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Presentation

Operator: Good day, and welcome to the Inovio Pharmaceuticals First Quarter 2019 Financial Results Conference Call.

(Operator Instructions)

Please note this event is being recorded.

I would now like to turn the conference over to Ben Matone, Director of Investor Relations. Please go ahead, sir.

Ben Matone: Thank you, operator. Good afternoon, everyone, welcome to the Inovio Pharmaceuticals First Quarter 2019 Investor Conference Call. With me today are Inovio's President and CEO, Dr. J. Joseph Kim; our Chief Financial Officer, Peter Kies; and our Chief Scientific Officer, Dr. Laurent Humeau.

Today's call is also being webcast live on our website, ir.inovio.com, and a replay of today's call will be made available. Following a general business update, we will conduct a question-and-answer segment, which will be reserved for equity research analysts.

As a reminder, we will be making certain forward-looking statements that relate to our business which include our plans to develop our immunotherapy platform in combination with our proprietary delivery devices, as well as developments and timing on certain clinical data readouts and our capital resources. These statements involve certain assumptions, risks and uncertainties and could cause actual results to differ materially from these statements.

All of these statements are based on the beliefs and expectations of management as of today. We assume no obligation to revise or update forward-looking statements, whether as a result of new

information, future events or otherwise. Investors should read carefully the risks and uncertainties described in today's press release, which is posted on our website, as well as the risk factors included in our filings with the SEC.

With that, I would like to turn the call over to our CEO, Dr. J. Joseph Kim.

J. Joseph Kim: Thanks, Ben, and good afternoon, everyone. I will first provide you today with my strategical review, and then our CFO, Peter Kies, will detail our financials. Our Chief Scientific Officer, Dr. Laurent Humeau, also joins our call today. Dr. Humeau will update you on our exciting R&D efforts with focus on our dMAb and dBTE programs, a new area we're extremely excited about given the potential these technologies have for both patients and our shareholders.

I would like to start off by saying that Inovio remains on track on meeting our clinical development timelines, along with our business development and commercial plans.

You've heard me say many times before, Inovio aims to be the go-to player for treating all HPV-related diseases from pre-cancers to cancer. We're an aggressive management team that isn't just waiting for our Phase 3 VGX-3100 data to come in. To that end, we have applied for and were granted an advanced therapy medicinal product certificate by the European Medicines Agency. Second, we continue to make a significant advancement in our efforts to develop a pretreatment biomarker kit that could target patients most likely to respond positively to treatment with VGX-3100, which in turn can potentially enhance absolute efficacy of the product.

I'll tell you what each of these strategic activities mean for the product and our company.

First, the EMA certificate was awarded following an extensive evaluation of our CMC quality and nonclinical data by the EMA's Committee for Advanced Therapies. This is a big deal. It's a huge accomplishment for us because since the inception of the program in 2009, only 11 ATMP certifications have been awarded by the EMA. The certificate represents an important developmental milestone for VGX-3100, as it will facilitate and expedite the preparation, filing and review of a future European market authorization application for VGX-3100. A similar-caliber review will also be conducted during the BLA approval process with the FDA for VGX-3100. Thus this latest recognition, we believe, also provides a foundation for the FDA when they review our data and manufacturing capabilities and helps to de-risk the regulatory submission.

Additionally, this latest recognition is a testament to Inovio's technical excellence, cross-functional development expertise and high-quality standards beyond VGX-3100 and towards Inovio's overall technology, which in turn helps bolster our ongoing partnership discussions on other programs.

As it pertains to the EMA and what it means for VGX-3100's commercial potential, we estimate that in Europe alone, there are roughly 250,000 new cases annually of cervical pre-cancer that's caused by HPV 16 and 18, for which the current standard of care, just like it is in the U.S., is surgery. The proportion of cervical high-grade pre-cancers caused by HPV 16 and 18 is about 55%, and it's estimated that about 325 million women at age 15 years or older are at risk of

developing cervical cancer, where 26,000 women will die from this cancer in Europe each year. In addition, there are almost 40,000 annual cases in the rare diseases caused by HPV 16 and 18 such as vulvar and anal dysplasia.

Remember that our CELLECTRA 5PSP device is already CE marked and already approved in Europe. So while we continue to execute our ongoing Phase 3 and Phase 2 clinical trials that target HPV-related diseases with VGX-3100, these latest milestones bring us closer to commercialization. Moreover, we see a real opportunity to treat patients in Europe, and the latest certificate from the EMA offers an important step towards approval for VGX-3100 and helps form the valuation potential for this therapy globally.

