



GeoVax Expands Immuno-Oncology Pipeline with Acquisition of Clinical-Stage Cancer Program

License of Gedeptin® Adds Orphan Drug Clinical Program for Treatment of Advanced Head and Neck Cancers

ATLANTA, GA, September 28, 2021 – GeoVax Labs, Inc. (Nasdaq: GOVX), a biotechnology company specializing in developing human vaccines and cancer immunotherapies, today announced that it has entered into an Assignment and License Agreement (the “License”) with PNP Therapeutics, Inc. (“PNP”), that grants GeoVax exclusive rights to develop and commercialize Gedeptin®, a novel patented product for the treatment of solid tumors.

The License provides exclusive worldwide rights to key intellectual property, including Gedeptin patents, know-how, regulatory filings, clinical materials, and trademarks. The patent portfolio covering Gedeptin, was originally licensed from the University of Alabama at Birmingham (UAB) and Southern Research Institute (SRI) by PNP. Under the License, GeoVax will become the successor to PNP under its license agreement with UAB/SRI. Detailed financial terms of the transaction were not disclosed, but include a combination of upfront payments, milestone fees, and royalties on net sales.

A cycle of Gedeptin therapy consists of three intra-tumoral injections of Gedeptin over a two-day period followed by infusion of a prodrug, fludarabine phosphate, once a day for three days. A Phase 1 dose ranging study, evaluating the safety of a single cycle of Gedeptin therapy, found the therapy to be well tolerated, with evidence of a reduction in tumor size in patients with solid tumors.

A Phase 1/2 trial, evaluating the safety and efficacy of repeat cycles of Gedeptin therapy in patients with recurrent head and neck squamous cell carcinoma (HNSCC), with tumor(s) accessible for injection and no curable treatment options, is currently enrolling. The initial stage of the study is being funded by the FDA pursuant to its Orphan Products Clinical Trials Grants Program. The FDA has also granted Gedeptin orphan drug status for the intra-tumoral treatment of anatomically accessible oral and pharyngeal cancers, including cancers of the lip, tongue, gum, floor of mouth, salivary gland and other oral cavities.

The Gedeptin technology was developed with funding support from the National Cancer Institute of the National Institutes of Health. The License also grants GeoVax the rights to expand the use of Gedeptin to all human diseases and/or conditions including, but not limited to, other cancers.

David Dodd, GeoVax President and CEO, commented, “The signing of this license agreement is an important and exciting event for GeoVax and our stockholders, as it adds a clinical program in immuno-oncology to our pipeline, which is one of the primary focus areas for our company. The initial stage (10 patients) of the ongoing clinical trial for Gedeptin is being funded by the FDA pursuant to its Orphan Products Grants Program, with five patients having been enrolled to date. Our immediate objective will be to accelerate patient enrollment to complete this stage, then expand the trial to additional study sites and at least 25 patients in total. Based on PNP’s End-of-Phase-1 meeting with the FDA, we believe that a successful outcome from the expanded trial may lead to labelling discussions with the FDA at the end of the study.”

Dodd added, “In addition to the immediate opportunity resulting from the existing clinical program, the license to the Gedeptin technology opens additional opportunities to potentially develop novel therapies for other indications. We also feel that potential synergies exist between the Gedeptin technology and our GV-MVA-VLP™ platform related to immuno-oncology, providing further expanded opportunities for developing novel

cancer immunotherapies that may benefit cancer patients across multiple cancers. As we continue to advance our programs such as MVA-VLP-MUC1, we will also evaluate synergistic opportunities between the two technology platforms.”

In conclusion, Dodd commented, “Approximately one year ago, we achieved a critical strategic watershed with the successful recapitalization, financing and listing of GeoVax on the Nasdaq stock market. Since then, we have further strengthened the Company resources and status, including our ability to finance the Gedeptin transaction, including expansion and acceleration of the clinical trial using our current cash reserves. We have progressed our two core product development areas related to SARS-CoV-2 vaccines and immuno-oncology. Today’s announcement accelerates our progress within immuno-oncology, providing a pivotal clinical-stage status via the Gedeptin program. We similarly remain focused on accelerating progress related to our SARS-CoV-2 vaccine and look forward to providing further updates soon.”

