

#### **GeoVax Corporate Overview**

#### January 2025

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 forward-looking 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.



**GeoVax:** Phase 2 clinical-stage biotechnology company developing **immunotherapies** and vaccines against a wide range of cancers and infectious diseases

Innovate

Unique, patented products addressing unmet medical needs

Differentiate

Targeting populations underserved by existing products/standard of care

Pursuing expedited registration pathways

Worldwide distribution and administration via business collaborations





A compelling **opportunity** with a value-driven **strategy** 



### **Priority Programs Advancing**

#### GEO-CM04S1: Next-generation COVID-19 vaccine

- Underserved immunocompromised patients
- Generally healthy individuals -- BARDA Project NextGen

#### GEO-MVA: Mpox/Smallpox vaccine

Gedeptin<sup>®</sup>: Solid Tumor Therapy



# COVID-19: GEO-CM04S1





#### 1<sup>st</sup> Generation COVID-19 Vaccines (mRNA: Pfizer/BioNTech; Moderna; Protein subunit vaccine: Novavax)

- Limited breadth of protection: Requiring reconfiguration/updating as new variants emerge (e.g., Delta, Omicron, JN.1, etc.)
- Limited durability (e.g., 4-6 months vs goal of ~12 months)
- Inadequate protection for immune-compromised patients

\*\*\*\*\*\*

### **Next-Generation COVID-19 Vaccines**

- Increased breadth of protection: Encompassing new variants without the continuous need for reconfiguration/updating
- Increased durability (e.g., ~12 months)
- Protection for immune-compromised patients

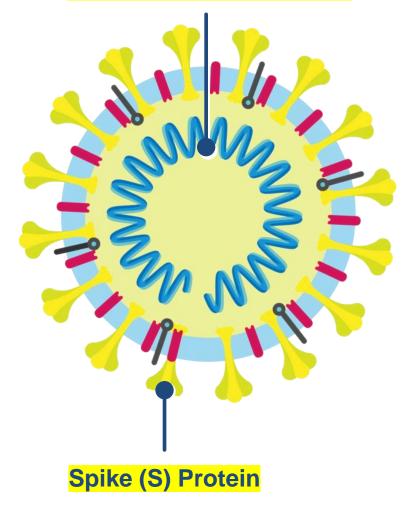




### **Critical Importance of Both Antibodies & T-cells for Protection**

GEO-CM04S1 S+N Proteins are Co-Expressed

Nucleocapsid (N) Protein



#### Immune Responses for Protection against Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2)

COVID-19 Disease Severity				
	Asymptomatic Infection	Symptomatic Infection	Severe Disease, Hospitalization	Death
Antibodies	<mark>++++</mark>	<mark>+++</mark>	++	++
T Cells	+	++	<mark>+++</mark>	<mark>+++</mark>

Both humoral (antibody) and cellular (T cell) immune responses contribute to protection against SARS-CoV-2. "+" signs denote the relative importance of antibodies and T cells for protection at each stage of disease severity, with more "+" signs indicating greater importance/protection.





#### GEO-CM04S1





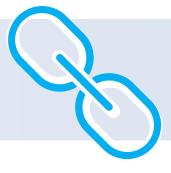
**COVID-19 Vaccine** 

Greater breadth of variant protection

#### GeoVax platform (MVA): recognized safety, potent, durable, minimal refrigeration/freeze-dried delivery

- Current vaccines do not provide sufficient protection for those with depleted immune systems
- GEO-CM04S1: More robust, durable protection reduces need for boosters
- Can be used as booster to existing vaccines or stand-alone for immunocompromised patients