Staying on HPV therapies, at last month's AACR annual conference, Inovio made scientists and investors take notice. We presented data for the first time on our novel HPV therapy, INO-3106, against HPV type 6, which demonstrated clinical efficacy in a study of two patients with recurrent respiratory papillomatosis, or RRP. RRP is an HPV-associated rare disease that can cause noncancerous tumor growth, leading to life-threatening airway obstructions and occasionally progressing to cancer. Currently, the disease is incurable and can only be treated by surgery to remove the tumors, which only temporarily restores the airway. The tumor always recurs and the surgery must be repeated, usually multiple times a year.

In this pilot clinical study, we enrolled two adult patients with RRP who tested positive for HPV 6. Their condition had required surgery approximately every six months to clear their tumor growth from their throats. Since their last dose of HPV -- Inovio's HPV therapy, both patients have been surgery free due to lack of tumor recurrence. One patient has not needed surgery for over two years, the other for over one year. You will certainly see a more complete report, now being prepared for a medical publication. Based on these early breakthrough results, we plan to develop -- further develop INO-3106 as a novel noninvasive immunotherapy for the treatment of RRP, a rare orphan disease, for both adult and pediatric populations. Please note, the same HPV strain that causes RRP also predominantly causes genital warts, another of these diseases.

What we see here is more support, more giant steps towards our goal of being recognized as the go-to immunotherapy provider to effectively treat all major HPV-related pre-cancers and cancers.

Let me summarize and list five achievements towards that goal. First, we've demonstrated already strong efficacy in our Phase 2b study with VGX-3100 for treating cervical dysphagia and for eliminating the root cause, HPV virus. Second, we had two patients who achieved a complete response, or full cancer remission, in a head and neck cancer study of patients treated with MEDI0457 followed by a checkpoint inhibitor. Third, we just reported recent clinical efficacy in patients with RRP through treatment with INO-3106. Fourth, as mentioned above, we were granted an EMA certificate validating two out of three sections of our future European and potential FDA application for nonclinical and manufacturing processes. And fifth, we're accelerating our quest for commercializing a VGX-3100 pretreatment biomarker diagnostic test, potentially with a partner.

These events, when taken together, add up to Inovio having the potential for robust and much-

needed therapeutic products for treating HPV-associated diseases; therapies that most importantly provide a noninvasive option for patients suffering with diseases caused by HPV. And for women with cervical dysplasia, a therapy that provides an alternative to surgery, an option that doesn't complicate women's reproductive health, a mission that we at Inovio take great pride in preserving.

Before I pivot to our oncology combination studies, I want to provide a brief update regarding our pivotal Phase 3 programs and its two trials, REVEAL 1 and REVEAL 2.

Last month, we announced the initiation and opening of sites to enroll REVEAL 2, the confirmatory portion of our Phase 3 program. The early initiation of REVEAL 2 marks another milestone for our lead product, VGX-3100. In addition, we are still exploring with our China partner, ApolloBio, to have sites within China potentially contribute to the recruiting efforts for REVEAL 2. I am confident in our team's experience and expertise to advance the REVEAL program towards -- forward to deliver on our goal to file a BLA application for VGX-3100 in 2021, and most importantly, remember that patients are waiting and our efforts are bringing an innovative, impactful therapy to people where surgery is their only option.

You can certainly expect to hear more about our Phase 3 progress on our next earnings call in August.

Shifting to our oncology combination programs, I will begin with MEDI0457 and our ongoing global partnership with AstraZeneca. We announced in early April a third milestone payment from AZ triggered by the dosing of a patient in a Phase 2 trial evaluating MEDI0457 in combination with their PD-L1 checkpoint inhibitor, targeting cervical, anal, penile and vulvar cancers associated with HPV. This third Phase 2 milestone stresses the potential breadth of MEDI0457 in treating multiple HPV-associated cancers, and it also complements our overall goal, which I stated earlier, on leading the HPV treatment in the market. We remain appreciative and delighted to see AZ expand the use of MEDI0457 and to continue the evaluation of the combination of immunotherapy with their checkpoint inhibitor in multiple cancer types that are caused by HPV.

Turning to our own INO-5401, which continues to be validated in two combination studies for bladder cancer and glioblastoma, or GBM. I will begin with GBM study, moving forward in a combination with Regeneron's PD-1 checkpoint inhibitor Libtayo. In this GBM trial, our goal is to increase the overall survival of patients facing a disease where neither the standard of care nor clinical outcomes have really changed clinically in a significant way in more than a decade. We started the month of April with an exciting milestone that was the completed enrollment of 52 patients three months ahead of schedule.

We expect to report interim results from our GBM study before the end of this year. By then, we will have PFS-6, or progression-free survival at six months, data from 100% of the patients. We will also have progression-free 12-month survival data from roughly 50% of the patients at that time.

