SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of report (Date of earliest event reported): September 29, 2021

GEOVAX LABS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-39563**	**87-0455038**
(State or other jurisdiction of incorporation or organization)	**(Commission File No.)**	**(IRS Employee Identification No.)**

1900 Lake Park Drive, Suite 380
Smyrna, Georgia 30080
(Address of principal executive offices) (Zip code)

(678) 384-7220
(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the Registrant under any of the following provisions.

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b)).

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13(e)-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	GOVX	The Nasdaq Capital Market
Warrants to Purchase Common Stock	GOVXW	The Nasdaq Capital Market

Indicate by check mark whether the Registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (Section 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (Section 240.12b-2 of this chapter). Emerging growth company ☐

If an emerging growth company, indicate by check mark if the Registrant has elected not to use the extended transition period for complying with any new or revised financial reporting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 Regulation FD Disclosure.

On September 29, 2021, GeoVax Labs, Inc. (the "Company") hosted a conference call and webcast with accompanying slides regarding the Company's previously disclosed acquisition of exclusive rights to develop and commercialize Gedeptin®, a novel patented product for the treatment of solid tumors, through an Assignment and License Agreement with PNP Therapeutics, Inc. A transcript of the conference call and a copy of the slides are being furnished as Exhibit 99.1 and Exhibit 99.2, respectively, to this Current Report on Form 8-K. The foregoing summary of the conference call and of the slides is not complete and is qualified in its entirety by reference to the full text of Exhibit 99.1 and Exhibit 99.2. The Company undertakes no obligation to update, supplement or amend the materials attached hereto.

The information in Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1 and 99.2, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to liability under that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Forward-Looking Statements

This Current Report on Form 8-K and other reports filed by the Company from time to time with the Securities and Exchange Commission (collectively the "Filings") contain forward-looking statements and information that are based upon beliefs of, and information currently available to, the Company's management as well as estimates and assumptions made by the Company's management. When used in the Filings the words "anticipate", "believe", "estimate", "expect", "future", "intend", "plan" or the negative of these terms and similar expressions as they relate to the Company or the Company's management identify forward looking statements. Such statements reflect the current view of the Company with respect to future events and are subject to risks, uncertainties, assumptions and other factors relating to the Company's industry, operations and results of operations and any businesses that may be acquired by the Company. Should one or more of these risks or uncertainties materialize, or should the underlying assumptions prove incorrect, actual results may differ significantly from those anticipated, believed, estimated, expected, intended or planned. Except as required by law, the Company does not undertake to update its forward-looking statements.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Gedeptin® License Conference Call Transcript dated September 29, 2021
99.2	Gedeptin® License Conference Call Slide Presentation dated September 29, 2021
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: September 30, 2021

GEOVAX LABS, INC.

By: /s/ Mark W. Reynolds
Mark W. Reynolds
Chief Financial Officer

Exhibit 99.1

GeoVax Labs, Inc.

GeoVax Gedeptin License Announcement Call

Wednesday, September 29, 2021, 4:30 PM Eastern

CORPORATE PARTICIPANTS

David Dodd - *Chairman, Chief Executive Officer*

Mark Reynolds - *Chief Financial Officer*

Mark Newman - *Chief Scientific Officer*

John Sharkey - *Head, Business Development*

Eric Sorscher - *Professor, Emory University School of Medicine and Medical Founder of PNP Therapeutics*

Jules Abraham - *CORE, Investor Relations*

PRESENTATION

Operator
Good afternoon, and welcome everyone to the GeoVax Gedeptin License Announcement Call. My name is Gary with Chorus Call, and I will facilitate today's call.

With me are David Dodd, Chairman and CEO, Mark Reynolds, Chief Financial Officer, Mark Newman, Ph.D., Chief Scientific Officer, John Sharkey, Ph.D., Head, Business Development and Eric Sorscher, MD, Professor, Emory University School of Medicine and Medical Founder of PNP Therapeutics.

All participants will be in listen-only mode. Should you need assistance, please signal a conference specialist by pressing the "*" key followed by "0." After today's presentation, there will be an opportunity to ask questions. To ask a question, you may press "*" then "1" on your telephone keypad, to withdraw your question, please press "*" then "2." Please note, this event is being recorded.

I would now like to turn the conference over to Jules Abraham of CORE IR, who will provide a forward-looking statement regarding this call and information herein.

Jules Abraham
Thank you, Gary. Please note the following. 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 as risk factors in GeoVax's Form 10-K.

It is now my pleasure to introduce the Chairman and CEO of GeoVax, David Dodd. David.

David Dodd
Thank you, Jules. Good afternoon and thank you everyone for participating in this call, following our announcement of the licensing of Gedeptin from PNP Therapeutics. One year ago, we successfully recapitalized GeoVax, strengthened the balance sheet and listed on NASDAQ. Since then, we have further strengthened our cash reserves, while advancing our product development priorities, focused on accelerating in the clinical development in the areas of immuno-oncology and our coronavirus vaccine program.

We remain focused on those priorities and yesterday we announced the licensing of Gedeptin, which is a clinical stage immuno-oncology therapy, currently being evaluated to treat head and neck cancers. Gedeptin has been granted orphan drug status related to the treatment of head

neck cancers. The initial stage of the ongoing clinical trial is being funded by the FDA pursuant to its Orphan Products Clinical Trials Grant's program with five patients having been enrolled to-date. Our immediate objective will be to accelerate patient enrolment of this initial stage and expand the trial from the current single site to additional sites, completing at least 25 patients in total. IRB approvals have already been granted to two additional sites, facilitating our ability to rapidly accelerate the Gedeptin clinical program.

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 labeling discussions with the FDA at the end of the study. In addition to the immediate opportunity resulting from the existing clinical program, the license to Gedeptin technology opens additional opportunities to potentially develop novel therapies for other cancer indications as well as, for non-cancer indications. We also feel that potential synergies exist between the Gedeptin technology and our MVA-VLP platform related to immuno-oncology, providing further expanded opportunities for developing novel cancer immune-therapies. Finally, we want to underscore that we are financing the Gedeptin transaction including expansion and acceleration of the clinical trial using our current cash reserves.

Now, we'd like to further discuss the Gedeptin, this unique approach to potentially treating various cancers and benign tumors, our plans to accelerate the development of Gedeptin, and to then address what questions you may have.

To start, I'll turn the call over to Eric Sorscher, MD, Professor, Emory University School of Medicine, and Medical Founder of PNP Therapeutics to discuss the scientific and medical basis for Gedeptin including its unique mechanism of action, potential patient populations to target in the clinical development progress of Gedeptin thus far, as well as continued developments in progress related to this highly promising product. Eric.

Eric Sorscher
Thank you, David. I'd like to provide an overview of the development of Gedeptin including status of the clinical trial and plans for future expansion, if I can have the next slide, please.

So, the discovery and uniqueness of this project involves the concept of death from within the tumor itself. We've shown that by generating very potent anticancer compounds intratumorally, we can destroy otherwise refractory neoplasms and do this safely. I will be elaborating on that concept, which is emblematic of the overall approach we'll discuss today. Next slide, please.