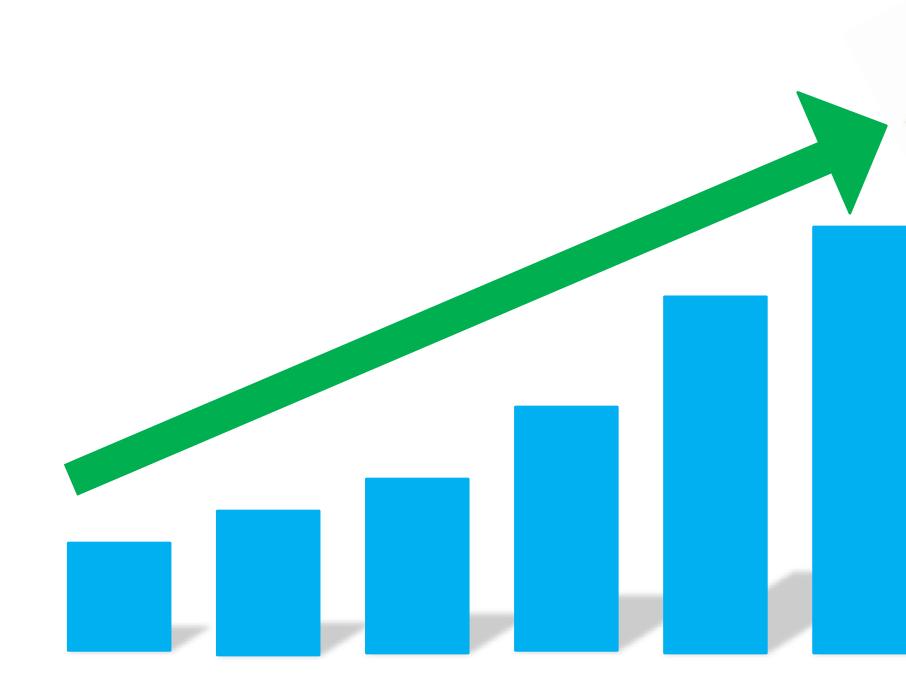




# Longer-lasting immune response



#### BARDA Project NextGen Award Valued at ~\$400 Million to Conduct Phase 2b Clinical Study Evaluating Next-Generation COVID-19 Vaccine Candidate, GEO-CM04S1 vs mRNA Vaccine



#### COVID-19

Geola



### **BARDA Project NextGen**

#### Phase 2b Head-to-Head Study in COVID-19

Randomized study evaluating GEO-CM04S1 vaccine with an FDA approved vaccine

Collaborator	Ν	Randomization	
SOL AL ADVANCED RESERVE	~10,000 Pts. ~ 80 Sites	1:1	
BARDA H BORNENT AUTHOR	Study Arms (Control vs		
	GEO-CM04S1 Vaccine	VS	

Study Activation H2 '25 > 80 Sites Confirmed



n Study Population

Previously Vaccinated Generally Healthy Adults

Treatment)

FDA-approved COVID-19 Vaccines



#### **GEO-CM04S1 – Phase 2 Clinical Trials** (In Addition to BARDA PNG Phase 2b Trial)



#### Immunocompromised/stem cell transplant patients

- Patients with hematologic malignancies receiving stem-cell transplantation or CAR-T therapy
  - Highest at-risk groups for severe infection, hospitalization and death
  - Primary vaccine in direct comparison to mRNA vaccines

#### Immunocompromised/Chronic Lymphocytic Leukemia (CLL) patients

- High at-risk population with abated antibody response
  - Major, currently unmet, medical need for alternative immune enhancement response (e.g., T-cells)
  - Booster vaccine in direct comparison to mRNA vaccine



#### **COVID-19 booster vaccine**

- Healthy adults following previous vaccination with an mRNA vaccine
  - Potential for broader and more durable protection vs that provided by currently available mRNA vaccines







#### **GeoVax Announces Positive Interim Data Review for Phase 2 Clinical Trial of COVID-19 Vaccine Booster** in Patients with Chronic Lymphocytic Leukemia

GEO-CM04S1 Improved Immune Response vs mRNA Vaccine

ATLANTA, GA, November 19, 2024 — GeoVax Labs, Inc. (Nasdaq: GOVX), a biotechnology company developing immunotherapies and vaccines against cancers and infectious diseases, today announced the completion of an interim data review by the Data Safety Monitoring Board (DSMB) for the ongoing Phase 2 clinical trial of GEO-CM04S1, GeoVax's dual-antigen next-generation COVID-19 vaccine, as a booster vaccine for patients with chronic lymphocytic leukemia (CLL).

Based on the interim analysis of immune responses from the patients enrolled to date, the DSMB determined that, while the mRNA control arm of the study failed to meet the predetermined primary endpoint, the study should continue enrollment of the experimental arm utilizing GeoVax's Next-Generation GEO-CM04S1 vaccine.

... "the outcome of the DSMB interim review appears to support our view of GEO-CM04S1 as a potentially superior COVID-19 vaccine booster within the CLL patient population"...