We are also targeting the unmet need in metastatic bladder cancer. Here, we are utilizing INO-

5401 in combination with Genentech's PD-L1 checkpoint inhibitor, Tecentriq. This Phase 2 trial continues to enroll and we remain proactive on opening up additional sites across the U.S. and Europe to advance the recruitment process. We remain on target to have interim data for this study announced before year-end. We believe this study, along with GBM, will help bolster our objective to demonstrate the synergistic antitumor effects with our immunotherapy combined with a checkpoint inhibitor.

Before I turn the call over to our CSO, I want to provide a brief update on a couple of key developments within our infectious disease portfolio.

The March edition of the peer-reviewed Journal of Infectious Diseases highlighted very positive data from Inovio's Ebola vaccine, INO-4201. The journal article detailed that the vaccine was safe, tolerable and generated strong T cell and antibody responses. Significantly, the data -- the study demonstrated that intradermal or skin administration of Inovio's CELLECTRA delivery device resulted in 100% of vaccinated subjects generating antigen-specific antibody responses that persisted more than one year in most subjects and generated robust T cell responses. INO-4201 has already demonstrated protection in 100% of nonhuman primates following a lethal challenge of Ebola virus. With strong preclinical and human data, Inovio is executing on our overall development strategy in advancing INO-4201 as a viable stockpile vaccine.

Most importantly, because Inovio's Ebola vaccine can be boosted multiple times without any antivector response, it could be employed to boost viral vector vaccines that cannot be effectively readministered. We now look to secure partner funding to further advance our Ebola vaccine as a standalone or as a boost for those previously immunized with viral vector vaccines.

In our upcoming August investor call, I also expect to update you more on the initiation of our first-in-man vaccine trial against Lassa fever. You'll recall that this is part of our partnership with CEPI, the Coalition for Epidemic Preparedness Innovations: a $56-million grant to support Inovio's clinical development through Phase 2 field trials of INO-4500, our Lassa fever vaccine, and INO-4700, our MERS vaccine. The shared goal of Inovio and CEPI is for our Lassa and MERS vaccines to be successfully tested and to be available as a stockpile as soon as possible for emergency use.

Overall, Inovio's class-leading synthetic nucleic vaccines, delivered intradermally with our CELLECTRA efficacy-enhancing systems, are well suited to rapidly produce countermeasures against emerging viral threats, potentially protecting large populations from pandemic. Inovio has rapidly advanced several global health vaccines, including vaccines against HIV, Ebola, MERS and Zika, and has reported near 100% immune response rate from multiple clinical studies. In this regard, I would like to share that Inovio has started the development of a commercial-scale intradermal device, which we call CELLECTRA 3PSP. You will hear more about this in the coming weeks.

With that, I would like to turn the call over to our CSO, Dr. Laurent Humeau, who will discuss some of our exciting R&D advancements. Laurent?

Laurent Humeau: Well, thank you, Joseph, and good afternoon to our investors and analysts. My

goal today is to paint a picture of what's on Inovio's product R&D horizon and how quickly these new developments may appear in the foreground. I am talking about Inovio's dMAbs and dBTEs. That is, Inovio DNA-encoded monoclonal antibodies, dMAb technology, and our DNA-encoded bispecific T cell engagers, or dBTEs.

First, dMAb.

Earlier this year, we initiated the first human study of our dMAb technology to prevent Zika virus infection. With this first clinical study, dMAbs are poised to be a disruptive entrant to the larger segment of pharmaceutical markets today, accounting for more than $100 billion in pharmaceutical sales each year, with treatments spanning cancer, infectious diseases, inflammation and cardiovascular diseases. With its synthetic design and inpatient production, dMAb represents a disruptive entrant to this important class of pharmaceuticals. Inovio and its collaborators have already received over $60 million in nondilutive grant funding to advance the dMAb platform in the last few years.

Please remember, with this initial trial target Zika virus infection, we will gain important product expression data from this study towards development of a broad range of dMAb programs targeting infectious disease, cancer immunotherapy, inflammation and, as well, therapy for cardiovascular disease. dMAb are really amazing science. Considering that when delivered directly into the body, the genetic instructions provided by the designed synthetic dMAbs instruct the body's cells to become the factory which manufactures the therapeutic antibody products, enabling a major leap in antibody technology.

At this year's AACR meeting, you could feel the buzz when we announced our first dBTE result. At the global conference, we told the world how our bispecific T cell engager generated potent anti-tumor activities in clear established tumors in preclinical studies. For this published study, Inovio developed a novel dBTE targeting the HER2 molecule, which was tested in a therapeutic model for the treatment -- sorry -- of ovarian and breast cancer. Importantly, just a single dose of Inovio's HER2 dBTE resulted in high level of corresponding BiTE in mice for up to four months, exceeding what is typically displayed with the currently approved BiTE's short half-life of only a few hours. The HER2 dBTE treatment effectively killed HER2-expressing tumor cells, resulting in a near-complete tumor clearance. Also presented was Inovio's CD19 dBTE, which can kill B cell cancers by targeting B-cell-specific marker CD19.