So, chemotherapy and radiation treatments often fail, and one of the predominant reasons for failure is that these modalities are unable to treat the quiescent, non-dividing or noncycling cells within a tumor mass. The PNP technology is specifically designed to destroy both non-dividing and dividing malignant cells, and in fact any cancer cell, whether it's dividing or not. Next slide, please.

The mechanism of action of the approach involves introduction into a tumor mass of Gedeptin, which is a replication-deficient adenovirus encoding the prokaryotic purine nucleoside phosphorylase, or PNP gene. That enzyme PNP does nothing by itself as shown in the left-hand portion of this slide but subsequently, as shown in the middle part of the diagram, fludarabine phosphate is administered, which is cleaved by plasma enzymes to the prodrug fludarabine.

Fludarabine has no activity against solid tumors, but when it interacts with the purine nucleoside phosphorylase gene expressed in tumor cells, fludarabine is converted to a very potent anticancer compound called fluoroadenine. You can see the structure of fludarabine in the right-hand corner

of the slide, and for the aficionados, the two major components, the sugar and the base in this structure. It is the purine base fluoroadenine that is cleaved off and confers an unprecedented level of cell killing. The approach works by a novel mechanism that interrupts DNA, RNA and protein synthesis and very efficiently destroys refractory solid tumors.

Fluoroadenine really represents the secret sauce of the strategy. A drug like fluoroadenine could not be given systemically because it is very toxic if released widely into the circulation. However, when fluoroadenine is generated intratumorally, it has a robust antitumor effect and elicits regressions and cures. If any small amount of fluoroadenine is released from the tumor into circulation, our preclinical and clinical data indicate the compound is diluted greatly in the host and rapidly metabolized and cleared by xanthine oxidase, a ubiquitous enzyme in mammals.

In our work to-date the strategy has been very safe. For example, when we treat animals or patients and check for fluoroadenine in their blood with a very sensitive assay, we are not able to detect the compound because of its rapid clearance. Next slide, please.

This slide provides an example of an experiment in which we treated a refractory glioma tumor in mice using the strategy. The important point again is to note that neither the PNP gene nor the prodrug by themselves have any anticancer effect. It's only when PNP is combined with fludarabine that we see tumor regressions.

So, in this slide you see three curves that are headed upwards. These three curves show tumors that are growing and killing animals either given vehicle (that is untreated), given the PNP gene alone but no fludarabine, or given fludarabine alone but no PNP. In all cases the tumors grow rapidly and kill the animals. It's a refractory tumor. But if we treat on days 14, 15, and 16, with both agents you see a fundamentally different result. These are the curves headed downward, these different schedule…three difference schedules are shown in which something less than 3% to 5% of the cells in each tumor express the PNP enzyme. You can see complete regressions and cures of the tumors specifically given PNP plus fludarabine.

These are tumors in which the PNP gene was provided before the malignant masses were grown in mice, and there are three salient points I want to make. First, the effect is very rapid, as soon as fludarabine is administered, tumors regress and the growth curves diverge. Second, as described a moment ago, the effect depends on both components, the PNP gene and prodrug, neither of these is active as a single agent, and antitumor activity is very robust. And third, the approach is safe.

Preclinical studies across numerous tumor types indicate animal models tolerate the treatment well and can go on to exhibit strong regressions of their cancers without serious sequelae. I also want to emphasize that much of the data such as this I'll be describing today has been peer reviewed and published in the literature. Could I have the next slide, please?

Some powerful aspects of the approach include the novel antitumor killing mechanism I've described, the activity against tumor cells regardless of their proliferative status, the lack of systemic or other toxicity, additivity or synergy with radiation therapy, and the ability to kill tumor stem cells (if you're a proponent of that view of cancer biology). We also have data showing…We also have data showing we can augment immune clearance of malignant tissue for example in combination with checkpoint blockade. So, I'll comment on that again in a moment. The findings regarding immune clearance provide a wonderful fit with GeoVax in this collaboration. Next slide, please.

Findings such as these led us to design an early phase clinical study. This was a standard 3-by-3 study design with a single treatment cycle. In the first two days of the week-long cycle, patients were given Gedeptin intratumorally, and then on days three, four and five with fludarabine one dose each day was administered. We evaluated four cohorts. In the first three cohorts we escalated fludarabine, in the fourth we escalated adenovirus encoding PNP.

The next slide shows the results of the two higher dosing cohorts. Although the cohorts were small, we saw significant decrease in tumor size in the six patients treated at higher dose levels. You can see, for example, in patient eight, complete regression of the tumor and then re-growth. In patient 11, the tumor was ablated, in other patients we saw modest antitumor effectiveness. Like any cancer intervention, it would be very unlikely that a single treatment cycle would cure a tumor, but data like this encouraged us to move forward with the study of repeat administration.

For example, in patient eight, we would love to treat again with another course of therapy at the time the tumor starts to regrow, that is at around day 30. Note that these were all patients who had failed every other modality for their solid tumors, had no other treatment options, and often with limited life expectancy. Most patients had head and neck squamous cell carcinoma.

In semblance to the animal studies I showed a moment ago, there are three important points to recognize, first, the adenovirus encoding PNP does nothing by itself. Look at patients 8, 9 and 11, for example. Second, as soon as fludarabine is dosed we see strong antitumor activity. Tumor regressions are rapid and require both components. And third, the approach is safe, as shown in the next slide please.

We saw no serious adverse events that were of a significant grade no dose limiting toxicities, and the intervention was very well tolerated according to the clinicians that ran this study. Next slide, please.

So, this led us to propose an additional clinical trial in which five cycles of treatment are being administered and the entire tumor burden is being addressed with larger volumes of Gedeptin, so that larger tumors can be both dosed. We are using the same drug schedule and regimen across multiple cycles that was shown safe in a single cycle. This study is early and ongoing, and we're excited by the prospect of expanding our clinical experience and findings in collaboration with GeoVax. And now the last slide, please.

And the final point I want to make involves a question often asked when I give presentations of that…of this type, and that is, how does the PNP approach perform in combination with checkpoint blockade inhibitors? The answer is that we have strong emerging data that PNP-based treatment is additive or synergistic with checkpoint blockade agents. We have found that PNP mediated regression of a tumor in one flank of an animal can robustly sensitize tumors on the contralateral flank that do not produce PNP that is when checkpoint blockade is given concurrently. Presumably this occurs by destroying tumor tissue at one site and exposing neo-antigens and enhancing tumor response and activity to checkpoint blockade at other tumor sites, so that an abscopal effect is achieved.

So now we have a system in which we'll be able to take a tumor in one anatomic location in a human host, treat it with PNP in combination with checkpoint blockade and potentially sensitize other tumors in the same patient to the checkpoint blockade drug. So, you can see why we've been excited about the use of Gedeptin as a therapeutic option in addressing various cancers. We have initially focused on head and neck malignancy, but potentially will expand to additional cancers and enhance utility of other cancer therapies such as checkpoint inhibitors.

Now, I'd like to turn the presentation over to Mark Newman, our Chief Scientific Officer at GeoVax, who will discuss how Gedeptin fits into the GeoVax immuno-oncology scope, including providing an expanded technology portfolio for developing therapies against various cancers.

