# Geolox

#### **BIO CEO & Investor Conference 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.



# Oncology – Gedeptin®

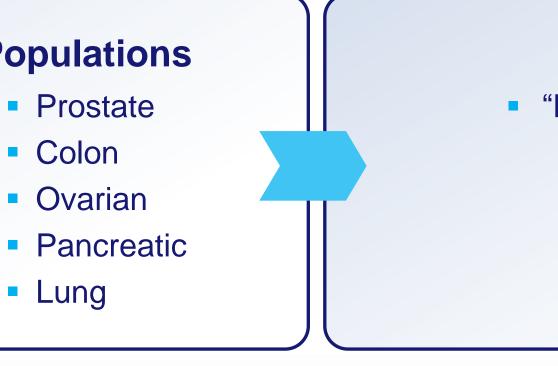




### **Gedeptin®: U.S. Medical Need**

#### **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) 15,000
- Early-Stage Head & Neck Cancer (new dx/yr) 67,000
- Other Solid Tumors (deaths/yr) 321,000



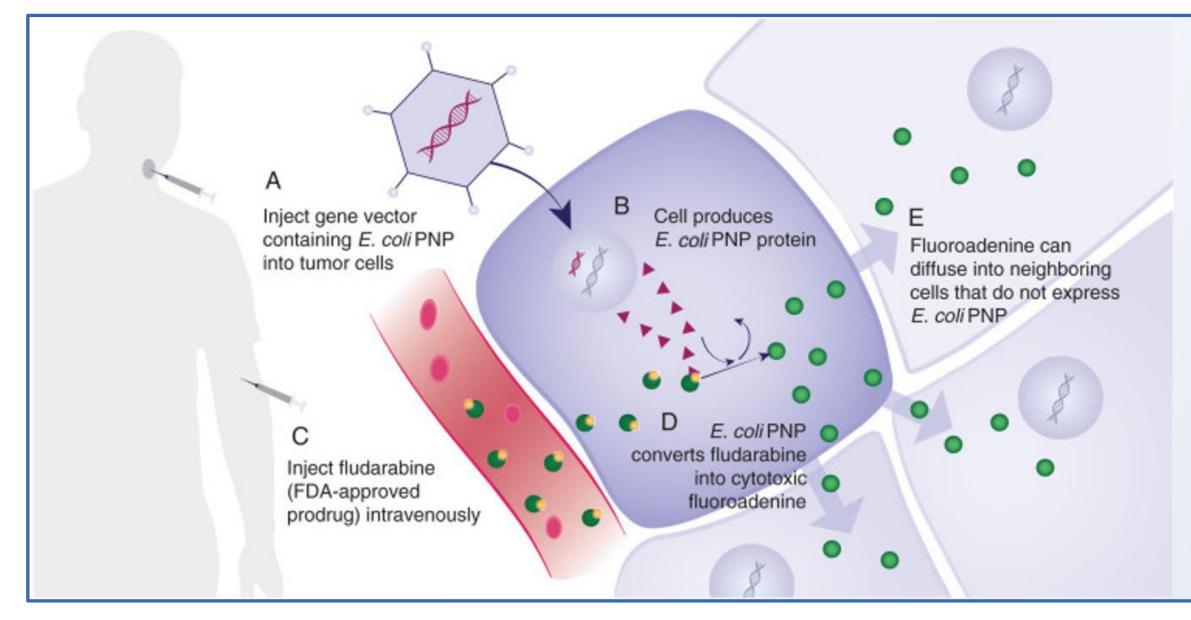
#### **Patient Characteristics**

"Needle-accessible" solid tumors

hs/yr) - 15,000 w dx/yr) - 67,000 000



### **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)

- Complete 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



# Infectious Diseases – Covid-19/GEO-CM04\$1



#### **GEO-CM04S1: U.S. Medical Need**





Prevalence of Immunosuppression Among US Adults, JAMA, J



#### **Patient Characteristics:**

- Under active medical management
- Impaired immune responses to Ab stimulation (e.g., authorized Covid-19 vaccines, mRNA, protein adjuvant)
- Greater risk of severe disease, hospitalization and/or death from SARS-CoV-2 infection