Based on these promising preclinical results, we plan to rapidly advance our dBTE candidate into clinical testing, as well as develop more tumor-targeting dBTEs for potential partnership.

Let me give you some background on dBTEs and the advantages they offer over gene therapy. First, BiTEs are a class of artificial bispecific monoclonal antibodies that has the potential to transform the immunotherapy landscape for cancer. They direct a host's immune system -- more specifically, the T cells' cytotoxic activity -- against cancer cells. In layman's terms, BiTEs are like a double-sided tape that binds to a tumor and to a cancer-killer T cell -- killing, killer T cell. One domain of the BiTE binds to the targeted tumor, like HER2- or CD19-expressing cells, while the other engages the immune system by binding directly to CD3 molecules on T cells. This double-binding activity drives T cell activation directly at the tumor, resulting in a killing

function and tumor destruction.

Now, you might be confused by our dMAb and dBTEs.

In fact, Inovio's dBTEs represent a new transformative application of Inovio's dMAb platform. The dBTEs share many advantages of Inovio's dMAbs, as they both are composed of engineered DNA sequences which encode antibody fragments. When administered by Inovio's CELLECTRA device -- delivery device, the patient's own cells become the factory to manufacture functional BiTES encoded by the delivered dBTE sequences. Inovio's dBTEs are developed with a novel synthetic nucleic design using plasmid vectors and unique formulations allowing for rapidity of development, long-term product stability at refrigeration, ease of validated and scalable manufacturing, and deployability.

I look forward to updating you on the progress of these two programs with immense potential. I will now turn the call back over to Joseph.

J. Joseph Kim: Thank you, Laurent. I speak for everyone here at Inovio when I express how excited we are about the future these novel technologies hold and the value potential they can offer for both the therapeutic field and for our patients.

I will now ask our CFO, Peter Kies, to provide a financial update. Peter?

Peter Kies: Thank you, Joseph. I'll first begin with our cash position as of the end of March, and then I'll wrap up with our total revenue for the quarter and the quarter-end financials.

As of March 31, 2019, cash, cash equivalents and short-term investments were $128 million, which compares to $81.2 million for the previous quarter. During the first quarter, Inovio completed a private placement of $78.5 million aggregate amount of 6.5% convertible senior notes due 2024, resulting in net proceeds of approximately $75.7 million.

Turning now to revenue for the quarter. Total revenue was $2.8 million for the three months ended March 31, 2019, which compared to $1.5 million for the same period in 2018. Total operating expenses were $31.4 million, which compares to $34.3 million for the same period in 2018. Year-over-year increase in revenue under collaborative research and development arrangements was primarily due to the milestone payment recognized in the first quarter of 2019 from AstraZeneca.

Net loss for the quarter ended March 31, 2019, was $29.2 million, or $0.30 per share, basic and dilutive. This compares to $32.4 million, or $0.36 per share, basic/dilutive, for the quarter ended March 31, 2018.

As a reminder, our financial statements for the first quarter of 2019 -- the balance sheet, income statement, statement of operations -- can be found in today's press release or in the Form 10-Q filed with the SEC. This can also be accessed on our website under Investor Relations, Financial Reports.

With that, I'll turn it back to Joseph.

J. Joseph Kim: Thank you, Peter. Before we open the line for questions, let me just say that the last several months have been extremely productive for Inovio by validating the company's versatile technology platform.

We ended the first quarter by featuring positive data from our Phase 1 Ebola vaccine study in a prestigious publication and starting our second Phase 3 trial of VGX-3100 ahead of schedule. Inovio further highlighted its capabilities in treating HPV-associated disease after presenting positive data from patients diagnosed with RRP, where we demonstrated a clinical benefit for these patients. Don't forget about our completion of Phase 2 GBM study enrollment ahead of the schedule, too. Additionally, we initiated the first-ever clinical study for our dMAb platform during the first quarter and unveiled an exciting new component within our platform involving our dBTE technology, which we're working rapidly to advance the first product into clinical testing. Lastly, we're entering the second quarter well financed following February's raise, which places us in a prime position to continue to deliver on our game-changing clinical programs.

In closing, Inovio remains on track on meeting our clinical development timelines, along with our business development and commercial plans.

With that, I look forward to taking your questions. Operator, please open the line for the analysts.

Questions & Answers

Operator: (Operator Instructions)

And our first question today comes from Charles Duncan with Cantor Fitzgerald.

