

# **Corporate Overview**

September 2024

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** 





- GEO-CM04S1: Next-generation COVID-19 vaccine BARDA Project NextGen
- GEO-MVA: Mpox/Smallpox vaccine
- Gedeptin<sup>®</sup>: Solid Tumor Therapy



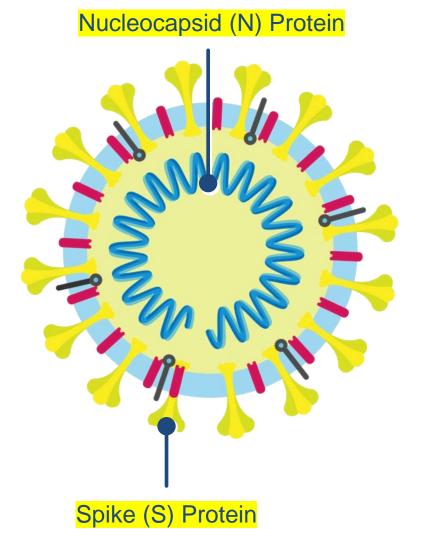
# COVID-19: GEO-CM04S1





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

#### GEO-CM04S1 S+N Proteins are Co-Expressed



#### **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

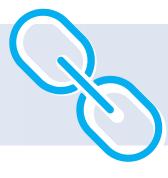
**COVID-19 Vaccine** 

More robust -- "Variant Agnostic"

#### 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 than authorized vaccines reduces need for boosters
- Can be used as booster to existing vaccines or stand-alone for immune compromised patients

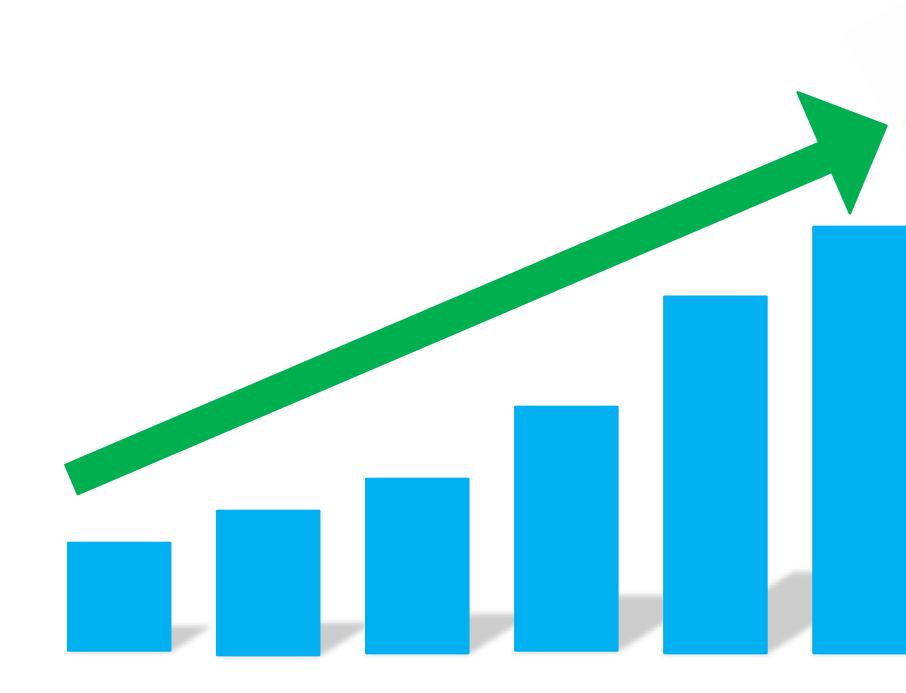




#### **More durable – longer duration**



#### 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
STOL AL ADVANCED PROSERT	~10,000 Pts. ~ 100 Sites	1:1
	S	tudy Arms (Control vs T
A DEVELOPMENT AUTHOR	GEO-CM04S <sup>2</sup> Vaccine	I VS

