

# Innovations to Serve Humanity



**NASDAQ: GOVX** 

# **Forward Looking Statements**

Certain statements in this presentation may constitute "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 forwardlooking statements and does not intend to do so. More information about these factors is contained in GeoVax's filings with the Securities and Exchange Commission including those set forth at "Risk Factors" in GeoVax's Form 10-K.



# About GeoVax Labs, Inc.

**GeoVax Labs, Inc.** is a Phase 2 clinical-stage biotechnology company developing **immunotherapies** and **vaccines** against a wide range of **infectious diseases** and **cancers** 



The development pipeline includes vaccines and immunotherapies addressing:

- Coronaviruses (SARS-CoV-2 & Variants)
- Solid tumors/Immuno-oncology (Head & Neck)
- Hemorrhagic fever viruses Ebola, Lassa, Marburg and Sudan
- Malaria
- Zika virus

GeoVax is well capitalized and debt-free

Nasdaq: "GOVX"

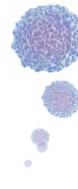


### **GeoVax Labs, Inc.** Consolidated Balance Sheet Information

(amounts in thousands, except share information)

	 Mar 31, 2022	Dec 31, 2021
Assets		
Cash and cash equivalents	\$ 16,258	\$ 11,424
Other current assets	379	205
Total current assets	 16,637	11,629
Property and other assets, net	218	168
Total assets	\$ 16,855	\$ 11,797
Liabilities and stockholders' equity		
Total liabilities	\$ 5,501	\$ 7,435
Stockholders' equity	 11,354	4,362
Total liabilities and stockholders' equity	\$ 16,855	\$ 11,797
Common shares outstanding	9,449,025	6,381,541





### GeoVax Announces \$20 Million Registered Direct and PIPE Offerings Priced at a Premium to Market Under Nasdaq Rules

ATLANTA, GA, May 25, 2022 — GeoVax Labs, Inc. (Nasdaq: GOVX), a biotechnology company specializing in developing human vaccines and cancer immunotherapies, announced today that it has entered into a definitive agreement with a single healthcare-focused institutional investor for the issuance and sale of 3,030,304 shares of common stock at a purchase price of \$1.65 per share (or pre-funded warrant in lieu thereof) in a registered direct offering priced at a premium to market under Nasdaq rules. In a concurrent private placement, GeoVax has also agreed to issue and sell to the investor 9,090,910 shares of common stock (or common stock equivalents) at the same purchase price as in the registered direct offering. In addition, the Company has agreed to issue to the investor in the offerings unregistered preferred investment options (the "investment options") to purchase up to an aggregate of 12,121,214 shares of common stock. The aggregate gross proceeds to the Company of both offerings are expected to be approximately \$20 million. The offerings are expected to close on or about May 27, 2022, subject to the satisfaction of customary closing conditions.

H.C. Wainwright & Co. is acting as the exclusive placement agent for the offerings.

# **COVID-19 and Variants**

Achieve clinical development status within 12-18 months



GOAL

Licensed GEO-CM04S1, COVID-19 vaccine; currently in two Phase 2 trials





# **SARS-CoV-2 Challenges**

- Virus Continues to Evolve requiring continuous modifications of current vaccines & dosing
- Current Vaccines' Limitations
  - Limited Protection for Immunocompromised
  - Limited Durability
  - Significant Distribution & Administration Challenges in Various Regions



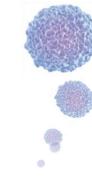
# **GEO-CM04S1**

#### Most Advanced Multi-antigen Covid-19 Vaccine Inducing Strong Ab & T-Cell Immune Responses

- Encodes Spike protein, targeting Ab immune response
  - Current vaccines only encode Spike protein technology unable to encode multi-antigens
- Encodes Nucleocapsid protein, targeting T-cell/cellular immune response
- Phase 1 demonstrated strong antibody & T-cell immune responses
- Potential for More Robust, Durable Protection
- Can be distributed with minimal/no refrigeration for distribution & administration worldwide







#### Phase 1 data published in a Lancet journal on GEO-CM04S1 shows it produced robust antibodies and T cells against SARS-CoV-2

The investigational vaccine is now being used in Phase 2 trials for immunocompromised patients and as a booster for healthy adult volunteers

LOS ANGELES and ATLANTA, Mar. 10, 2022 — A COVID-19 investigational vaccine, developed by City of Hope scientists and now licensed to GeoVax Labs Inc. (Nasdaq: GOVX), produced a robust neutralizing antibody and T cell (an immune cell) response against SARS-CoV-2 with no significant side effects in a Phase 1 clinical trial led by John Zaia, M.D., Aaron D. Miller and Edith Miller Chair for Gene Therapy, according to a study published today in The Lancet Microbe.