Pete Stavropoulos: Hi, guys, this is Pete Stavropoulos on for Charles. So I have a question about REVEAL 1 and the data. So measurement of the primary endpoint is at 36 weeks. Will you be releasing the efficacy data when it's in hand, or will you wait to complete the follow-up through Week 88?

J. Joseph Kim: At Week 88, as we discussed previously.

Pete Stavropoulos: Okay. And for the RRP study, have you met with the FDA to discuss the path forward? And since it's a rare disease, do you believe there's a possibility of going straight into a pivotal study?

J. Joseph Kim: We plan to meet with the FDA later this year. And we are certainly very excited about the data, and we feel that we would have an accelerated trial design and potentially going into pivotal, but of course, we have to meet with the FDA to confirm that.

Operator: And our next question comes from Gregory Renza with RBC Capital.

Gregory Renza: Joseph, I just wanted to start with respect to your mention of having a potential

update in August on the REVEAL trials and to stay tuned for that. Could you just elaborate on that a little further, what we can look for as far as that update?

J. Joseph Kim: Well, we expect to complete the enrollment of REVEAL 1 shortly, and certainly by -- way before August, fall. And we'll be able to give you some trajectory on how well we're doing initially in REVEAL 2. We have lots of other commercialization and other plans, including our biomarker work that we look forward to sharing in some detail in our next call.

Gregory Renza: Got it, got it. Thank you. And then just with respect to the back half of the year, certainly a lot going on, not just REVEAL and now RRP, meeting with the FDA, but also, of course, with 5401. So how could you help investors just put that all into context as far as how you are prioritizing and what you're looking for as far as those key value-driving potential events for Inovio? Thanks.

J. Joseph Kim: Yes, thank you, Greg. Well, INO-5401, first, with the GBM study, we completed enrollment of 52 patients in a very rapid fashion. It is a very difficult disease to treat, but we think combining our T-cell-generating 5401 with Regeneron's Libtayo, a PD-1 inhibitor, provides us with perhaps the best shot at this very difficult disease. So before the year ends, we expect to have PFS-6 in 100% of the patients. And about half the patients, it's the progression-free survival at Month 12. We will continue to be able to generate overall survival data leading into 2020 and beyond, but by year-end, PFS-6 in 100%, PFS-12 in about half the patient population. Bladder, we're looking forward to generating overall response rate. Also, this is a very high bar, as the cohort, our larger cohort, we're targeting previous checkpoint-refractory population, so patients who have already failed either PD-1 or PD-L1 inhibitors. So these are very sick patients as well, and we're hopeful to have a significant percentage of the first populations in terms of the overall response rates before the year-end.

As for VGX-3100, obviously we are putting a lot of effort in executing REVEAL 1 and completing it, as well as really getting REVEAL 2 launched and -- globally in about 20 countries to execute the REVEAL 2 recruitment process. I talked about the China potential; we haven't baked in China -- that's just an upside for us. So we continue our efforts with ApolloBio in that regard.

And in terms of our infectious disease, we expect to see a lot more publications, validating clinical publications, from our Phase 1 MERS vaccine study, from our HIV vaccine study with the HVTN. Also, we will be starting a new Lassa vaccine study in the U.S. funded by CEPI, and we look forward to updating you on those efforts in the next call as well.

dBTE, along with RRP, these are very hot, high-potential targets for their own right. As Laurent explained, we feel that our dBTE technology is a dramatic, transformative improvement over the conventional BiTE efforts, where we think we can finally fulfill the promises of a bispecific T cell engager programs using our synthetic DNA efforts. So we are in the process of down-selecting our top candidates to bring it into the clinical evaluation as rapidly as possible. And the others will just then be available for partnerships, because we think each of these dBTE candidates are of high value.

RRP, I already stated before, is an orphan disease. It's a very tough disease for the patients to deal with, having to schedule their lives around the surgeries to remove the tumor that recurs all the time. We're very excited about a small sample size but dramatic impact on these patients, and we look forward to bringing that to the next trial, hopefully a pivotal trial, as rapidly as possible after meeting with the FDA. So we're very excited about all of these programs.

Operator: And our next question comes from Chris Raymond with Piper Jaffray.

Christopher Raymond: Joseph, just -- I don't want to split hairs on timing, but I think on REVEAL 1, last quarter, I think you guys talked about enrollment being sort of nearly done. And I know this might be a moot question, but you're stating that it's almost done now at sort of, I guess, mid-year. Was there something that sort of happened in the last three months that -- I guess when we heard last quarter that it was nearly done, we anticipated it might have already been enrolled? Was there some slowdown in enrollment that happened, or is there something that took place the last three months? Thanks.