### **GEO-CM04S1** Development Plan

- Validate the Differentiation and Value of GEO-CM04S1
  - Broader (Variant Agnostic), more durable protection (~12) \_\_\_\_ months)
  - "Preferred COVID-19 vaccine for immunocompromised" patients"
- Expedited Registration Focused on Immunocompromised **Patient Populations**



**Global Development & Commercialization via Collaborations/Partnering** 







# Mpox & Smallpox: GEO-MVA





### WHO Declaration – Aug 14 & Nov 22

Newsroom ~

Emergencies ~

WHO Director-General declares mpox outbreak a public health emergency of international concern

Countries ~

14 August 2024 | News release |Reading time: 3 min (789 words)

World Health Organization

Health Topics ~

#### Media Contacts

中文

Africa CDC Declares Mpox A Public Health **Emergency of Continental Security, Mobilizing Resources Across the Continent** 

Data ~

العربية

Español



**Mpox & Smallpox** 

Русский

About WHO ~

Français

13 August 2024

Theme

**Emergency Response and Preparedness** 

Region

Central Africa, Eastern Africa, Northern Africa, Southern Africa, Western Africa



### **Mpox** – "What's the Big Deal?"

- WHO Declaration of State of Emergency (8/14 & 11/22, 2024)
- Different than 2022
  - Multiple Mpox variants now circulating
  - More virulent and higher mortality
  - Previously animal-human spread...now, human-human spread
- Vaccination is critical to reduce morbidity/mortality threat
- Africa & worldwide need for significant resources
  - Increased vaccine availability and better vaccine supply
  - Multiple, flexible manufacturing on Africa continent

**Mpox & Smallpox** 

Source: Adapted from MedCram.com







### **Symptoms**

The rash tends to first develop on the face before spreading elsewhere on the body





Soles 75% of cases







INTENSE HEADACHE

MUSCLE ACHES







SWOLLEN LYMPH NODES





#### Mpox & Smallpox











### "What's the Solution?"

#### WHO is coordinating global health response

#### WHO looking to access additional MVA-Mpox vaccine supply

- Requires engaging with companies having
  - Experienced with the MVA-platform
  - MVA based Mpox vaccine candidate(s) in development
  - Access to existing manufacturing capability for MVA

#### Critical need: cGMP MVA clinical batch

#### Strong preference to establish Regional/Local Africa based Mpox vaccine manufacturing

– Difficult for processes requiring Chicken Embryo Fibroblasts (CEFs) as starting materials

#### Critical need: Advanced, cell-line MVA Manufacturing Platform



#### **GEO-MVA**

#### GeoVax

Focused on expedited registration for 1st U.S.sourced vaccine against Mpox & Smallpox



- Currently: one supplier worldwide (MVA-BN) unable to meet demand
- Strong U.S. government interest in establishing a U.S. based supplier
  - HHS needs to replenish/re-stock SNS (Strategic National Stockpile)
- GeoVax advancing the development of GEO-MVA
  cGMP clinical batch manufacture & release: In Process
- In dialogue with various U.S. & Global stakeholders
- Regulatory discussion/guidance received supporting abbreviated approval pathway
- Implementation of Advanced MVA manufacturing platform



# Oncology: Gedeptin®

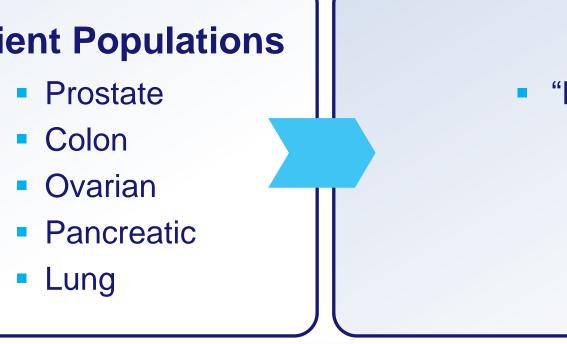




### **Gedeptin®: Significant Medical Need**

#### **Potential Target Cancer Patient Populations**

- Advanced Head & Neck (initial indication; Orphan Drug Status)
- Earlier-Stage Head & Neck
- Breast