COH04S1/GEO-CM04S1 is uniquely different than the many vaccines that have been developed because *it targets both the spike and nucleocapsid proteins, in contrast to the current U.S. Food and Drug Administration (FDA)-approved COVID-19 vaccines, which only target the spike protein.* 

<u>COH04S1</u> elicited neutralizing antibodies against the virus' spike protein, which interacts with the human cellular ACE2 receptor, allowing the virus to enter cells of the lung, heart and other organs, resulting in damage and significant inflammation. These neutralizing antibodies were effective against the original SARS-CoV-2 and subsequent viral variants. T cells were produced against the SARS-CoV-2 nucleocapsid protein, as well as its spike protein, after just one dose of COH04S1.

"This data confirms the powerful dual action of our vaccine," said Don J. Diamond, Ph.D., professor in City of Hope's Department of Hematology & Hematopoietic Transplantation and the vaccine's lead developer. "Given the multiple mutations in spike, leading to variants of concern and inconsistent protection from existing FDA-approved vaccines, we are excited about our approach incorporating two antigens in one vaccine. *Should a new mutation arise in the spike antigen that interferes with antibody recognition, we believe a person vaccinated with our vaccine would still have substantial T cell immunity against both the nucleocapsid and spike antigens that would protect them from the ravages of COVID-19*.

"The T cell response is especially important for immunocompromised cancer patients as they can readily lose the ability to produce antibodies during and after chemotherapy or other treatments that deplete antibody-producing cells," he added.

# **COVID Vaccine:** GEO-CM04S1



## Phase 2 : Primary vaccine for the Immunocompromised

- 1st ever trial in patients with weakened immune systems
- Direct comparison to the Pfizer/BioNTech mRNA vaccine





# COVID Vaccine: GEO-CM04S1

### **Phase 2: Booster vaccine**

- For healthy population fully vaccinated with an mRNA vaccine
- Potential for broader and more durable protection versus a 3rd or 4th mRNA dose



# **GEO-CM04S1 Updates**

- CRO assigned to accelerate Phase 2 clinical trials
- Phase 2 trials actively recruiting and dosing patients
- Significant interest related to needs for various immuno-compromised populations
- Business Development discussions & interest underway and increasing
- Resources available to successfully complete current clinical trials



# **COVID Vaccine:** GEO-CM02



## **Universal Coronavirus Vaccine**

- Potentially a Single-dose, Universal Coronavirus Vaccine
- Expanded virus/variant targeting providing robust antibody and cellular immune responses
- Advancing to Clinical Development



# Immuno-Oncology

GOAL

Achieve clinical development status within 12-18 months





Licensed Gedeptin®, immuno-oncology vaccine in Phase 2 trial for treating advanced Head & Neck cancers







#### License of Gedeptin<sup>®</sup> Adds Orphan Drug Clinical Program for Treatment of Advanced Head and Neck Cancers

**ATLANTA, GA, September 28, 2021** – GeoVax Labs, Inc. (Nasdaq: GOVX), a biotechnology company specializing in developing human vaccines and cancer immunotherapies, today announced that it has entered into an Assignment and License Agreement (the "License") with PNP Therapeutics, Inc. ("PNP"), that grants GeoVax exclusive rights to develop and commercialize Gedeptin<sup>®</sup>, a novel patented product for the treatment of solid tumors.

The License provides exclusive worldwide rights to key intellectual property, including Gedeptin patents, know-how, regulatory filings, clinical materials, and trademarks. The patent portfolio covering Gedeptin, was originally licensed from the University of Alabama at Birmingham (UAB) and Southern Research Institute (SRI) by PNP. ...

"Today's announcement accelerates our progress within immuno-oncology, providing a pivotal clinical-stage status via the Gedeptin program. We similarly remain focused on accelerating progress related to our SARS-CoV-2 vaccine and look forward to providing further updates soon."

# Immuno-Oncology Vaccine: Gedeptin®

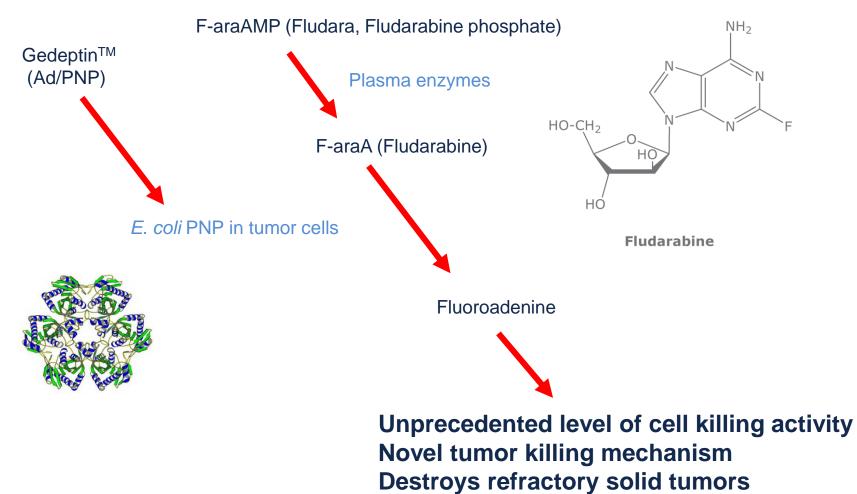


### Phase 2 : Advanced Head and Neck Cancers

- FDA orphan drug status granted
- Currently expanding the clinical trial to multiple sites, accelerating expanded patient enrollment
- Evaluating broader use of Gedeptin in conjunction with Immune Checkpoint Inhibitors (ICIs)

