



# Roth Annual Healthcare Conference

October 9, 2024

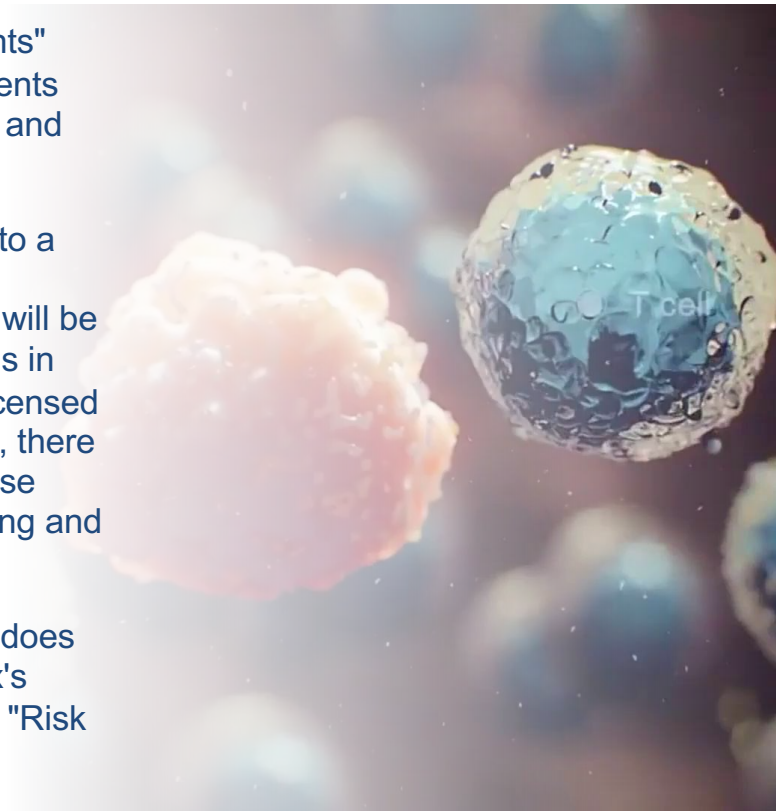
Nasdaq: GOVX

## 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**



**Differentiate**



**Accelerate**



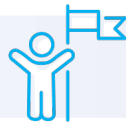
**Collaborate**



Unique, **patented products** addressing unmet medical needs



**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 – BARDA Project NextGen**
- **GEO-MVA: Mpox/Smallpox vaccine**
- **Gedepin<sup>®</sup>: Solid Tumor Therapy**

# COVID-19: GEO-CM04S1



## 1<sup>st</sup> Generation COVID-19 Vaccines

[mRNA (Pfizer/BioNTech; Moderna) and Protein subunit vaccines (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)*

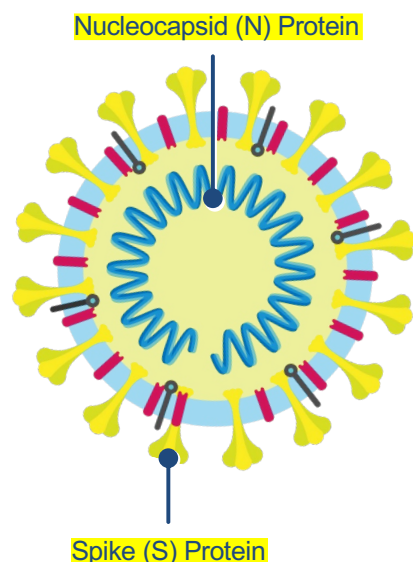
## Next-Generation COVID-19 Vaccines

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

# 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                | ++++                   | +++                   | ++                              | ++    |
| T Cells                   | +                      | ++                    | ++++                            | ++++  |

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.