Conference Call

Management will host a conference call at 4:30 p.m. ET on Wednesday, September 29, 2021 to review the transaction and discuss the Gedeptin technology. Following management’s formal remarks, there will be a question-and-answer session.

Participants are asked to pre-register for the call via the following link:

<https://dpreister.com/sreg/10160579/edd0533a8a>.

The conference call will be available through a live webcast found here:

<https://services.choruscall.com/mediaframe/webcast.html?webcastid=sC23U9pr>.

A webcast replay of the call will be available via the same link as the live webcast approximately one hour after the end of the call through December 28, 2021. A telephonic replay of the call can be accessed by calling 1-877-344-7529 (domestic) or 1-412-317-0088 (international) and using access code 10160579. The telephonic replay will be available until October 13, 2021.

About the Gedeptin® Technology Platform

Many common cancers (including prostate, breast, colon, lung, brain, melanoma, pancreas, ovarian, kidney) become untreatable despite the best medical intervention and the highest standard of care and are eventually fatal. Chemotherapeutic agents may be able to destroy these tumors, but many are much too toxic to administer systemically to already debilitated cancer patients. Most conventional anti-cancer drugs in use today derive their anti-tumor specificity from the ability to kill rapidly dividing cells. These drugs are suitable for systemic administration specifically because they are most toxic to cells that are dividing. However, many tumors such as head and neck squamous cell carcinoma (HNSCC) are resistant to treatment because they have a very low growth fraction (i.e., a relatively small percentage of tumor cells dividing at any particular point in time). Compounds toxic to non-proliferating cells generally are not used in the treatment of cancer, because most of the cells in a patient are not proliferating and such compounds have no selectivity when administered systemically.

Among the various gene therapy strategies for cancer treatment, GDEPT (Gene-Directed Enzyme Prodrug Therapy) has shown promise. In GDEPT a vector is used to selectively transduce tumor cells with a nonhuman gene, which expresses an enzyme that can convert a nontoxic prodrug into a very toxic antitumor compound. A prodrug is a pharmaceutical compound that remains inactive in its biochemical form until it reaches its target site, such as an organ or tissue, and then undergoes an immediate metabolic breakdown; it then releases the molecular compounds of the parent drug, or active ingredients, at the point of delivery. Because the nonhuman gene is only expressed in tumor tissue, the nontoxic prodrug is only activated in tumor tissue. Therefore, unlike conventional chemotherapy, GDEPT should result in selective killing of tumor cells with little or no systemic toxicity.

GDEPT strategies that produce potent cytotoxic agents (active against nonproliferating and proliferating tumor cells) and that have high bystander activity could have dramatic effects on the treatment of solid tumors. A

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bystander effect typically refers to the death, altered growth or damage of cells that have not directly received chemotherapy or irradiation. Earlier GDEPT approaches have had limited efficacy specifically because of poor bystander activity and inability to destroy non-proliferating tumor cells.

Gedepin potentially overcomes previous GDEPT limitations and may serve as a robust platform for development in multiple indications. Gedepin consists of a non-replicating adenoviral vector expressing an optimized *E. coli* purine nucleoside phosphorylase (*E. coli* PNP) that is injected intra-tumorally, and then followed by intravenous or intra-tumoral administration of a prodrug.

Among the prodrugs that have been evaluated for use with Gedepin, fludarabine phosphate (Fludara®) is of particular interest because (i) it is currently approved by the FDA for use in humans and (ii) it has demonstrated excellent *in vivo* antitumor activity in murine models when only 2-3% of tumor cells express *E. coli* PNP. Fludarabine is currently approved by the FDA to treat chronic lymphocytic leukemia, but has not been shown to be effective against other solid tumors. But when fludarabine is administered following Gedepin, the combination exploits the selective expression of the *E. coli* PNP gene in tumor cells to utilize fludarabine phosphate as a prodrug, resulting in the localized production of fluoroadenine (F-Ade), a potent cytotoxic compound with pronounced antitumor activity.

