

## GeoVax Vaccine To Be Used in a Phase 1 Trial of Genetically Modified Autologous Cell Therapy for HIV

IND Application Submitted to FDA for Phase 1 Trial

ATLANTA, GA, October 24, 2019 – <u>GeoVax Labs, Inc</u>. (OTCQB: GOVX) announced today its participation in a planned clinical trial led by researchers at American Gene Technologies (AGT) (www.americangene.com), to develop a therapy aimed at eliminating HIV from infected people.

On October 18, 2019, AGT announced the submission of an Investigational New Drug (IND) application to the U.S. Food and Drug Administration (FDA) for AGT's lead HIV program, AGT103-T, a lentiviral vectorbased gene therapy. Upon clearance by the FDA, this IND will allow AGT to initiate a Phase 1 clinical trial that will investigate the safety of AGT103-T in humans, measure key biomarkers, and explore surrogate markers of efficacy. AGT expects to begin recruiting patients for the Phase 1 study in January.

Pursuant to its collaboration agreement with AGT, GeoVax will provide its novel MVA-VLP HIV vaccine (MVA62B) for evaluation in an arm of the clinical trial in combination with AGT103-T. T cells obtained from vaccinated individuals will be reprogrammed by AGT's lentivirus vector and infused back into the study participants as a therapeutic cell product. MVA62B is the boosting component for GeoVax's preventive HIV vaccine (GOVX-B11) which has successfully completed a Phase 2a clinical trial and is awaiting funding in support of a Phase 2b pivotal trial.

Farshad Guirakhoo, PhD, GeoVax's Chief Scientific Officer, commented, "In a previous therapeutic Phase 1 clinical trial conducted by GeoVax, we demonstrated that our vaccine can potently stimulate production of both CD8+ and CD4<sup>+</sup> T cells in HIV-positive individuals – the intended use of the MVA62B vaccine in the proposed AGT therapeutic study. Our vaccine also has a well-documented safety profile in >500 humans. We are hopeful that the combination of technologies in these studies will yield a promising regimen that eliminates the HIV reservoir from people infected with the disease in the absence of antiretroviral drugs."

David Dodd, GeoVax's President and CEO, stated, "Finding a cure for HIV/AIDS remains an elusive but critical goal, and GeoVax is pleased to be a contributor to this important effort. While current antiretroviral therapy is effective at suppressing the viral load of HIV-infected individuals and preventing progression to AIDS, the long-term use of ART can lead to loss of drug effectiveness and can come with severe side effects. Additionally, the financial burden of drug and other medical costs to both the individual and to society at large is staggering, with average lifetime medical costs of treating an HIV-positive individual in the U.S. estimated to exceed \$350,000."

## About GeoVax

GeoVax Labs, Inc. is a clinical-stage biotechnology company developing human vaccines against infectious diseases and cancer using a novel patented Modified Vaccinia Ankara-Virus Like Particle (MVA-VLP) based vaccine platform. On this platform, MVA, a large virus capable of carrying several vaccine antigens, expresses proteins that assemble into VLP immunogens within (*in vivo*) the person receiving the vaccine. The production of VLPs in the person being vaccinated mimics virus production in a natural infection, stimulating both the humoral and cellular arms of the immune system to recognize, prevent, and control the target infection. The MVA-VLP derived vaccines elicit durable immune responses in the host similar to a live-attenuated virus, while providing the safety characteristics of a replication-defective vector.

GeoVax's current development programs are focused on preventive vaccines against HIV, Zika Virus, hemorrhagic fever viruses (Ebola, Sudan, Marburg, and Lassa), and malaria, as well as therapeutic vaccines against chronic Hepatitis B infections and multiple cancers. The Company has designed the leading preventative HIV vaccine candidate to fight against the subtype of HIV prevalent in the commercial markets of the Americas, Western Europe, Japan, and Australia; this program is currently undergoing human clinical

trials managed by the HIV Vaccine Trials Network (HVTN) with the support of the National Institutes of Health (NIH). For more information, visit <u>www.geovax.com</u>.

## Forward-Looking Statements

Certain statements in this document are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act. These statements are based on management's current expectations and are subject to uncertainty and changes in circumstances. Actual results may differ materially from those included in these statements due to a variety of factors, including whether: GeoVax can develop and manufacture its vaccines with the desired characteristics in a timely manner, GeoVax's vaccines will be safe for human use, GeoVax's vaccines will effectively prevent targeted infections in humans, GeoVax's vaccines will receive regulatory approvals necessary to be licensed and marketed, GeoVax raises required capital to complete vaccine development, there is development of competitive products that may be more effective or easier to use than GeoVax's products, GeoVax will be able to enter into favorable manufacturing and distribution agreements, and other factors, over which GeoVax has no control. GeoVax assumes no obligation to update these forward-looking statements and does not intend to do so. More information about these factors is contained in GeoVax's Form 10-K.

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