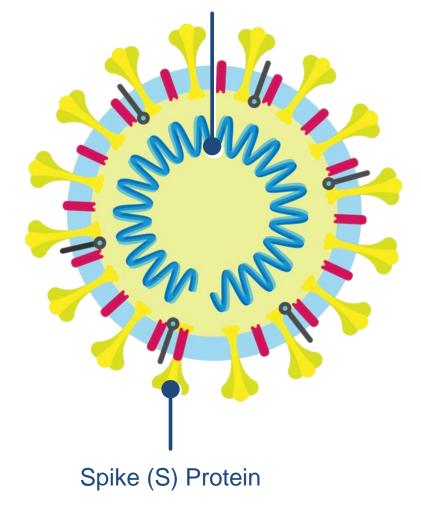
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Feb 15, 2024		



#### **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>	

Humoral and cellular immune responses contribute to protection against SARS-CoV-2 infection and coronavirus disease 2019 (Covid-19). Plus signs denote the relative importance of antibodies and T cells for protection in each category of disease severity, with more plus signs indicating greater importance.







**Covid-19 Vaccine** 

More robust, durable

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

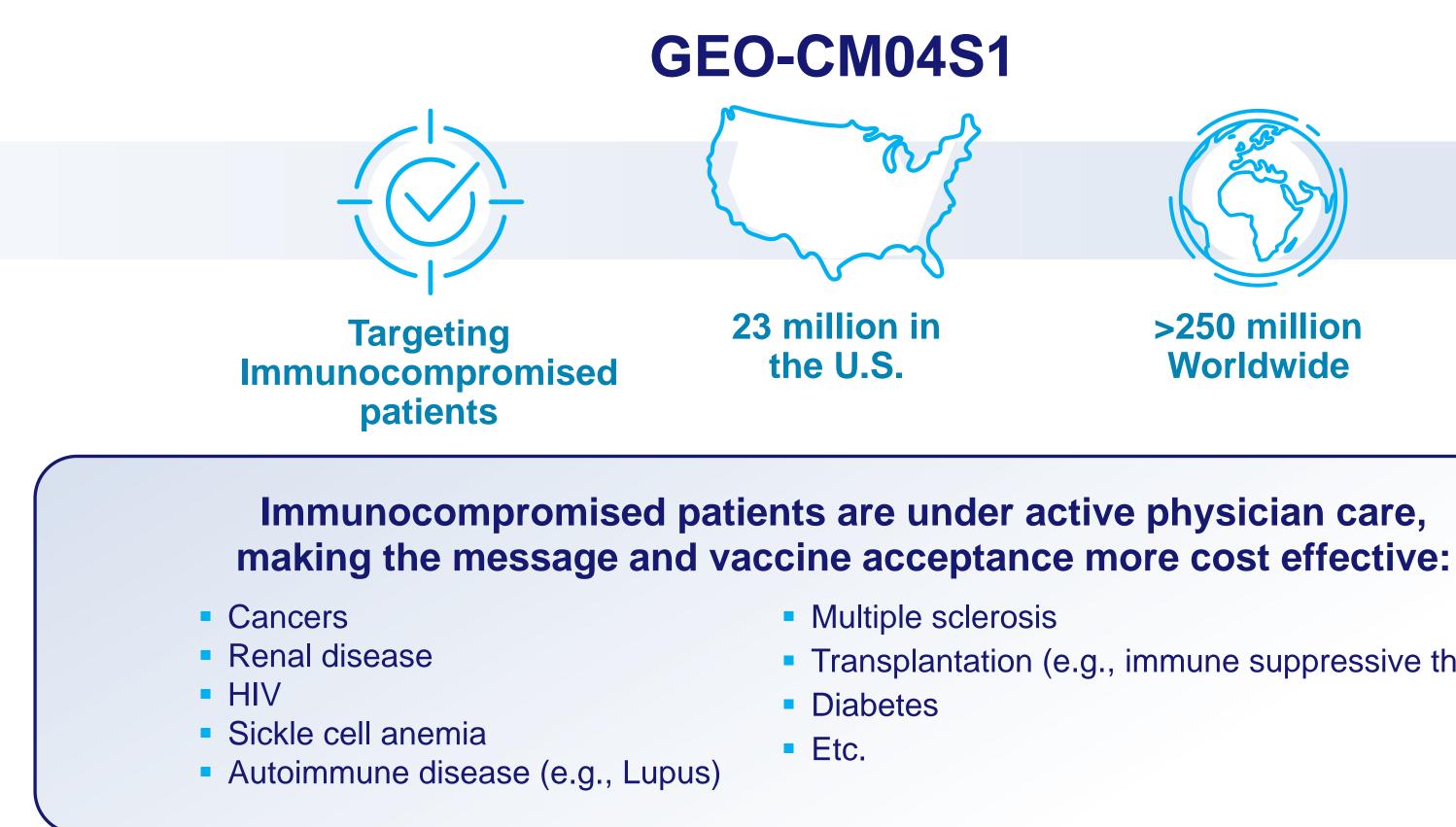
- Current vaccines do not provide sufficient protection for those with depleted immune systems
- GEO-CM04S1: More robust, durable protection than existing authorized vaccines
- Variant agnostic reduces need for boosters
- Can be used as booster to existing vaccines or stand-alone for immune compromised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