J. Joseph Kim: Thanks, Chris. No, I think we are in the efforts of juggling -- wrapping up on REVEAL 1 as well as launching REVEAL 2. So these things happen in large trials, and perhaps -- we want to make sure that we're projecting our projections. We will certainly be done by mid-year in full enrollment of REVEAL 1. And we're very bullish on how we're progressing in enrollment in REVEAL 2. So I don't think there's -- I can tell you there's not been a slowdown. But perhaps giving a more detailed projection -- we're closer to the detailed projection now. So we're very happy to do that in -- by mid-year. And of course, the most important thing is getting to our data and filing our BLA in 2021, and remain on track on that, and certainly we're doing everything we can to execute that big picture.

And I don't want to -- I just want to touch on the ATMP certification again. It is a big deal. It is a huge accomplishment, because as you know, there are three sections in MAA or BLA, both for Europe and the FDA. And ATMP just validates that two out of three sections -- obviously we don't have clinical safety and efficacy data from Phase 3 yet, but all but that is certifying that our CMC section and our nonclinical sections are approvable based on the high level of quality that we perform. So we think this is a huge accomplishment for our team, but also a de-risk for our shareholders in that there are countless small to midsized companies who are delayed in getting their products approved because of either the CMC shortcoming or the nonclinical section. So we still have one big section to complete, and that's where we're devoted -- we're devoting our efforts in executing both REVEAL 1 and REVEAL 2. And I have full confidence in our team to accomplish those efforts.

Operator: And our next question comes from Joel Beatty with Citi.

Shawn Egan: Hi, guys, this is Shawn Egan on for Joel. The first [inaudible] kind of on the dMAb platform. Maybe kind of -- can you frame what are the most important things you hope to kind of learn or show in the initial study? And also give us a sense of -- based on your preclinical work, what type of serum levels and concentrations of antibody we could expect? And speed to onset, how quickly after administration are we going to get antibodies in the blood?

J. Joseph Kim: Okay. Well, thank you. So our first dMAb trial targets Zika, and as Laurent explained, obviously we want to check for the expression of those mAbs circulating in the patients, activity of the binding to Zika proteins. But for the platform perspective, we are escalating the dose to make sure what kind of expression levels we're getting with our first trial. So we will be able to report on those.

In nonhuman primates, we have been able to scale up from several hundred nanograms per mL to several micrograms per mL in our development process. So this is just the first human study, and what we learn in terms of the blood level expression of these monoclonal antibodies, as well as the pharmacokinetics of that, the half-life, the peak, the Cmax, and so on, is going to give us great information for the whole platform.

Now let me just add here -- even though it wasn't specifically asked, I think it would behoove me to touch on this -- is that dBTEs, one of the reasons why we're so excited about dBTEs, as well as our dMAbs, but dBTEs even so, is -- and Laurent didn't mention that earlier -- is that the BiTEs are effective in human serum in patients at 100-picogram levels. So those are -- in just -- in layman's terms, the BiTEs are effective in these functionality antitumor effects in the blood at 2,000- to 10,000-fold less in concentration. So as we continue to optimize the expression of dMAbs in our clinical studies, we think we can achieve the dBTE expression right now with the first trial for dBTEs. So -- now, that really pushes our urgency to target dBTE as one of our next major thrusts into our oncology program.

Shawn Egan: Great, thank you. And then a follow-up on HPV 6 program. I know 3106 -- congratulations on the data. And based on your initial work, can you kind of frame how big the RRP population is? And I know that you mentioned warts as well, but are there any other HPV-6-positive indications with an unmet need that you could -- that could potentially benefit from this therapy?

J. Joseph Kim: Yes, thank you. Yes. So there's about 20,000 RRP patients in this country. There are about 2,000 new cases every year. Throughout the world, you can multiply that by several-fold. So this is a rare indication, you may even say ultra-rare indication. What we're so excited about is, this is the third clinical efficacy example of our products targeted to HPV-caused diseases that we have seen very dramatic efficacy levels or clinical benefits. Cervical dysplasia in a 167-patient double-blinded study, some early complete responses in head and neck cancer with MEDI0457, and now with INO-3106.

Now, HPV 6 and HPV 11 are the major causes of RRP. In our pilot study, we just tested HPV 6 effects. We are planning to expand to include HPV type 11, which will comprehensively cover all RRP indications prior to going into the next study, hopefully pivotal.

In terms of other indications we can address, genital warts are really the big thing for HPV 6 and 11. There are about half a million new cases in the U.S., so these are much bigger targets. Obviously, different clinical manifestation compared to a life-threatening RRP, but nevertheless, we think we have a potential to develop this orphan and rare targeted disease program, which, over time, could have the potential to treat other indications like genital warts. And we are extremely excited about the potential of our program against these diseases.