Study Activation H1 '25 > 80 Sites Confirmed



**Study Population** 

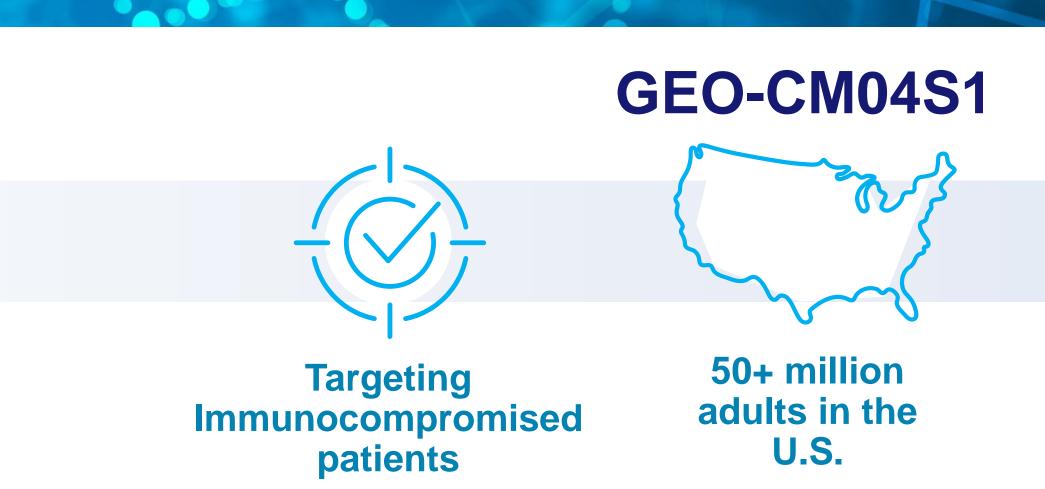
**Previously Vaccinated** Healthy Volunteers

#### Treatment)

**FDA-approved COVID-19** Vaccines







Data estimate based on: (a) data from the most recent (2021) U.S. National Health Interview Survey; and (b) summation of various medical conditions and treatments associated with immunocompromised conditions, or weakened immune systems





#### > 400 million adults Worldwide



# **GEO-CM04S1 – Phase 2 Clinical Trials**



#### 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



#### **Booster to mRNA vaccine**

- Healthy population following vaccination with an mRNA vaccine
  - Potential for broader and more durable protection versus multiple, continuous mRNA doses





# **GEO-CM04S1 Development Plan**

- Validate the Differentiation and Value of GEO-CM04S1
  - Broader (Variant Agnostic), more durable (6-12+ months) protection
  - "Preferred COVID-19 vaccine for immunocompromised patients"
- Expedited Registration Focused on **Immunocompromised Patient Populations**



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







# Mpox & Smallpox: GEO-MVA





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



# **GEO-MVA**

- Currently one supplier worldwide unable to meet demand
- High U.S. federal government interest in establishing a U.S. based supplier
- HHS interest in replenishing/re-stocking Strategic National Stockpile (SNS)
- GeoVax advancing development
  - **o cGMP Master Seed Virus produced**
  - In dialogue with various U.S. & Global stakeholders
  - Regulatory discussion/guidance underway

#### WHO Global Health Emergency Declaration



#### **GEO-MVA: Critical Global Medical Need**

#### **Target Patients Candidates For**

- Mpox (Monkeypox)
- Smallpox (Strategic National Stockpile/SNS)





#### **U.S. Stockpile Target Requirement**

- 66M at risk Americans
- 132M doses

#### **U.S. At Risk Population**

- 7M Adult Males at risk\*
- 14M doses

\*Source: Mpox cases reported to CDC: Age and Gender (August 23, 2023); \*Gallup Poll: LGBT Identification (Feb 2022)