Mark Newman
Thank you, Eric. I am only going to add only a few comments to highlight the potential synergy and flexibility that the Gedeptin technology adds to the GeoVax cancer immunotherapy program. The slide 14, this is the slide you have seen before if you have seen some of our presentations. I just want to point out that we fully recognize that cancer is a very difficult disease to treat successfully and the combinations of both existing and new technologies and products are likely to be required for maximum benefit.

We've described previously the GeoVax approach is based on three components. Active vaccination using our proprietary MVA-VLP vaccine approach in combination with peptides and adjuvants to both induce and focus immune responses, both cellular and antibody responses to the selected tumor-associated antigen. We have this in our portfolio -- details were presented previously.

Following the induction of immune responses, checkpoint inhibitors can be used to both augment and maintain effective levels of tumor specific responses. These checkpoint inhibitors are drugs that are already approved for human use, they're standard of care options for certain cancers and their effectiveness may in fact be increased when used in combination with other therapies such as vaccines or the Gedeptin.

And finally, technology that targets and effectively and directly kills tumor cells is needed, as the effect of using Gedeptin. Gedeptin can function independently, but also additively, reducing the burden to the immune system by reducing the size of the tumor that the immune system must attack and control. So, the addition of Gedeptin literally fills out the three legs of our approach.

Final wrap up slide is to bring this back into the fold with our MUC1 cancer immunotherapy target. Now, each of the modalities that we're working with could contribute to an effective treatment of cancer independently, but we firmly believe that synergism is likely to happen.

For example, in our MUC1 program, the Gedeptin treatment of accessible tumors could lead to cell death, this would serve to initially induce immune responses, which basically means as the tumor is dying, the cells themselves serve as the vaccine. The immune responses that are induced could be boosted or then further focused by vaccination with the MVA-VLP and peptides. These would then be augmented and maintained through the use of the approved checkpoint inhibitors, so it's a one, two, three punch, and of course, alternative orders could be used. We could start with the MUC1 vaccine, which would then be followed by Gedeptin treatment, and then followed by a checkpoint inhibitor.

Now, which works best will have to be determined in animal models and clinical experimentation. But this will allow us to determine optimal treatment regimens, which may in fact be varied for different tumor types and individuals and based on tumor locations in a manner that quickly approaches individualized medicine. So having the options here is really a tremendous advantage for GeoVax.

Now, I'll turn this back to David.

David Dodd
Thank you, Mark and Eric. So, I hope everyone can see why we're so excited about the potential for Gedeptin become a core therapeutic option and addressing various tumors, initially focused on head and neck cancers, but potentially expanding to additional cancers, benign tumors, and enhancing the utility of other cancer therapies such as checkpoint inhibitors. Indeed, we're most excited about the many opportunities accompanying the Gedeptin license, as well as, to work closely with Eric and his colleagues towards improving therapeutic options for various cancers.

My colleagues and I will now answer your questions. I'm therefore turning the call over to the operator for instructions on the Q&A period.

QUESTION AND ANSWER

Operator
We will now begin the question-and-answer session. To ask a question, you may press "*" then "1" on your telephone keypad. If you are using a speakerphone, please pick up your handset before pressing the keys, to withdraw your question, please press "*" then "2." At this time, we will pause momentarily to assemble our roster.

Our first question comes from Jason McCarthy with Maxim Group. Please go ahead.

Jason McCarthy
Hi all, congratulations on a very nice transaction. So, we're really excited to see what's going to come next out of this program. And my first question for Dr. Sorscher relates to Gedeptin and the immune response right, because you had mentioned you get an abscopal effect, and I'm assuming it tumors that are out distal from the tumor that you inject, have you done or published any work on T-cell responses or shifting T-cell types in the tumor microenvironment?

Eric Sorscher
Thank you for that excellent question. Yes, we have data in a number of different tumor types that are tumors treated with PNP fludarabine on one side of the body such as a triple negative breast cancer and this is work with a well respected CRO, but tumor on the left side when it regressed with PNP fludarabine can lead to enhanced activity of checkpoint blockade for a non-PNP tumor contralaterally. And so, the evidence is that we're opening up and alerting the immune system to these tumors elsewhere in the animal models. That allows us a system for better understanding, as you've correctly pointed out, the nature of the abscopal effect and the means of the immune clearance. And so, we have a number of large experiments planned and in progress, looking at key cell infiltrates, markers of checkpoint blockade, markers of cell proliferation, and other parameters that will help us get a better handle on what we need to optimize in order to give the strongest possible abscopal anti-tumor activity.

Jason McCarthy
Can you talk a little bit about what differentiates the particular platform specifically in terms of being able to have active toxic drug hit bystander cells whereas, you know, some of the published literature and other attempts that this type of therapy has not been as successful?

Eric Sorscher
Sure. This is fundamentally different from anything that's been attempted before. No drug like fluoroadenine has been generated intratumorally. It is a drug that kills dividing and non-dividing cells in contrast to previous attempts. It's a drug that really permeates and partitions between and among tumor cells through transport mechanisms, presence in the…present in the tumor

cells themselves, and objectively generates a bystander effect, to which nothing really compares. If you think about some of the early generation attempts, those attempts generated drugs that basically killed the cells in which they were established - in which the enzyme was established. And that's, as I say, quantitatively and fundamentally different from the sort of data I've shown today and that many other laboratories have shown that even a small percentage of cells in a tumor can generate sufficient toxin to regress and strongly inhibit the entire tumor. So, this is a novel approach, it's come with many years of hard work, and it distinguishes itself readily from what's been done in the past.

Jason McCarthy
Great. And can you talk a little bit about the delivery approach for intratumoral injection, is it direct injection, are you using electroporation or what is that procedure entail?

Eric Sorscher
Yes. Our groups have tried a surfeit of a delivery mechanisms. Of course, that is key to the overall technology, and ultimately, we decided to begin our clinical efficacy studies with a rather basic delivery vehicle, our first-generation adenovirus, that could be injected directly there is specificity because the adenovirus is predominantly in the tumor parenchyma itself, it's well suited for many tumor types, including head and neck. We've had an extensive program looking for mechanisms for delivery to metastatic tumors, there are many good ideas. Once we get through the head and neck, clinical studies, we're looking at the nanoparticles as a sort of cutting edge means of targeting metastatic tumors. We could deliver into a tumor vascular bed, for example in hepatoma or renal cell, there are many options here, but our first approach and our focus has been on head and neck to show efficacy in human subjects, so that we can move on to these other indications and ultimately think about treating distant metastases by sensitizing them to checkpoint blockade.

Jason McCarthy
So, when you're talking about head and neck and you are in unresectable or basically, I should say that you're basically in second line I'm assuming, so there's nothing approved, really, and response rates with checkpoints alone, you think historically are like 10% to 15%. So, what's the bar for drugs like this one in a setting like this? Do you need to be 20%-25% or 30%, better than what a checkpoint is, if you're thinking about a combination?

Eric Sorscher
I think that's correct. We keep in mind that at the end of Phase 1 meeting, we were instructed that something better than standard-of-care would be what we would need here. And so, we need to be above 20% or 25% significantly above that. Phase 1 data suggests that should be possible, but it needs to be established in later phase studies, but I think the bar is better than standard-of-care and that's of course what we're shooting for.