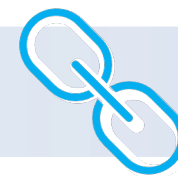
## GEO-CM04S1



COVID-19 Vaccine



More robust -- “Variant Agnostic”



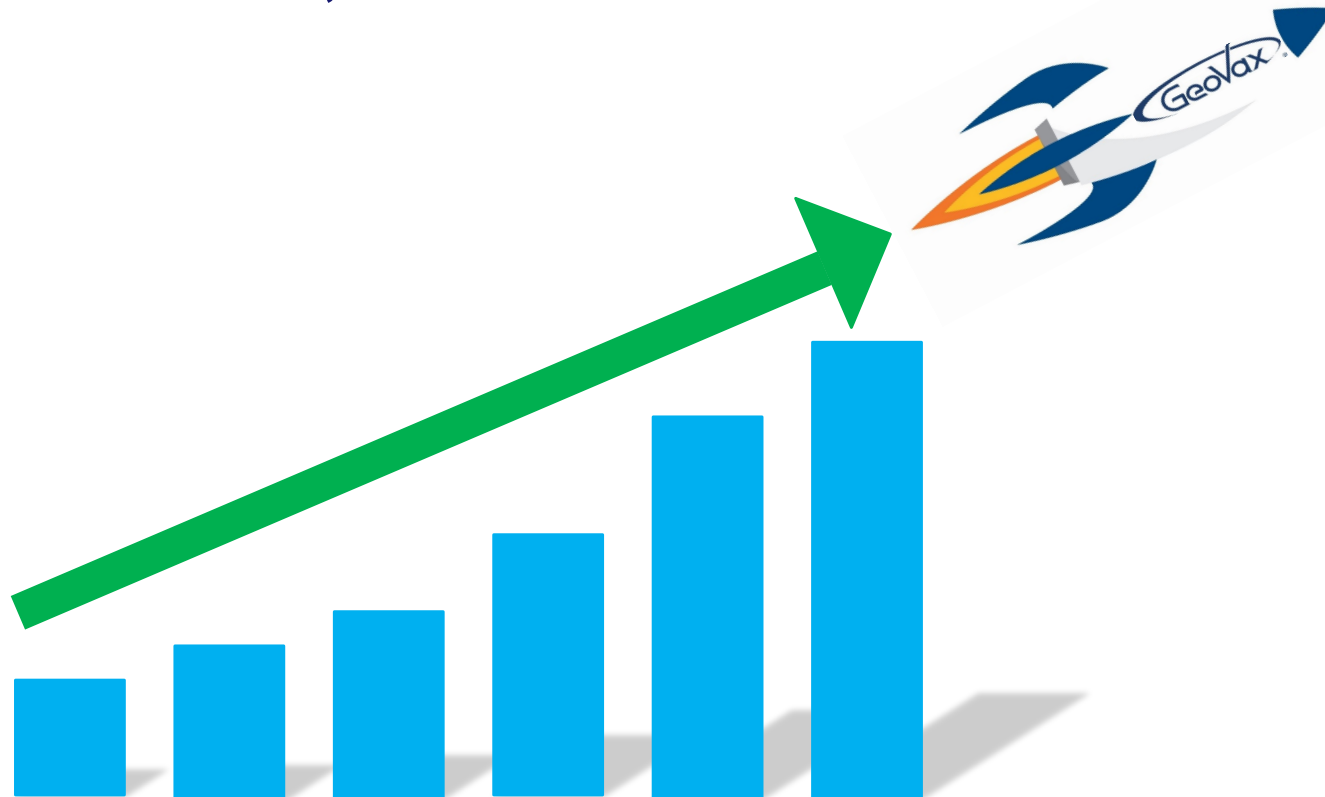
More durable – longer duration

**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




**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**



# 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                            |
|--|-----------------------------|---------------|---|
|  | ~10,000 Pts.<br>~ 100 Sites | 1:1           | Previously Vaccinated<br>Healthy Volunteers |
| Study Arms (Control vs Treatment)  |                             |               |   |
| GEO-CM04S1<br>Vaccine  |                             | VS            | FDA-approved<br>COVID-19 Vaccines           |

Study Activation H1 '25  
> 80 Sites Confirmed

## **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



### **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 (~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



# WHO Declaration – August 14, 2024

[Health Topics ▾](#)[Countries ▾](#)[Newsroom ▾](#)[Emergencies ▾](#)[Data ▾](#)[About WHO ▾](#)

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

[العربية](#)[中文](#)[Français](#)[Русский](#)[Español](#)

