Encode Ideas, LP Key Opinion Leader Conference Call with Dr. Jonathan Zager, Principal Investor Conference Call Transcript

Date: Wednesday September 30th 2020
Time: 3:00 PM ET
Speakers: Hogan Mullally
Partner, Encode Ideas

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Moffitt Cancer Centre

Operator:
Good morning, ladies and gentlemen. Welcome to the Encode Ideas LP Key Opinion Leader Call with Dr. Jonathan Zager, Principal Investigator for Delcath's Phase III FOCUS Study.

As a reminder, this conference call is being recorded.

I would now like to turn the meeting over to Hogan Mullally, Partner, Encode Ideas.

Hogan Mullally:
Thank you, and welcome everyone to the call, we really appreciate you participating.

My name is Hogan Mullally, I'm a partner at Encode Ideas, and pleased to be joined on this call by Dr. Jonathan Zager, Chief Academic Officer and a Surgical Oncologist and Senior Member of the Department of Cutaneous Oncology and Sarcoma at Moffitt Cancer Centre. Dr. Zager is also the principal investigator in the pivotal Phase III FOCUS Study, investigating melphalan/hepatic delivery system via percutaneous hepatic perfusion, or as we'll refer to it throughout the call, PHP, in the treatment of metastatic ocular melanoma.

Before we begin our discussion on metastatic ocular melanoma and PHP, I'd like to run through some standard disclosures with Dr. Zager. First, I'd like to highlight that this call is being recorded and transcribe. Second, you the expert, attest that you will not disclose any confidential or material of non-public information. Finally, if you're participating in a clinical trial and/or a member of a scientific advisory Board, clinical trial steering committee, and/or data safety monitoring Board, you will not disclose any information that is not publicly available and information that would break any confidentiality agreements, by which you are bound.

Dr. Zager, do you agree to these terms?

Jonathan Zager, M.D.:
I do.

Hogan Mullally:
Terrific, okay. I'll be serving as the moderator for the call. I'd just like to note that this call is intended for information purposes only. This is not for investment advice. The content of this call, including any and all information provided regarding individual securities or industries do not constitute financial, legal, or tax advice. Also, Encode Ideas covers Delcath Systems, the developers of PHP, for which we have been compensated in the past by Delcath. The firm, including the general partners of Encode Ideas, own equity in the Company. We have not been compensated for hosting this event today.

Finally, although I'm not an insider of Delcath, I too am required to keep any material and non-public information I may be aware of confidential.

We asked investors to submit questions to us in advance of the call; we'll do our best to get to most of those questions, but due to some time restrictions, we may not be able to get to them all.

Okay, all the formalities are done. First off, Dr. Zager, thank you for making the time for this call, I know our audience is looking forward to hearing about your experience in treating metastatic ocular melanoma, and in particular your experience and opinion on using PHP. I think the best way to start is to sort of maybe frame the call with giving us a brief background on what Moffitt Cancer Centre's about, and in particular, your practice at Moffitt. Would you mind just giving us a quick overview of that?

Jonathan Zager, M.D.:

Sure. I am a Surgical Oncologist at Moffitt. My specialty is melanoma in skin and soft tissue malignancies, but mostly melanoma. Within that disease site specialty, my clinical and research focus—and I guess, subspecialty expertise is in regional therapies for regionally metastatic melanoma. I have been performing PHPs since, I think, 2008, ever since the last Phase III trial, and then in between both Phase III trials as compassionate use cases.

Moffitt Cancer Centre is one of the NCI/NCCN designated cancer centres, ranked highly in the country, in U.S. News and World Report. It's the only NCI/NCCN designated cancer centre in Florida. We have an extremely busy Cutaneous Oncology program, probably one of the busiest in the world, seeing close to 3,000 new patients a year, and obviously not just ocular melanoma—but see ocular melanoma patients in the Cutaneous Oncology clinic and offer them a variety of treatments. If they have liver-only disease, right now PHP is our go-to treatment if they're eligible for the clinical trial, and it has been, for the last decade plus. But we do have options for these patients.

Hogan Mullally:
All right, terrific. How many metastatic ocular melanoma patients do you figure you see a year? I mean, I know—it sounds like, obviously, you see far more cutaneous melanoma, given the higher prevalence, but how many metastatic ocular melanoma patients do you estimate you would see on an annual basis?

Jonathan Zager, M.D.:
Tough to say; in the department, I can't really estimate it. Me personally, so all the patients that need a regional-type treatment will come to me, anywhere—it depends on the month, anywhere, three to five a month, me personally.

Hogan Mullally:
Yes.

Jonathan Zager, M.D.:
That's probably a good figure.

Hogan Mullally:
Okay. You mentioned you've been doing PHP since 2008. How many do you estimate you've done over your time with the technology?

Jonathan Zager, M.D.:
At least 120, 125, maybe some more. I haven't reassessed the total number lately, but at least 120 or so.

Hogan Mullally:
Okay. When a patient arrives at Moffitt and arrives at your clinic, they've got liver metastases, the vast majority of the time, I assume—and have they been pre-treated? Have their meds been treated at the community by their medical oncologist, or are they coming in treatment-naïve? What do you generally see?