Jason McCarthy
And then, last question as it relates to GeoVax's one of their core platforms on the MVA VLP MUC1 program in particular, is head and neck the high expressor of MUC1. Is there a potential to have a combination of these two approaches? Maybe even a triple combination with a checkpoint?

Eric Sorscher
Maybe I'll defer that question to one of the GeoVax colleagues, but I would say it's something that we have excellent head, neck models to evaluate formally including patient derived xenografts and syngeneic head and neck tumors with very active, NIH funded programs in those settings

and we would welcome the opportunity to test those together, someone from GeoVax may also want to comment though.

Mark Newman
Sure, this is Mark Newman again. Yes, definitely, we're looking at all the different combinations. Remember the MUC1 vaccine is targeting the aberrantly glycosylated mucin gene. So, it's not so much the location, it's the type of tumor. So…and yes, depending on the type you pick, altered glycosylation levels of MUC is well established. So, these combinations are really what excite us.

Jason McCarthy
Great and I'll jump back in the queue. I might have some follow-up questions. Thank you.

Jules Abraham
All right. Thanks Jason.

Operator
The next question is from Jeffrey Kraws with Crystal Research Associates. Please go ahead.

Jeffrey Kraws
Thank you. A few questions much like Jason and first of all, how many patients do you think you're going to have to utilize to, and I'll just rattle off a few of the questions, how many patients do you think you're going to have to enroll to be able to specifically power that to get above the, 20%-25% in a significant enough fashion to get an approval? The second question relates to the drug delivery since you're…I understand why you're using adenovirus, but you are obviously experimenting, I love the technology, but you're experimenting with what might be the better drug delivery approach to get the drug in there and as you said, as you get through this you may try other pieces. Are the patents going to be around the drug delivery and if so, would it be beneficial for you to partner with one of the drug deliveries companies that has already sophisticated drug delivery in this area, as opposed to taking it on yourself? I'll stop there and just…

Eric Sorscher
David, would you like or John to address it, or would you like me to provide…

David Dodd
Yes, if you'd like to address, there were two causes there, one was, I know we've discussed and we have a target for the number of patients, so if you'll take that and then you might want to elaborate somewhat in terms of the approach with the drug delivery.

Eric Sorscher
Yes. Thank you. So then of course, we won't know until we see the effectiveness. The Phase 1 data was in a very small number of patients and in the higher two dosing cohorts we saw, I think a 60 plus percent response rate PRs and CRs after one cycle. So, we got a P-Value in that study with three patients per cohort. In a perfect and ideal world, we could do this with a small number of patients, in a real world it's going to take a larger number and I think we're looking at 25 as the next step with the valued help of GeoVax and we don't know the answer to the numbers, and it will depend on the kinds of data we see as we treat larger tumors and address the entire tumor mass across multiple cycles. We're just getting started in the second study.

The question about vehicle delivery, I agree with everything that you've said. The patents could well be centered on a delivery vehicle. For example, a vehicle that uses a non-viral mechanism for targeting tumor parenchyma in distant disease. That would be an excellent way to develop IP

and to move forward. For instance, we've looked over the years at many delivery systems and all of the ones that come to mind, we've worked with commercial groups, and we've looked at academic collaborations and have published extensively in the area. But what I have to say is that for most of these or maybe all of these vehicles, some of them very creative and exciting in concept, we have been very meticulous and rigorous in the way we've done this. And we have ways to measure in the metastatic tumors what levels of PNP have been delivered. And the levels of PNP that we get are not sufficient typically with even the best of these vehicles, many of them subsequently failed in the clinic and so we haven't taken them forward.

We know that with a first generation adenovirus we can see excellent levels of PNP activity, we can regress tumors and that's the reason we took that approach into the clinic. But we are very keen for any creative mechanism and there are many out there some of which we are exploring now under CDA with groups or least…confidentially with groups to try to develop a means of a meaningful and tumor regressive sorts of powerful delivery mechanisms for metastatic tumors and specific tumor subtypes including both breast and head and neck.

Jeffrey Kraws
Well, I like the fact that it's almost a triple approach, which is the drug working in combination with another product and an immune response so it's not trying to do all by itself. So, I like that. The question in general, head and neck cancer are about 4% of all cancers in the US and if you look at the last National Cancer Institute data that was reported, about 72% of the death, the 14,620 deaths that took place last year that were recorded, 72% of those were in men. Is there a reason why in your opinion there is a higher incidence of head and neck cancer in men than there is in women?

Eric Sorscher
Well, whether you see viral underpinnings of the tumor and whether it's social, behavioral or whether it's molecular, a molecular predisposition, I don't know the answer to that and I am not sure anyone does but it's a really important point to keep in mind. It's certainly been our experience in terms of recruitment and so forth for this trial. There may be…risk factors maybe more prominent in men. I don't think the answer is known with certainty but an excellent question.

Jeffrey Kraws
And with the last question, with the IP approach as you said you could look at going at it from the drug delivery, but you feel very comfortable obviously UAB does generally a very good job with IP, so you probably have done a good job with the underlying IP and then you would supplement that by whatever drug delivery approach you feel works the best?

Eric Sorscher
David, if it's okay, I will just comment on that and then maybe you can….

David Dodd
Yes.

Eric Sorscher
Well, the answer is yes…the answer is yes UAB has done a fine job and we feel very secure in the IP position. David….

Jeffrey Kraws
Great. Thank you very much.

David Dodd
I think it was good and Jeff, I was going to mention as we have commented on at the end of the phase 1 meeting the FDA indicated that replicating the results, they had seen in approximately 20 patients would be such that they would consider going straight to labeling. So, we are targeting to complete 25 to 30 patients with which we expect to complete the…we'll accelerate, we'll expand the sites. We expect that 2022 will complete the patient types of enrolment and all and then basically be moving forward in…towards completion of patient evaluations in 2023 with the BLA filing targeted potentially for first half of 2024. Now, that's assuming the data support it and we don't have to go forward with the Phase 3 trial, but that's based on what has been seen today and discussions with the FDA.

Jeffrey Kraws
I haven't looked at the] molecule yet but given, you know, manufacturing questions et cetera, so some things you plan on manufacturing, something you plan on out licensing, something that's easy to manufacture. What's the situation with that?

David Dodd
John Sharkey, do you want to comment on that?

John Sharkey
Sure. The fludarabine is actually commercially available. It was originally known as Fludara and its a hematological agent that as Eric mentioned has no effect on solid tumors. The Gedeptin is a replication defective adenovirus, and we are already talking with the manufacturers of clinical supplies concerning scale up. Given the size of the initial market, if it would be approved here, we don't see any barriers with the current technology to be able to scale it up.

Jeffrey Kraws
Great. Thank you.

Operator
The next question is from Kumarguru Raja with Brookline Capital. Please go ahead.

Shubhendu [ph.]
Hi, I am Shubhendu calling in for Kumar. Thanks for taking my question. So, in mouse models, a 2% to 3% expression of E. coli PNP is shown to be sufficient for anti-tumor effects. Now what kind of PNP expression level would be considered meaningful for effective bystander activity in human solid tumors and do you think it will vary between different types of tumors?