#### **Patient Prevalence (U.S.)**

- Advanced Head & Neck Cancer (deaths/yr) 16,000
- Early-Stage Head & Neck Cancer (new dx/yr) 71,000
- Other Solid Tumors (deaths/yr) 321,000



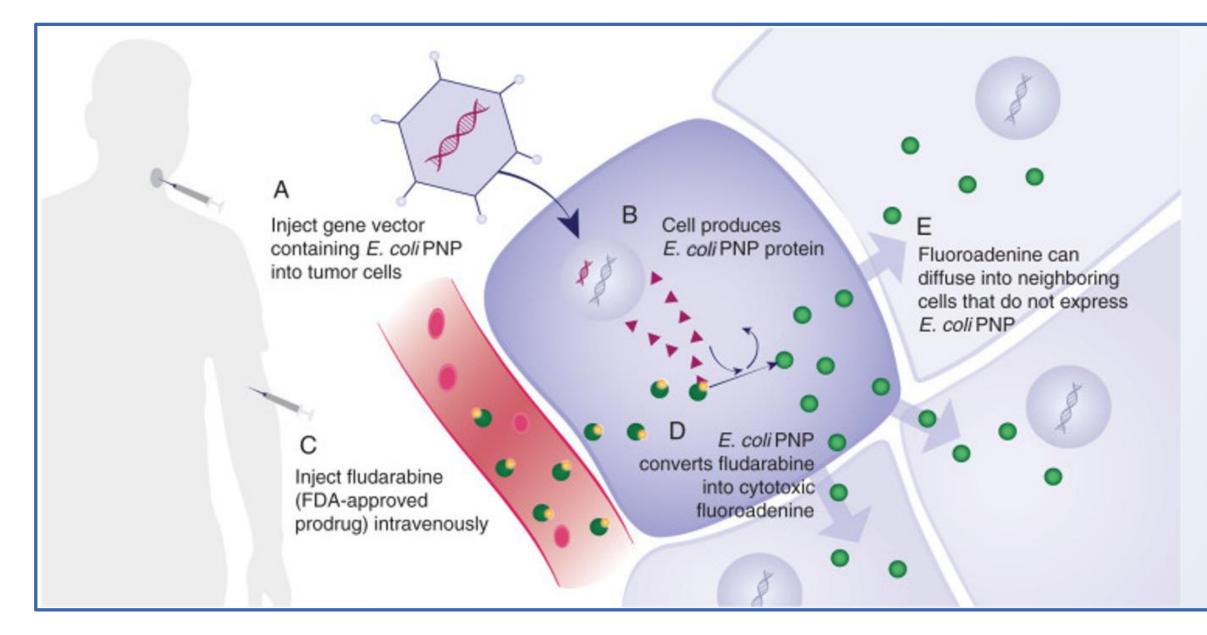
#### **Patient Characteristics**

"Needle-accessible" solid tumors

hs/yr) - 16,000 w dx/yr) - 71,000 000



### **Gedeptin®** Mechanism of Action



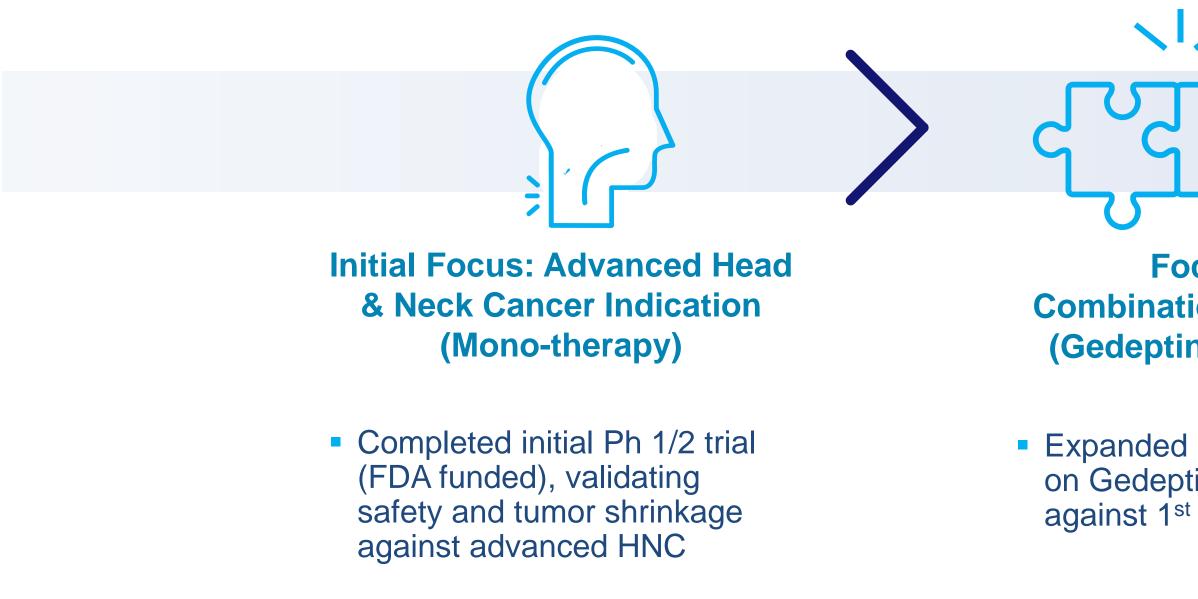
Phase I dose-escalating trial of Escherichia coli purine nucleoside phosphorylase and fludarabine gene therapy for advanced solid tumors - PMC (nih.gov)