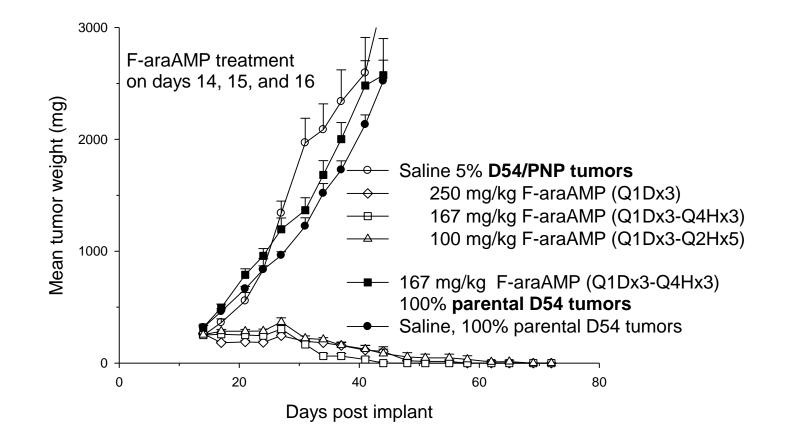


# **Mechanism of Action**

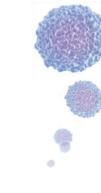




# Tumor Response When < 5% of Cells Express PNP







Phase I dose-escalating trial of Escherichia coli purine nucleoside phosphorylase and fludarabine gene therapy for advanced solid tumors

### **Conclusions:**

This first-in-human clinical trial found that localized generation of fluoroadenine within tumor tissues using E. coli PNP and fludarabine is safe and effective. The pronounced effect on tumor volume after a single treatment cycle suggests that phase II studies are warranted.

Annals of Oncology 26: 1481–1487, 2015 doi:10.1093/annonc/mdv196



# **Gedeptin®** Updates

- CRO assigned to accelerate Phase 2 clinical trial
- Phase 2 trial expanded to multi-sites; additional sites under consideration
- Actively recruiting and dosing patients
- Business Development discussions & interest underway and increasing
- Resources available to successfully complete current clinical trial
- Animal data regarding Gedeptin in conjunction with ICIs continues to be encouraging





# Immuno-Oncology Vaccine: MVA-VLP-MUC1

## **Advancing to Clinical Development**

- Focused on combining GeoVax immuno-oncology vaccine and ICIs to enhance the performance of ICI therapy
- Notice of Allowance issued for GeoVax MVA-VLP cancer vaccine patent



# Vaccine: Hemorrhagic Fever Viruses (Ebola, Lassa, Marburg, Sudan)



Support NIH and DoD through IND-enabling activities

# ACHIEVED



- 100% protection single dose vaccine against Ebola
- Sudan & Marburg data presented at the 2021 World Vaccine & Immunotherapy Congress
- Notice of Allowance for GeoVax MVA-VLP Ebola vaccine patent





2022

### Focus.

- Successfully advance the three Phase 2 clinical programs in support of Gedeptin® and GEO-CM04S1
- Ensure appropriate resources to support the IND-enabling initiatives of our priority internal programs and operational enhancements and developments

# **Strong IP for GeoVax Technology**

STO granted or pending patent applications spread over 20 patent families



### **Our patent portfolio covers**

- COVID-19 vaccines
- Immuno-oncology
- Hemorrhagic fever
  (Ebola, Marburg, Sudan, Lassa)
- Zika, Malaria vaccine
- HIV
- HPV-associated cancer
- Hepatitis B vaccine



Pipeline Focused on Nea Value Drivers	ar-term	Status	Funding
Coronavirus			
COVID-19 (Immunocompromised patients)	GEO-CM04S1	Phase 2	Internal
COVID-19 (Booster to mRNA)	GEO-CM04S1	Phase 2	Internal
Pan Coronavirus	GEO-CM02	IND-Enabling	Internal & Non-Dilutive
Immuno-Oncology			
Solid Tumors (Head & Neck)*	Gedeptin®	Phase 2	Internal & Non-Dilutive
MUC1 – Solid Tumors	MVA-VLP-MUC1	IND-Enabling	Internal & Non-Dilutive
Infectious Disease			
Lassa Fever**	GEO-LM01	IND-Enabling	Non-Dilutive
Ebola, Marburg, Sudan**	GEO-EM01	IND-Enabling	Non-Dilutive
Zika Virus**	GEO-ZM02	IND-Enabling	Non-Dilutive
Malaria**	GEO-MM01	Exploratory	Non-Dilutive



\*: Orphan Drug status granted; \*\*: Indication within FDA Priority Review Voucher program