#### "Variant Agnostic"









#### >250 million Worldwide

Transplantation (e.g., immune suppressive therapy)



### **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 of GEO-CM04S1 Addressing Immunocompromised Patients
  - Broader (Variant Agnostic), more durable protection (6-12 + months)
  - "Preferred Covid-19 vaccine for immunocompromised" patients"
- Expedited Registration Focused on **Immunocompromised Patient Populations**



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

#### Covid-19





# Infectious Diseases – Mpox & Smallpox/GEO-MVA



#### **GEO-MVA**

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



- Currently one supplier worldwide unable to meet demand
- High federal government interest in establishing a U.S. based supplier
- HHS interest in replenishing/re-stocking Strategic National Stockpile (SNS)
- GeoVax rapidly advancing development



#### **GEO-MVA: U.S. Medical Need**

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

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





#### U.S. Stockpile Target Requirement

- 66M at risk Americans
  - 132M doses

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#### **US 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**

 Smallpox: U.S. Government Strategic National Stockpile (SNS)

Mpox: Adults at risk



# Milestones, Catalysts & Summary





### **2024 Milestones & Catalysts**



#### **GEO-CM04S1 (Next-Generation Covid-19** Vaccine) – Phase 2 Clinical Program

- Immunocompromised/stem cell transplant patients: Expansion sites actively recruiting; interim data r H1
- Immunocompromised/Chronic Lymphocytic Leukemia (CLL) patients: Enrollment completed H2 '24; interim data H1
- Healthy patient booster trial: Initial Data H1; Study results H2

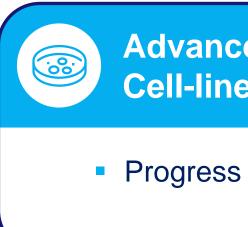


Gedeptin<sup>®</sup> (Solid Tumor Therapy) – **Phase 2 Clinical Trial** 



#### **GEO-MVA (Mpox; Smallpox)**

Progress re expedited regulatory registration pathway: H1



Initial Ph 1/2: Study data results H1 Plans for expanded Ph 2 study: H1 Updates & Plans re Gedeptin + ICI: H2

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

Progress for GEO-CM04S1 and GEO-MVA



### **GeoVax Clinical Portfolio: U.S. Revenue Opportunity**

Product	Disease	Target	Est'd Reven
GEO-CM04S1	Covid-19	Primary Vaccine For Immune Compromised Patients	<b>\$ 7</b> ,
Gedeptin®	Cancer	Advanced Head & Neck Cancer	<b>\$ 2</b> ,
Gedeptin®	Cancer	Early-Stage Head & Neck Cancer	\$ 11
GEO-MVA	Smallpox/Mpox	US Strategic National Stockpile & Adult Men at High Risk of Mpox	<b>\$ 7</b> ,

U.S. Market nue Potential \$(000)

,400,000

2,625,000

1,725,000

\$25-\$30 Billion in U.S. Market Revenue Potential

7,300,000



### **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

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



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## Thank You !!!