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

### Media Contacts

news / press releases

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



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 (8/14/24)
- Different than 2022 – more virulent and higher mortality
- Spread by close contact (sex) but can be casual contact
- Vaccination is critical to reduce morbidity/mortality threat
- Africa & worldwide need for significant resources
  - Medical care
  - Vaccine supply, distribution & administration

Source: Adapted from MedCram.com





# Symptoms

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



FEVER



INTENSE HEADACHE



MUSCLE ACHES



BACK PAIN



LOW ENERGY



SWOLLEN LYMPH NODES



SKIN RASH/ LESIONS





## Africa

- 17,000 infected (96% in DRC)
- 500+ deaths (70% children)
- Critical needs
  - 20M doses of Mpox vaccine – max of 2M-5M doses likely available by end of 2025!!!
    - **Single-source supplier worldwide with limited production capability**
    - **Additional, potential Mpox vaccine suppliers??**

\$4B needed to support medical care and support

Source: Adapted from MedCram.com



## Mpox – 2024 vs 2022

### Clade Ib (2024)

- **Endemic to Central Africa**
  - Most common strain in DRC
  - 400 new cases per week (majority in children)
- **More virulent**
- **More deadly (~ 10% mortality)**
- **Migrating worldwide!!!**

≠

### Clade IIb (2022)

- **Endemic to West Africa**
- **Less infectious**
- **Less deadly (~ 1% mortality)**

Source: Adapted from MedCram.com

## Available Vaccines Against Mpox

### ACAM 2000

- Older version
- Designed for Smallpox, but also effective for Mpox
- Live virus
- Replicating in humans
  - Contraindicated in pregnant women, immunocompromised; etc.)
- Side effects (Not 1<sup>st</sup> choice)

### MVA-BN

- Newer version
- Designed for Smallpox, but also effective for Mpox
- Live virus (weakened)
- Non-replicating in humans
  - Safe in immunocompromised, pregnant women, etc.
- Better tolerated/less side-effects

Source: Adapted from MedCram.com

## **“What’s the Solution?”**

- **WHO coordinating global health response**
- **Seeking additional Mpox vaccine supply candidates**
  - Experienced with the MVA-platform
  - MVA-Mpox vaccine candidates
  - Manufacturing capability of MVA-Mpox vaccine candidates
  - Local-Africa based MVA-Mpox vaccine Manufacturing capability

### **Critical need:**

**cGMP Master Seed Virus of MVA**

**cGMP Master Virus Bank of MVA**

**Advanced MVA Manufacturing Process**



**GeoVax**

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



## **MVA**

- Currently one supplier worldwide (MVA-BN) – 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 (GEO-MVA)**
  - cGMP Master Seed Virus produced
  - cGMP Master Virus Bank in process development
  - Evaluating options to accelerate towards manufacturing
  - In dialogue with various U.S. & Global stakeholders
  - Regulatory discussion/guidance received
  - Advanced MVA manufacturing process underway

# Oncology: Gedeptin®



## Gedepin<sup>®</sup>: Significant Medical Need

### Target Cancer Patient Populations

- Advanced Head & Neck (initial indication; Orphan Drug Status)
- Earlier-Stage Head & Neck
- Breast
- Prostate
- Colon
- Ovarian
- Pancreatic
- Lung