#### **Customer Profile**

#### Mpox: WHO Global Health Emergency Declaration

Smallpox: U.S. Government SNS



# Oncology: Gedeptin®

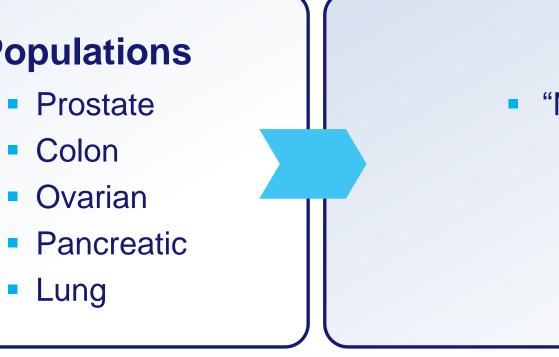




### **Gedeptin®: Significant Medical Need**

#### **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



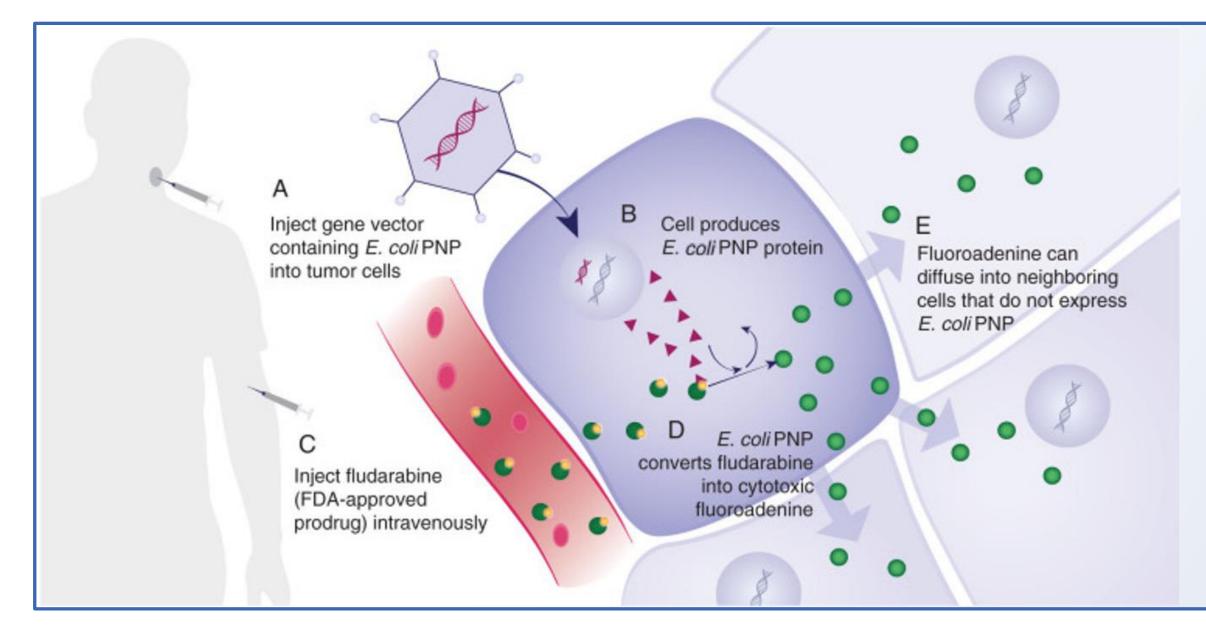
#### **Patient Characteristics**

"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 Data<sup>\*</sup>**

#### Phase 1/2 study of Ad/PNP with fludarabine for the treatment of head & neck squamous cell carcinoma





**MEDICINE** 

**Stanford Cancer Institute** 





Evaluation of Gedeptin<sup>®</sup> as an experimental therapy for refractory tumors (NCT03754933)

Safety and efficacy of repeat cycles of Gedeptin<sup>®</sup> therapy in patients with recurrent head and neck squamous cell carcinoma (HNSCC) with tumor(s) accessible for injection and no curable treatment options



#### Data highlights (8 patients):

- No dose limiting toxicities or serious adverse events (SAEs) are attributable to treatment
- No adverse events above grade 3 severity
- Up to 5 cycles of Gedeptin® treatment administered without limiting sequelae
- Intratumoral expression of the PNP transgene bt RT-PCR established in treatment tumors to date
- Impaired tumor growth (i.e., stable disease using RECIST 1.1 evaluation criteria) in targeted lesions seen in 5 of 7 patients (tumor response assessment in 1) patient remains under study)



#### Conclude from interim analysis that administration of Gedeptin<sup>®</sup> is safe and feasible

\* Poster presentation at the July 10, 2023 American Association for Cancer Research (AACR) and the American Head and neck Society (AHNS) joint Head and Neck Cancer Conference in Montreal, QC, Canada 1. Stanford Cancer Institute, Stanford University; 2. Emory University School of Medicine; 3. PNP Therapeutics, Inc.; 4. Thomas Jefferson University; 5. GeoVax Laboratories; 6. Vanderbilt University



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# **Gedeptin® Clinical Development Plans**

#### **Initial Focus: Advanced Head** & Neck Cancer Indication (Mono-therapy)

- Completed initial Ph 2 trial (FDA funded), validating safety and tumor shrinkage
- Initiate expanded Ph 2 trial focused on expedited registration

**Secondary Focus: Additional Solid Tumor Indications** (Mono-therapy)

Clarify next mono-therapy indication and protocol



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



**Tertiary Focus: Combination-Therapy** (in conjunction with ICIs)

- Complete current preclinical studies of Gedeptin in conjunction with ICIs
- Clarify initial clinical indication and trial of Gedeptin + ICI therapy





#### 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





# **2024 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: Enrollment completed; initial data results
- Healthy patient booster trial: **Data results**



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

trial activation



- Progress re expedited regulatory registration pathway
- Expanded U.S. & Global stakeholder discussions



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

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

Progress for 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 !!!