Eric Sorscher I can address that. The study that I showed in this particular presentation is the human tumor xenografts in an immuno-deficient animal and we do this very rigorously by ex vivo transducing the tumors before establishing the tumors in certain experiments. So, we know exactly what percentage of cells express and what level expression on a per milligram tumor tissue bases we have. A 2% to 3% is the number that's worked across a number of cell types we published with anti-tumor activity and significantly lower levels of transduction. Others have seen this as well. I would like to point out in the clinical studies and in some of our preclinical studies 2% to 3% is a pretty big ask and we suspect that some of the clearance we are seeing is because again an immunologic component is ablating surrounding tumor tissue, but I think for our purposes we note the sorts of levels I've described. The PNP activity we need to see for example in a murine model or we think in a human tumor it's approximately 200- or 300-units pro-drug converted per milligram tumor tissue per hour. We have assays in our laboratories that we use to monitor this in all of our in vivo studies. So, we can…we have a good I think approximation

what the target is. We can achieve that with a replication deficient adenovirus, and we are looking for other delivery vehicles, as I said a second ago, that we can use in this context. Does that answer your question?

Shubhendu [ph.]
Yes, thank you. And just another question, I am just curious that once the prodrug has been metabolized for drug how does one ensure that the toxicity and immune effects, the bystander effects that you see is limited only to the tumor spots?

Eric Sorscher
Yes, it's a great question and a very reasonable one and part of the answer to that question is, in our preclinical work and this is literally hundreds of CRO conducted experiments, we haven't seen problems with toxicity. Part of the answer is what we have seen in the clinical studies as well. And I think our best explanation for this is that the…any of the fluoroadenine, the active toxin that's generated intratumorally at high concentrations, any of that released from the tumor is diluted throughout the host. So, it's a very low level and it's rapidly metabolized by Xanthine oxidase. So, in both our preclinical work and then our clinical studies when we have taken blood samples and asked, can we find fluoroadenine systemically, the answer is no and that's with an assay that's about 2 logs the magnitude of what you see with a NOAEL in rats. So, we feel secure that so far at least in the clinical study we haven't seen toxicity that appears to be limiting and we expect that's because if the drug leads to tumor where it's been generated and where it's at highest concentration where it's having its beneficial effects, it will be diluted, metabolized and cleared rapidly and we can't detect it in the circulating compartment.

Shubhendu [ph.]
Great. Thank you so much.

Eric Sorscher
Thank you.

Operator
Again, if you have a question, please press "*" then "1." The next question is from Yuan Zhi with B Riley. Please go ahead.

Yuan Zhi
Hi, team, congratulation on the new pipeline, this is Yuan Zhi from B Riley Security. Maybe my question will be directed to Eric. I will ask if there is a limit of the size of the two solid tumors that you can target, because you can imagine that when you inject the non-replicating viral vector into the solid tumor, there is a limit that to certain extent that they can reach?

Eric Sorscher
Yes, it's an excellent question and there is a limit, everything depends on being able to distribute the virus and the PNP reasonably well within the tumor mass, and if we inject a very small volume, we won't be able to achieve that if we are dealing with the tumor the size of the softball. And so, in our clinical studies what we have done is we have increased the volume and the number of injections as well to evenly and I think effectively distribute the material to the tumor. But it's an important parameter that we have to be aware of. So far, what we are coming to is the need to make sure that we get the material well distributed throughout the tumor mass in order to see anti-tumor activity. There is no doubt that if the PNP gene is expressed in a tumor cell, it will kill that cell when we give fludarabine and many other cells in the region will be killed as well.

There is some immunologic component we think that's contributing here that helps, but we have to get the material distributed well to the tumor and the clinicians have to do a good job of injecting the tumor through multiple needle tracks, redirecting the needle and so forth in getting it well distributed in the tumor mass, it doesn't have to be in every cell by any stretch of the imagination. But, as you say, in a very large tumor a small volume…we will get better results with a larger volume, and with a real effort to distribute the material well to the tumor, so that even an untreatable refractive tumor can see the benefit of this approach.

Yuan Zhi
Yes, got it. Very helpful. And another question is related to PNP. So, I want to hear your comments to those are if cancer cells or human cells have a homolog or similar enzyme of PNP that is able to hydrolyze a healthy compound?

Eric Sorscher
Yes. The human homolog is a trimer, its structure is known, the prokaryotic PNP is a hexamer, its structure is known, they are fundamentally different in terms of the active site and the amino acid sequence and so forth, the human enzyme does not cleave drugs like fludarabine and adenine-containing nucleosides, so there has been no problem with overlap of the sort that you are alluding to. It's a really good question.

Yuan Zhi
Have you measured the activity within base line, that in a normal cancer human cell, what is the activities they are able to hydrolyze the product?

Eric Sorscher
Yes, its zero. We have done this hundreds of times. There is negligible background in terms of the base line metabolism. It really requires the prokaryotic enzyme to see the cleavage and liberation of the base.

Yuan Zhi
Got it. And maybe the last question is, beyond the head and neck cancer, what other solid tumor will be your interest? I know you guys tend to target and maybe this question can be directed to the broader team, and I know you guys had targets to these orphan tumor at the first what others would be up for option?

Eric Sorscher
David and John, would you like me to…

David Dodd
Yes, I would just say at this stage our focus is on, is clearly on accelerating this program, getting the three sites underway and getting as quickly as possible all the patients we need enrolled and being treated through the regimen. We'll be evaluating other opportunities for other tumors. We have got some on our list to evaluate the potential interest and we'll acknowledge those as we move forward. But we don't have a list right now and sequence of what we want to go and if we did, we'd probably would not be discussing it anyway at this time. But we appreciate…we again appreciate the question, it's a good question and we have done a lot of thinking about it, as we go through this. But right now, we are not laying out a sequence of what we plan to go after.

Yuan Zhi
Yes, thank you for answering all the questions.

David Dodd
Okay, well. Thank you, Yuan.

Operator
This concludes our question-and-answer session. I would like to turn the conference back over David Dodd for any closing remarks.

CONCLUSION

David Dodd
Yes, thank you, everyone. You had some great questions, and I hope we didn't wear Eric out and scare him away. But anyway, thank you Eric and everyone else for participating. But, especially for those who have participated in this conference call for your interest in our continued progress and in fact transformation of GeoVax. And yesterday's announcement accelerates our status within Immuno-oncology. We said at this time last year, our goal was within 12 to 15 months to be in the clinic and Immuno-oncology as well as within the SARS COVID-2 area. And with the announcement via Gedeptin we are there in Immuno-oncology and we are still pursuing the move forward with our NVA VLT MUC 1. So, it provides a new definition of what GeoVax is and where we are going. And we certainly remain focused on accelerating our progress related to our SARS COVID-2 or our universal coronavirus vaccine and we look forward to providing further updates soon.

I would like to acknowledge and thank our GeoVax staff and many other persons who continue to support, assist and advise us towards achieving success. I especially want to thank the PNP therapeutics team and board for that development of Gedeptin and their collaboration in achieving this agreement. For all of us, it remains a great pleasure serving our shareholders. Our goal is to drive forward with our development, so that we can be bringing value forward for our shareholders and for clinicians and especially for patients out there, while providing an opportunity for people to invest themselves and develop very promising and exciting careers.