### Patient Characteristics

- “Needle-accessible” solid tumors

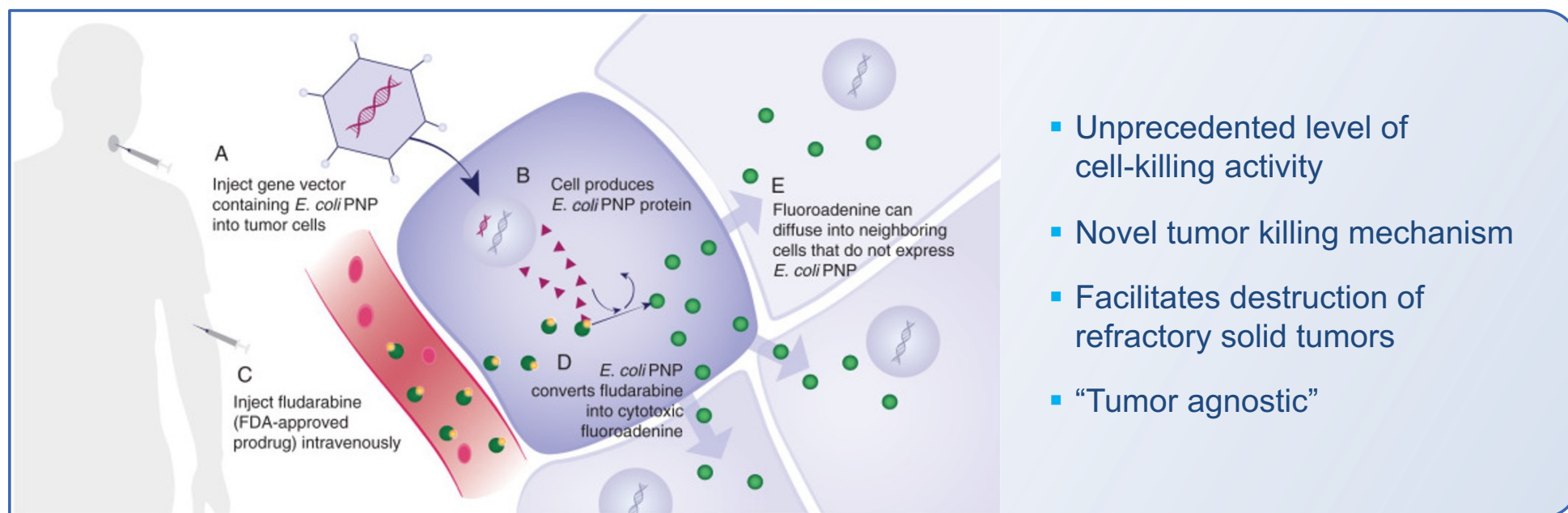


### Patient Prevalence (U.S.)

- 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

Source: American Cancer Society (ACS) Cancer Facts & Figures 2024

## Gedepin® Mechanism of Action



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

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



# Gedepin® Clinical Data\*

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



Stanford Cancer Institute



A. Dimitrios Colevas<sup>1\*</sup>, Eric J. Sorscher<sup>2\*</sup>, William Parker<sup>3</sup>,  
Roan Courtney Raymundo<sup>1</sup>, Jeong S. Hong<sup>2</sup>, Regina Rab<sup>2</sup>,  
Camilo Henao<sup>4</sup>, Nikki Schmitt<sup>2</sup>, Madison Stallings<sup>2</sup>, Kelly T.  
McKee, Jr.<sup>5</sup>, Eben Rosenthal<sup>6</sup>, Joseph Curry<sup>4</sup>



Evaluation of Gedepin® as an experimental therapy for refractory tumors (NCT03754933)



Safety and efficacy of repeat cycles of Gedepin® 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):

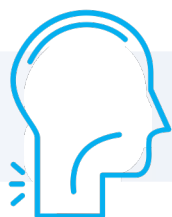
- No dose limiting toxicities or serious adverse events (SAEs) are attributable to treatment
- No adverse events above grade 3 severity
- Up to 5 cycles of Gedepin® treatment administered without limiting sequelae
- Intratumoral expression of the PNP transgene bt RT-PCR established in treatment tumors 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 Gedepin® 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

## Gedepin® Clinical Development Plans



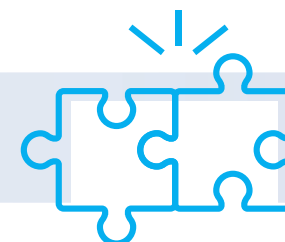
### Initial Focus: Advanced Head & Neck Cancer Indication (Mono-therapy)

- 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



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

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



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



## **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**



### Gedepin® (Solid Tumor Therapy) – Phase 2 Clinical Trial

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



### GEO-MVA (Mpox; Smallpox)

- Progress re cGMP GEO-MVA production
- Expanded U.S. & Global stakeholder discussions



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

- Progress for GEO-CM04S1 and GEO-MVA



## GeoVax Portfolio: 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<br>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**

# GeoVax Strategy



**Innovate**



**Differentiate**



**Accelerate**



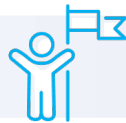
**Collaborate**



Unique, **patented products** addressing unmet medical needs



**Targeting populations** unserved 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**



**Thank You !!!**