# Geolax

#### GeoVax Corporate Overview BIO CEO & Investor Conference

February 10-11 2025

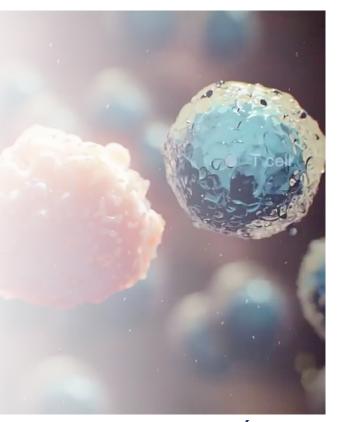
Nasdaq: GOVX

#### **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** 





#### **Priority Programs Advancing**

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

- Underserved immunocompromised patients; seeking expedited authorization path
- Generally healthy individuals -- BARDA Project NextGen

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

 Expand global access and supply; seeking expedited authorization path

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

- Tumor agnostic
- Orphan status granted for Advanced Head & Neck cancer



# 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





#### **BARDA Project NextGen**

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

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

Collaborator	N	Randomization	Study Population	
BARDA BARDA BARDA BARDA BARDA	~10,000 Pts. ~ 80 Sites	1:1	Previously Vaccinated Generally Healthy Adults	
	Study Arms (Control vs Treatment)			
	GEO-CM04S1 Vaccine	VS C	FDA-approved OVID-19 Vaccines	

Study Activation H2 '25 > 80 Sites Confirmed



#### COVID-19

#### 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



#### COVID-19



#### 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"...

## Mpox & Smallpox: GEO-MVA



#### WHO Declaration – Aug 14 & Nov 22





Mpox & Smallpox





#### **Symptoms**

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



Palms 75% of cases

Soles 75% of cases





LOW ENERGY



SWOLLEN LYMPH NODES SKIN RASH/ LESIONS





BACK PAIN







#### "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 manufactured & released: Vialing in-process
- In dialogue with various U.S. & Global stakeholders
- Regulatory discussion/guidance received supporting abbreviated approval pathway
- Implementation of Advanced MVA manufacturing platform

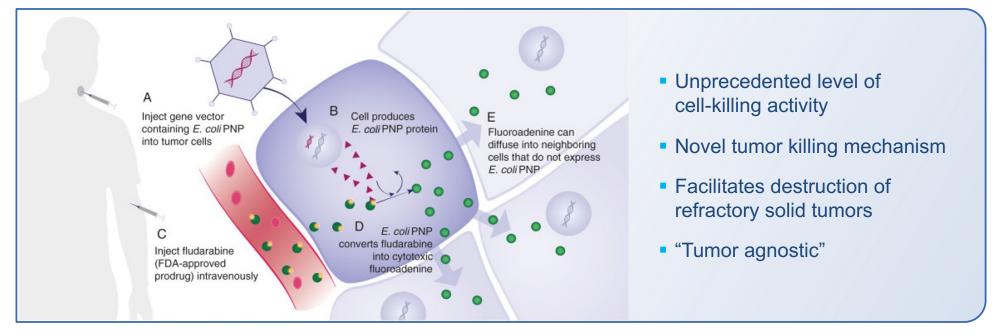


# Oncology: Gedeptin®



#### Oncology

#### **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)



#### Oncology



#### 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...

..."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**

<ul> <li>PNG: Operational progress re trial activation</li> <li>Immunocompromised/stem cell transplant patients: Additional sites initiated; interim data results</li> <li>Immunocompromised/Chronic Lymphocytic Leukemia (CLL) patients: Interim analysis indicated GEO- CM04S1 superiority vs mRNA</li> <li>Healthy patient booster trial: Data results</li> </ul>	<ul> <li>Phase 2 trial Gedeptin® + ICI: Operation progress re trial activation</li> </ul>
GEO-MVA (Mpox; Smallpox)	Advanced, Transformative Continuous Cell-line MVA Manufacturing
<ul> <li>Progress re cGMP GEO-MVA production</li> <li>cGMP clinical batch : Vialing in-process</li> <li>Expanded U.S. &amp; Global stakeholder discussions</li> </ul>	<ul> <li>Process Development underway; GEO-CM04S1 and GEO-MVA</li> </ul>

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

Product	Disease	Target	Est'd Market Revenue Potential \$(Billion)
GEO-CM04S1	COVID-19	Primary Vaccine For Immune Compromised Patients/Booster to mRNA	\$ 30.0+
GEO-MVA	Mpox/Smallpox	Global Health Emergency U.S. SNS	\$ 10+
Gedeptin®	Cancer	Early-Stage Head & Neck Cancer	\$ 12.4
Gedeptin®	Cancer	Advanced Head & Neck Cancer	\$ 2.8

~\$55 Billion in Market Revenue Potential



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### Thank You !!!