Shawn Egan: That's very helpful, thank you. And just a really quick final question: Could you provide any update on kind of the blinded sensory rate or discontinuation rates from the oncology checkpoint combos you have going on?

J. Joseph Kim: We don't have that, and -- you mean the 5401 study?

Shawn Egan: Yes.

J. Joseph Kim: Yes, we don't see dramatic discontinuation or any rates like that compared to our other studies that we've done in our platform. So there is nothing in either the 5401 study about the discontinuation or dropouts compared to all of our other vaccine or immunotherapy studies.

Operator: And our next question comes from Stephen Willey with Stifel.

Stephen Willey: Joseph, was just maybe wondering if you had any commentary around the Bristol disclosure today with respect to the 498 study not meeting OS in GBM, and I guess if you view that outcome as supportive of the fact that you need some kind of additional immunostimulant on board to generate an immune response in this disease setting?

J. Joseph Kim: Yes. Your question answered your question, or your statement actually. I concur with what you just said. It's not surprising that CheckMate-498 failed. In fact, it's not just nivo's issue. None of the other PD-1 or PD-L1 inhibitors on their own have shown significant clinical benefit, either antitumor responses or, more importantly, on survival benefit on their own. That's the reason why we've targeted GBM with our T cell generating INO-5401 in combination with a checkpoint inhibitor, in this case with Regeneron's PD-1 inhibitor. So yes, I think you are -- your analysis I concur with, because PD-1 alone, without the presence of antigen or tumor-specific T cells around, is not going to be successful.

So what does that mean for our 5401 GBM study? We're certainly optimistic that -- and hopeful to see overall survival benefits compared to these checkpoint therapy alone or even just standard of care. So we're very cautiously but very optimistic that our data will pan out in the next few quarters.

But before the year-end, we will be able to progressively show our PFS-6, PFS-12, OS-12, OS-18 -- the first two before the year-end and then OS information in early 2020.

Stephen Willey: Okay, that's helpful. And with respect to 3106, is that something that you look -- you intend to look at with respect to intradermal delivery? And just given, I guess, some of the immunological data that you had shown, I think it was with the Zika vaccine, showing kind of improved T cell responses with intradermal versus intramuscular, how should we think about your leveraging that data to maybe pursue intradermal as kind of like the go-forward administration method of choice?

J. Joseph Kim: Yes. Steve, I love your enthusiasm for intradermal CELLECTRA-3P delivery, and I share that. But if I had an RRP, here's the situational decision tree we're facing, literally,

today, is these two patients have had clinical benefit, received four doses with our intramuscular delivery. We are -- and as we discussed at our last call and so on, we have just a factor of 10 more data on 5P or intramuscular delivery of our therapies generating very high levels, and specifically activated CD8 T cells. That's not to say that we're not working to bring in the intradermal delivery into all of these potential targets, including, first of all, vaccines, and then into our oncology or other immunotherapy programs.

In fact, I might have glossed over very quickly, but we've initiated our commercial development or design of our CELLECTRA 3PSP, very analogous to our 5PSP, commercial-level intradermal delivery system. And you will hear a lot more about these efforts in the coming weeks, but we are accelerating our efforts to bring about a commercial delivery system that targets intradermal. And I share your enthusiasm that more tolerable, better potentially immunological compartments through the skin gives us a lot of versatility and targetability improvements for all of our vaccines and therapies. So we're moving ahead. Every quarter, you're going to see differences and additional data sets that not only validates our intramuscular delivery but also add additional validation of our intradermal delivery of our therapies.

Stephen Willey: All right. And then just one last one from me. So with respect to the dBTE program and -- I guess it kind of sounds like this is something that we could possibly see in the clinic at some point, how do you envision getting around the FDA MABEL requirements for T-cell-redirecting therapies, specifically just given that you have such a prolonged onset of effect and it's going to take a while to clear each individual dose. How do you envision dose escalation playing out in the clinic with a dBTE?

J. Joseph Kim: Again, another great question. We plan to work very closely with the FDA. As you know, the FDA is extremely interested in overall bispecific antibody programs, in particular the BiTEs. And how do we go about that with the new trials and new efforts? We do it just like we did with our Zika dMAb. You start at very low doses, you test expression, you move up, escalate to the next dose, and so on. We think the advantages -- potential advantages of our dBTE technology is so overwhelming compared to the potential risks, and we, and perhaps future partners, will certainly be in a position to advance this as rapidly and safely as possible. So this is not anything we haven't done before, either with our immunotherapies, our vaccines, now with dMAbs, and then within the next couple -- few quarters, we -- as you said, and as I said, we'd love to bring our first candidate to the clinical evaluation. I can give you a hint -- it's either going to be the HER2-targeted dBTE or the CD19-targeted dBTE, two of which we have presented at AACR. And you'll certainly hear a lot more about our plans in the future.

