent both malaria infection and transmission by targeting antigens derived from multiple stages of the parasite's life cycle. Our vaccine constructs are currently being evaluated in small animal models.