Ongoing Phase 1/2 Clinical Trial – Currently, Gedepin is in a Phase 1/2 clinical trial, being conducted at Stanford University in collaboration with Emory University. The trial design involves repeat administration using Gedepin followed by systemic fludarabine, as a way to gain additional information prior to expansion towards a larger patient trial. The initial stage of the study (10 patients) is being funded by the FDA pursuant to its Orphan Products Grants Program. Five patients have been enrolled to date.

Orphan Drug Status – The FDA has granted orphan drug status to Gedepin, for the intra-tumoral treatment of anatomically accessible oral and pharyngeal cancers, including cancers of the lip, tongue, gum, floor of mouth, salivary gland and other oral cavities. The orphan drug designation is awarded to drugs designed to treat a rare disease or condition that affects fewer than 200,000 people in the U.S., and it is applied specifically to novel therapeutics that could represent a major improvement in treatment. Orphan drug status provides regulatory incentives, reduced fees, and a more rapid review by the FDA, and stipulates that competing therapies can be blocked from the market for up to seven years. Additionally, this status qualifies the drug sponsor for various development incentives, including tax credits for qualified clinical testing.

About GeoVax

GeoVax Labs, Inc. is a clinical-stage biotechnology company developing human vaccines against infectious diseases and cancer using a novel patented Modified Vaccinia Ankara-Virus Like Particle (MVA-VLP) based vaccine platform. On this platform, MVA, a large virus capable of carrying several vaccine antigens, expresses proteins that assemble into VLP immunogens in the person receiving the vaccine. The production of VLPs in the person being vaccinated can mimic virus production in a natural infection, stimulating both the humoral and cellular arms of the immune system to recognize, prevent, and control the target infection. The MVA-VLP derived vaccines can elicit durable immune responses in the host similar to a live-attenuated virus, while providing the safety characteristics of a replication-defective vector.

GeoVax's current development programs are focused on preventive vaccines against COVID-19, HIV, Zika Virus, hemorrhagic fever viruses (Ebola, Sudan, Marburg, and Lassa), and malaria, as well as therapeutic vaccines against multiple cancers. The Company has designed a preventive HIV vaccine candidate to fight against the subtype of HIV prevalent in the commercial markets of the Americas, Western Europe, Japan, and Australia; human clinical trials for this program are managed by the HIV Vaccine Trials Network (HVTN) with the support of the National Institutes of Health (NIH). GeoVax's HIV vaccine is also part of a collaborative effort toward a functional cure for HIV.

Forward-Looking Statements

This release contains forward-looking statements regarding GeoVax's business plans. The words "believe,"

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“look forward to,” “may,” “estimate,” “continue,” “anticipate,” “intend,” “should,” “plan,” “could,” “target,” “potential,” “is likely,” “will,” “expect” and similar expressions, as they relate to us, are intended to identify forward-looking statements. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our financial condition, results of operations, business strategy and financial needs. Actual results may differ materially from those included in these statements due to a variety of factors, including whether: GeoVax is able to obtain acceptable results from the current phase 1/2 clinical trial involving Gedepin or additional tests of its preventive vaccine, GeoVax’s immuno-oncology products and preventative vaccines can provoke the desired responses, and those products or vaccines can be used effectively, GeoVax’s viral vector technology adequately amplifies immune responses to cancer antigens, GeoVax can develop and manufacture its immuno-oncology products and preventative vaccines with the desired characteristics in a timely manner, GeoVax’s immuno-oncology products and preventative vaccines will be safe for human use, GeoVax’s vaccines will effectively prevent targeted infections in humans, GeoVax’s immuno-oncology products and preventative vaccines will receive regulatory approvals necessary to be licensed and marketed, GeoVax raises required capital to complete 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.

Further information on our risk factors is contained in our registration statement on Form S-1 and the periodic reports on Form 10-Q and Form 10-K that we have filed and will file with the SEC. Any forward-looking statement made by us herein speaks only as of the date on which it is made. Factors or events that could cause our actual results to differ may emerge from time to time, and it is not possible for us to predict all of them. We undertake no obligation to publicly update any forward-looking statement, whether as a result of new information, future developments or otherwise, except as may be required by U.S. federal securities law.

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