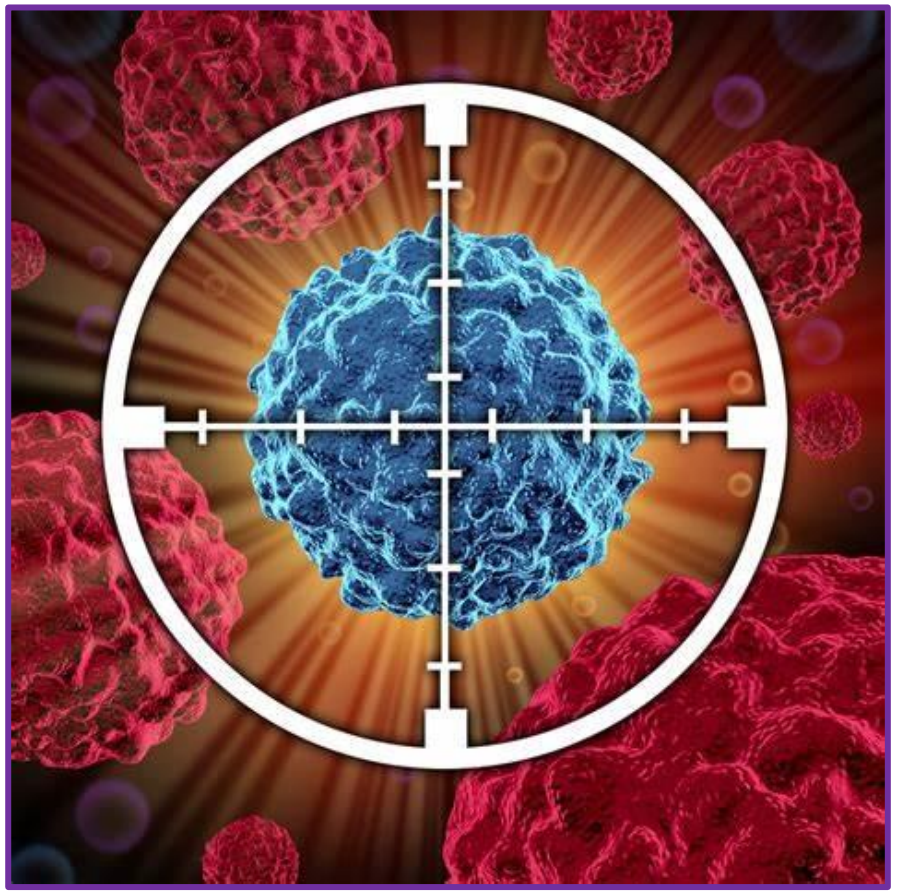
So, it's a great pleasure to speak with you and we look forward to updating you as we go forward with other exciting announcements. Thank you and have a safe and enjoyable evening.

Operator
The conference has now concluded. Thank you for attending today's presentation. You may now disconnect.

Exhibit 99.2

Gedeptin® License
Conference Call

Innovations in Cancer Therapy



GeoVax Labs, Inc.

NASDAQ: GOVX

September 29, 2021

GeoVax
Vaccines Serving Humanity

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 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. …

"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."

The Discovery and its Uniqueness: Tumor Death From Within

NIH funded academic studies by our group have shown that intratumoral production of a profoundly active compound leads to pronounced anticancer activity and destruction of otherwise untreatable tumors.

Chemotherapy and Radiation Treatments Frequently Fail

- These modalities fail to treat the large numbers of silent, quiescent cells in a tumor mass.
- The PNP technology is specifically designed to destroy these cells.

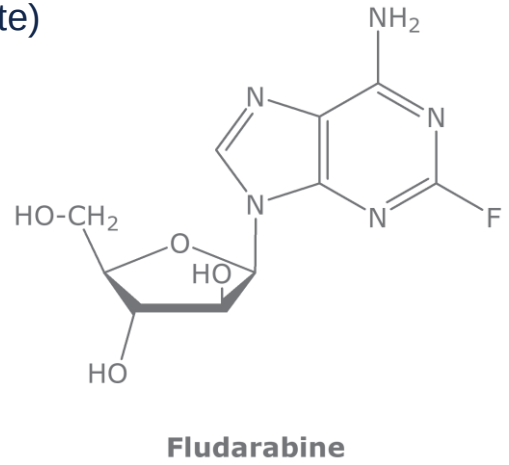
Mechanism of Action

F-araAMP (Fludara, Fludarabine phosphate)

Gedeptin™ (Ad/PNP)

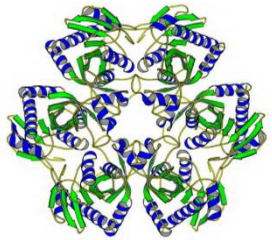
Plasma enzymes

F-araA (Fludarabine)