Operator: And the next question comes from Jason McCarthy with Maxim Group.

Naureen Quibria: Hi, this is actually Naureen on for Jason this afternoon. So I have a question with regards to your dBTE program. You had amazing great data, preclinical data, with the HER2-directed agent preclinically, and more recently, you probably saw AstraZeneca and Daiichi, they reported fantastic data with their antibody-drug conjugate with HER2 directed toward metastatic breast cancer patients. So I was just wondering, to help us understand conceptually, how you would see a dBTE program in -- the advantages of that over, say, an ADC?

J. Joseph Kim: Well, I -- Naureen, I think that's a great question. So I think the HER2-targeted ADC is a great program. I guess our partner, AZ, thought so as well, and I think they invested $5.5 billion in this. So certainly -- it really strikes to the value of these anticancer products. When you're successful, these are highly valuable.

There are different mechanisms that come into play. Drug conjugated -- antibody drug conjugates certainly have their role. We also think tapping into the body's or the immune system's own killer T cells to target these cancers using the dBTE program will also be very important developments. So without having the same level of data, it's hard to cross-compare. Certainly, if we can achieve the similar level or even more successful clinical levels compared to that HER2 ADC, we and our shareholders will certainly be very pleased.

The potential, also, of our dBTEs is, we've just shown two of our first candidates, and certainly we have the focus of the developing our first one, and then we are, at the same time, Laurent and his team in R&D are pumping out several additional candidates. I mean, we're only limited by resources of partners to help us execute in the clinic. But our dBTE technology now is well validated in science, and we look forward to bringing multiple candidates, the first one by ourselves, but multiple others with partners in the future.

Naureen Quibria: Great. That's really helpful. And continuing along the same lines with the dBTE program, sometimes with bispecifics you do see generation of cytokine release syndrome, and your dBTE -- it appears it can elicit potent effects. So how would you -- would cytokine release syndrome be something of concern with yours as well?

J. Joseph Kim: Yes. I mean, certainly the class -- whenever you're potently engaging T cells, especially the killer T cells, that's the yin and the yang of T cells, is you want to be able to harness it but also be able to manage it. So as I answered Steve Willey's question, we're going to be very careful and methodical in our dosing escalation in our first trials, number one. Number two, looking at the pharmacokinetics of dBTE expression, compared to the bolus injection of traditional BiTEs, where you see the Cmax right away and they dissipate in a matter of hours, as you know, a lot of the cytokine storm and other toxic effects occur during the early peaking of the concentrated antibodies.

So of course, I'm just waving my hands here, because I only have preclinical data, but we think the total expression profile of dBTEs can be potentially beneficial in limiting the potential cytokine storm, but obviously we're going to go in with our eyes wide open, so our clinicians, our clinical team, our PIs, our sites will all be ready to manage if any side effects and so on.

Now, what I can point you to is, how do we manage cytokine storm in CAR T patients? As you know, every CAR T patient conveys some level of cytokine storm or side effects with this type of toxicity, and they manage it in the clinic. So the clinical benefits certainly overwhelmingly outweigh the clinical management of the side effects that they're able to utilize CAR Ts. We are going to look at this approach in a similar fashion. That may be the worst-case scenario, but we will see. I think, as I said earlier, the expression profile of dBTEs may be beneficial in this regard as well.

Naureen Quibria: Great. And just one last question. You mentioned a biomarker diagnostic for your VGX-3100 program. Have you actually had any discussions with potential partners on that front?

J. Joseph Kim: Yes.

Naureen Quibria: Okay, thank you.

J. Joseph Kim: So what we have done is discovered and are honing the biomarkers that we have discovered. Certainly, developing commercial kits are not in our wheelhouse currently, so it would make a lot of sense for us to bring in additional innovative leaders in that field to partner with us. And again, you will hear more about that in the coming weeks.

Operator: This will conclude the question-and-answer session. I would like to turn the conference back over to Joseph Kim for any closing remarks.

J. Joseph Kim: Yes, thank you for staying with us. As you can tell from our voices, we're extremely excited about our later-stage clinical executions of VGX-3100 as well as our execution of our immuno-oncology programs. At the same time, we're making great progress of our vaccines. Our CELLECTRA-3PSP initiation is very, very important and highly valuable, we think, and our technology, as well as, as you can tell from the analysts' questions, I think half the questions revolved around RRP and our exciting dBTE programs. We're very excited about those as well. And I look forward to bringing more information in the next few weeks and months to come. So thank you very much for your time.

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