- Unprecedented level of cell-killing activity
- Novel tumor killing mechanism
- Facilitates destruction of refractory solid tumors
- "Tumor agnostic"



### **Gedeptin<sup>®</sup> Clinical Development Plans**





**Global Development & Commercialization via Collaborations/Partnering** 





**Focus: Combination-Therapy** (Gedeptin<sup>®</sup> with ICI)

Expanded Ph 2 trial focused on Gedeptin + ICI therapy against 1<sup>st</sup> recurrent HNC





#### GeoVax Announces Phase 2 Plans for Gedeptin® Cancer Therapy Following Clinical Advisory Committee Review

Company plans Phase 2 trial in first-recurrence head & neck cancer, in combination with immune checkpoint inhibitor

Atlanta, GA, July 31, 2024...

...The primary goal of the planned Phase 2 trial will be to establish efficacy of neoadjuvant Gedeptin therapy combined with an immune checkpoint inhibitor in first-recurrence squamous cell head and neck cancer...The Company has initiated the necessary planning activities, including protocol development, manufacturing, and CRO selection with the trial activation anticipated during the first half of 2025...

... "We look forward to activation of this trial and are pursuing development plans in additional solid tumor indications in partnership with leading academic oncology centers..." added David Dodd, GeoVax's Chairman and CEO.



# Milestones, Catalysts & Summary





### **2025 Milestones & Catalysts**



**GEO-CM04S1 (Next-Generation COVID-19** Vaccine) – Phase 2b & 2 Clinical Program

- PNG: Operational progress re trial activation
- Immunocompromised/stem cell transplant patients: Additional sites initiated; interim data results
- Immunocompromised/Chronic Lymphocytic Leukemia (CLL) patients: Interim analysis indicated GEO-CM04S1 superiority vs mRNA
- Healthy patient booster trial: **Data results**



**Gedeptin<sup>®</sup> (Solid Tumor Therapy)** – **Phase 2 Clinical Trial** 

trial activation



Phase 2 expanded trial: **Operation progress re** 

**Advanced, Transformative Continuous Cell-line MVA Manufacturing** 

Process Development underway; GEO-CM04S1 and GEO-MVA



### **GeoVax Portfolio: Revenue Opportunity**

Product	Disease	Target	Est' Revent \$(
GEO-CM04S1	COVID-19	Primary Vaccine For Immune Compromised Patients/Booster to mRNA	\$
GEO-MVA	Mpox/Smallpox	Global Health Emergency U.S. SNS	
Gedeptin®	Cancer	Early-Stage Head & Neck Cancer	\$
Gedeptin®	Cancer	Advanced Head & Neck Cancer	

t'd Market nue Potential 6(Billion)

\$ 30.0+

\$10+

\$ 12.4

\$ 2.8

#### ~\$55 Billion in Market Revenue Potential



### **GeoVax Strategy**

Innovate

Unique, patented products addressing unmet medical needs

Targeting populations unserved by existing products/standard of care

Differentiate

Pursuing expedited registration pathways





#### Worldwide distribution and administration via business collaborations



# Geoloxe

## Thank You !!!