Fludarabine

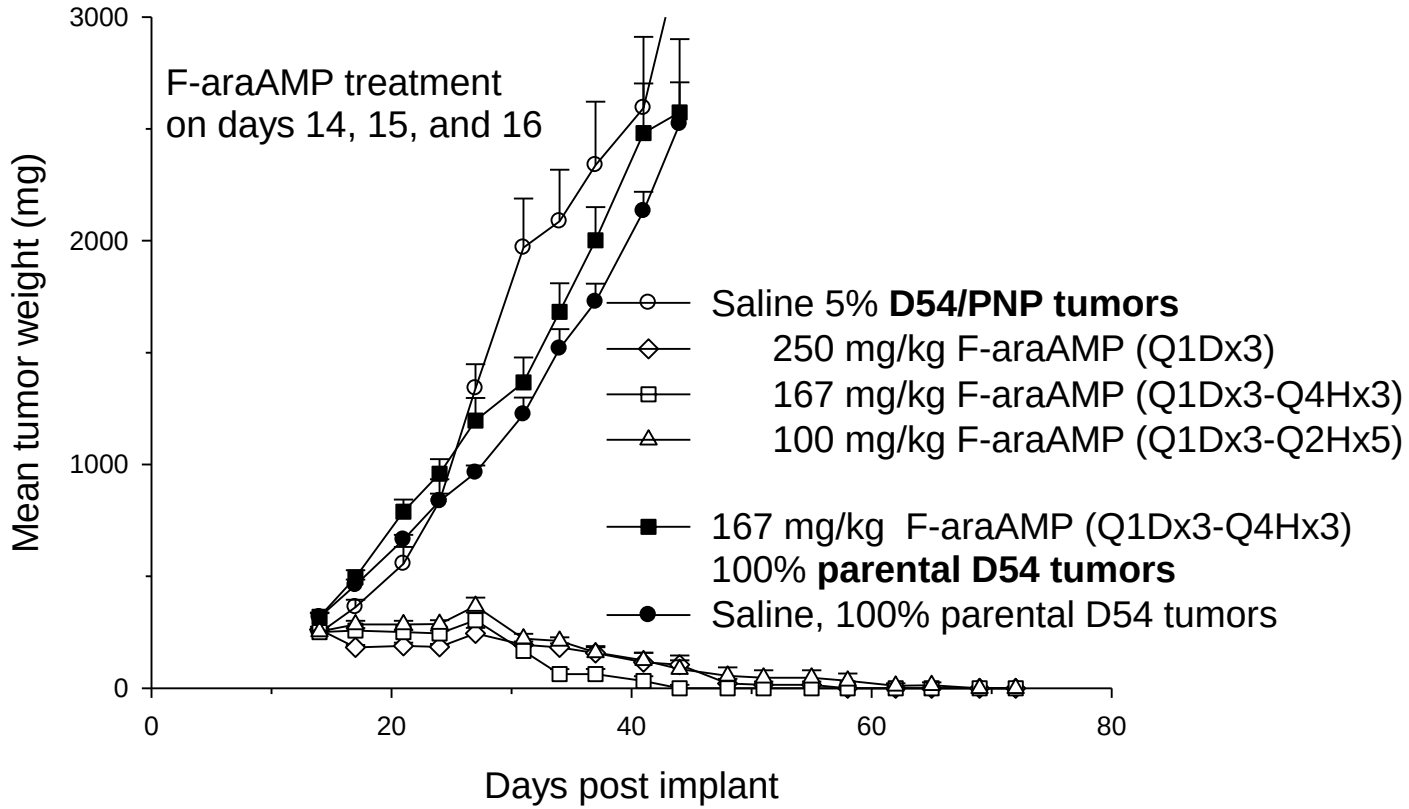
E. coli PNP in tumor cells



Fluoroadenine

Unprecedented level of cell killing activity
Novel tumor killing mechanism
Destroys refractory solid tumors

Tumor Response When < 5% of Cells Express PNP



Powerful Aspects of the PNP Technology

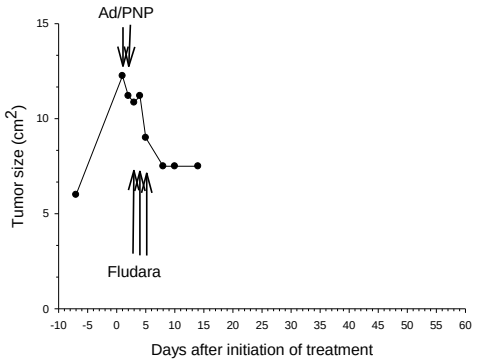
- Novel tumor-killing mechanism
- Active against both proliferating and non-proliferating (stealth) tumor cells
- No significant systemic or other toxicity observed
- Additive/Synergistic with radiation therapy
- Designed to kill tumor stem cells
- May augment immunologic clearance of malignant tissues

Phase I/IIa Clinical Protocol
NCT – 01310179: Single Cycle

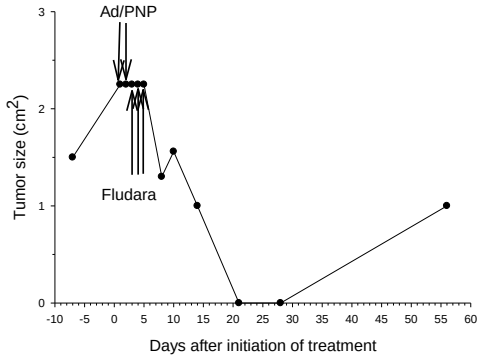
- Standard 3+3 study design, single treatment cycle
- Ad/PNP vector administered IT twice (AM/PM) on Day 1, once on Day 2
- Fludarabine administered IV daily on Days 3 - 5
- Cohorts 1 to 3 – Escalate fludarabine
- Cohort 4 – Escalate Ad/PNP

Phase I/IIa Clinical Trial – Single Cycle Pronounced Tumor Responses

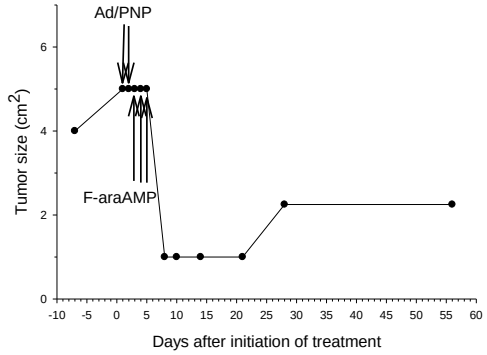
Patient 7



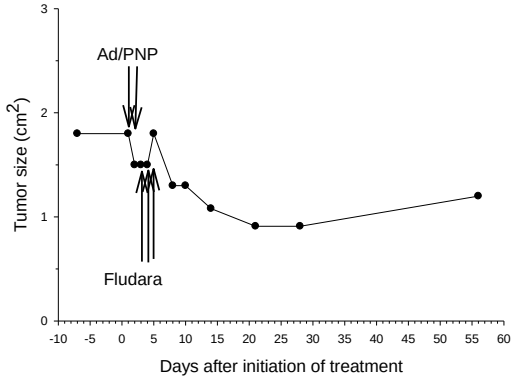
Patient 8



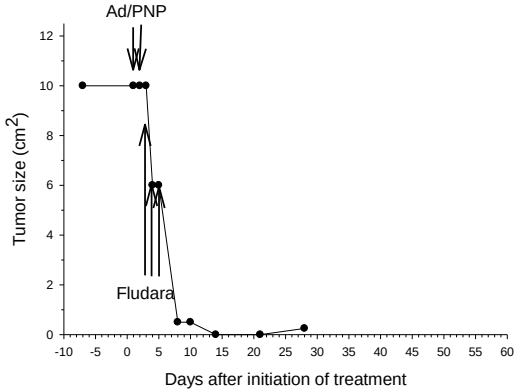
Patient 9



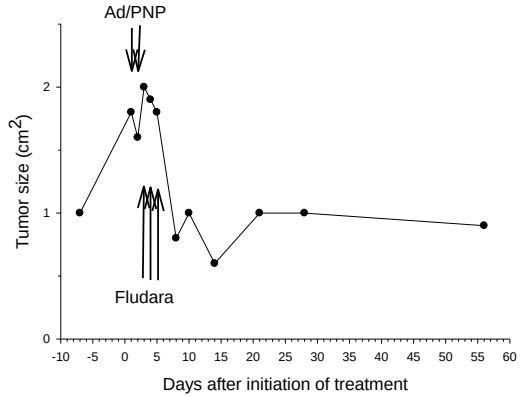
Patient 10



Patient 11



Patient 12



At the high dose of F-araAMP (cohorts 3 and 4) there was substantial antitumor response

Phase I/IIa Safety Overview: Single Cycle No Treatment-Related SAEs

	Cohort 1	Cohort 2	Cohort 3	Cohort 4	Total
TEAEs	3	3	3	3	12
TEAEs ≥ grade 3	2	3	1	1	7
TEAEs leading to hospitalization	1	0	1	1	3
TEAEs leading to treatment termination	0	0	0	0	0
TEAEs leading to death	0	0	0	0	0
Treatment-emergent SAEs	2	1	1	1	5
Treatment-related AEs	3	3	3	3	12
Treatment-related AEs ≥ grade 3	0	1	0	1	2
Treatment-related SAEs	0	0	0	0	0
Dose limiting toxicities	0	0	0	0	0

TEAEs,	Treatment-Emergent Adverse Events
AEs,	Adverse Events
SAEs,	Serious Adverse Events

Treatment emergent AE/SAE is defined as an AE/SAE that occurred following initiation of study treatment, that may or may not be related to study drug

Approved Phase I/IIa Clinical Protocol – Multiple Cycles NCT - 03754933

- **Utilizes dose and schedule found safe and effective in Phase I/IIa trial (as a single cycle*)**
- **Up to 5 cycles will be administered**
- **The entire tumor burden will be treated**

*** Cycle = Two days of Gedeptin followed by 3 days of fludarabine**

Improves Efficacy of Check Point Blockade Inhibitors

Our recent studies indicate that PNP-based treatment may be additive or synergistic with checkpoint blockade type agents.

PNP therapy appears to robustly sensitizes tumors, that do not express *E. coli* PNP, to checkpoint blockade inhibitors, presumably by destroying tumor tissue at one site, exposing neoantigens, and enhancing immune response and activity of checkpoint blockade at other sites (i.e. abscopal effect).

GeoVax Concept to Cancer Immunotherapy

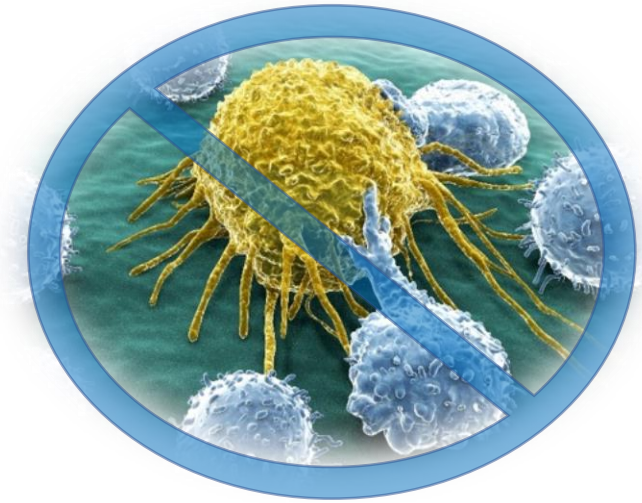
Triple-threat Approach:

1. Tumor antigen specific immune responses induced with a vaccine
2. Immune inhibition is blocked with checkpoint inhibitors
3. Tumor cells are killed using an oncolytic agents

STIMULATE MVA-VLP with TAA to provoke immune system

BLOCK Checkpoint inhibitor to reverse immune tolerance

KILL Achieve oncolysis using Gedeptin



TUMOR REGRESSION

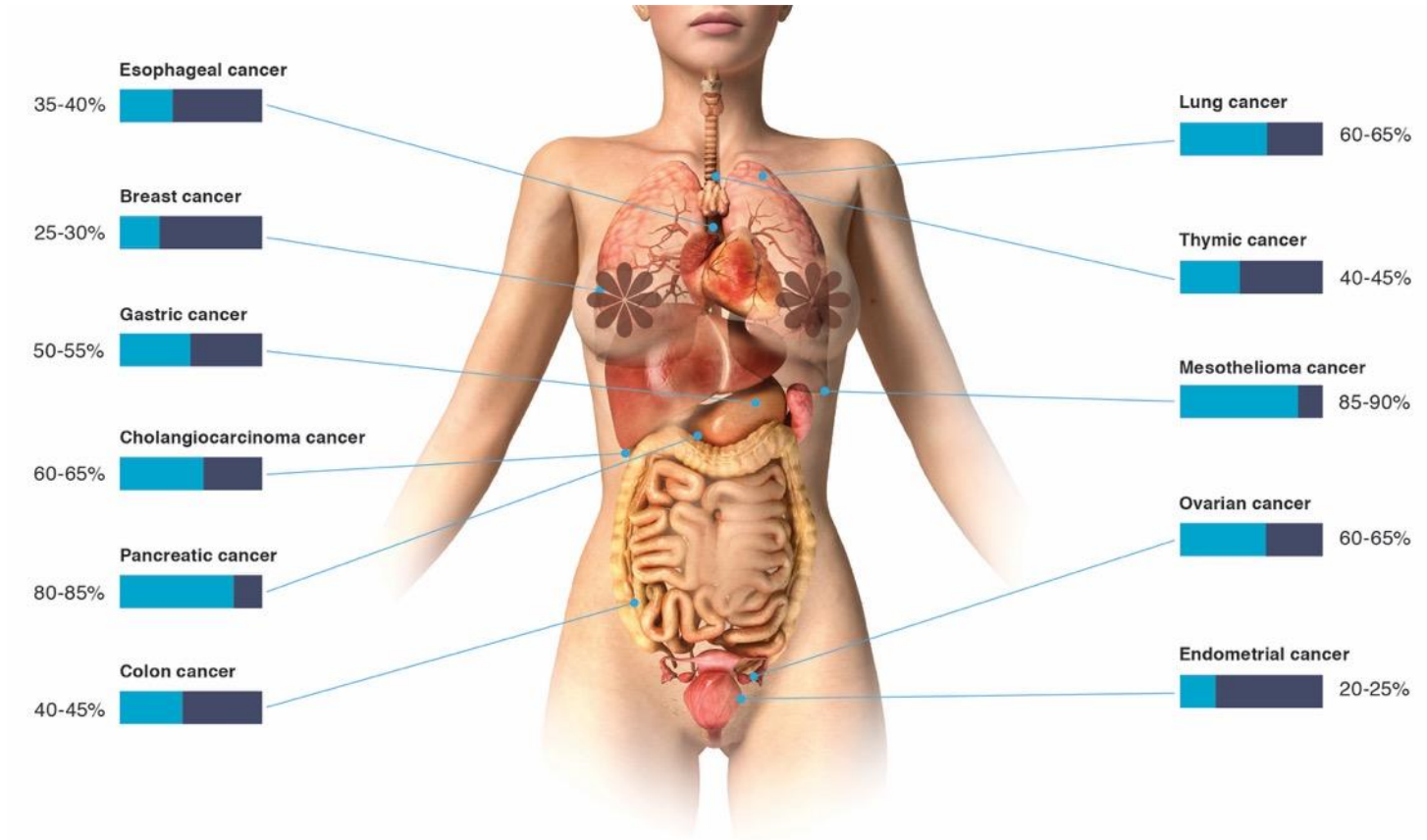
GeoVax Vaccines Serving Humanity

MUC1 - Cancer Immunotherapy Focus

Combination cancer vaccine strategy to utilize standard-of-care (SOC) treatments + vaccination, and immune checkpoint inhibitors (CPI) to unleash a patient's immune system to fight cancers

GeoVax novel Cancer Immunotherapy is based on combinations of technology

- MVA-VLP cancer vaccines to induce T-cell responses
- Peptides + adjuvants to focus immune response on TAA
- Immune check-point inhibitors to unleash the immune system (Standard of care)
- Gedeptin to mediate direct tumor killing




Q&A Session
GeoVax

Thank You

Creating Vaccines to Serve Humanity

GeoVax®
Vaccines Serving Humanity

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