Jonathan Zager, M.D.:
That's a great question. I would say it's about 50/50, maybe a little bit more to the previously treated patients. They are treated in the community with either single-agent anti-PD-1 therapy or combination immunotherapy, or their medical oncologist has referred them to interventional oncology and they've been treated with Y90 or chemoembolization or bland embolization.

I would say that's probably greater than half the patients, and then the other half of the patients are being followed by either their medical oncologist, after just a diagnosis of ocular melanoma and are in surveillance with surveillance imaging. Those patients usually come to me with lower burden disease, because they're getting frequently imaged, they're not treated before they come to me; they're diagnosed at an earlier disease burden and then get sent to me, treatment-naïve.

Hogan Mullally:
I got you. The patients that come to you, then, who have received previous, let's say systemic therapies like immunotherapy, they obviously have not responded, and that's why they're coming to see you. I mean, what kind of response rates are you seeing, for patients that are treated with IOs from their community medical oncologist? I'm sure you've got a deep familiarity with immunotherapy given your cutaneous melanoma focus, but I'm curious about its efficacy in ocular melanoma.

Jonathan Zager, M.D.:
Unfortunately, the immunotherapy approach to ocular melanoma isn't as near as efficacious as it is in the cutaneous oncology realm. I would say, single-agent, you're talking about less than 10%, maybe even less than single-digit percent response rates. In combination immunotherapy, there is a couple reports in the literature of very few patients that might show 15% response rates at best. I'm trying not to talk about the five patient series where two of the five patients you treated responded, and someone's going to claim 40% response rate.

But overall, I wouldn't say that combination immunotherapy is effective more than 10% to 15%, at most, of the time. These patients are usually treated with multiple rounds of systemic immunotherapy, or combination immunotherapy, and/or regional therapies, and they come to me, yes, with progressive disease; pre-treated, progressive disease. Obviously at that point, if they're treated for three or four months before they're re-imaged, their disease burden is that much greater than it would've been four months prior, if they came prior to any of these systemic therapies.

Hogan Mullally:
I guess it's maybe a loaded statement or point, but I guess, in many ways, you'd prefer to see these patients before they've been treated. Ideally, you see them with low disease burden and not potentially—and I don't want to use the word "wasting" three, four months on immunotherapy. But with such a low response rate, in many ways you'd prefer that, once these patients have earlier signs of metastatic disease, that they're showing up at Moffitt as opposed to having spent three or four months receiving systemic immunotherapy from their medical oncologist only to progress and eventually show up later on with more progressive disease.

Jonathan Zager, M.D.:
Yes, I agree. I think that percutaneous hepatic perfusion, or PHP, does not burn any bridges for systemic therapy afterwards. One would say that systemic therapy beforehand does not burn any bridges for PHP, which is probably true. Except for the fact that there is some evidence in the literature that, while the evidence that's out there, PHP works, from the previous Phase III trial, from studies that I've published out of Moffitt Cancer Centre on expanded access and compassionate use patients. We also can relate that to burden of disease. The earlier the treatment and the less burden of disease, the more effective PHP will be.

Hogan Mullally:
Got you.

Jonathan Zager, M.D.:
You can send me the patients—if the message is, if they can send me the patients upfront and let me try PHP, I think we could have a better response rate, and I won't burn the bridge for single-agent combination immunotherapy, or anything, if PHP doesn't work.

Hogan Mullally:
Okay, makes sense. You referenced some data you've generated at Moffitt with PHP, comparing it to other regional therapies. Can you speak to the data that you've—I know it's a little dated now, it was published a few years ago, but can you speak to that retrospective comparison against Y90 and chemoembolization?

Jonathan Zager, M.D.:
Yes. I mean, like you mentioned, it is a little dated. In being fair, it is a small, little comparison trial. I think we had 30 or something patients on it, where we compared ocular melanoma metastatic to the liver, treated with Y90, PHP, or chemoembolization. Some of the patients had two therapies: they had PHP that might have failed and went to Y90, and vice-versa, chemoembolization that might've failed and went to PHP.

What we found from that, since it was low numbers, the treatment was definitely—overall survival and recurrence-free survival were definitely in favour of PHP, especially PHP versus Y90 and PHP versus chemoembolization. I think hepatic progression-free survival was in favour of PHP. But I think overall survival for the patients, because of the low numbers and the early assessment in our study, wasn't significant between the groups. Certainly, the response rates in the liver seemed to be significantly in favour, in terms of PHP versus those other two modalities.

That's the only really small comparison that I know of in the literature, and definitely favouring the significant prolongation of hepatic progression-free and overall progression-free survival in favour of the PHP group.

Hogan Mullally:
Okay, terrific. I'd like to talk a bit about the PHP procedure itself. Once a patient is scheduled for their PHP procedure, when they arrive, how long the procedure is itself, and then, when they are discharged from the hospital. Maybe, I'd like to frame it—I know you're in the midst of the FOCUS Study right now and you've got more rigour around the protocol as to how patients are treated. I'm thinking more so into the future.

If, when PHP is approved and it's available to use as an FDA-approved product, how do you see PHP being used in your practice, as far as when the patient arrives, their actual procedure, and when they're discharged?

Jonathan Zager, M.D.:
Great question. In my experience, even outside of the current Phase III trial, these patients will come in the day before—not necessarily have to come in the day before, but I am treating them even on the compassionate use as if they were on a clinical trial. Because the compassionate use, you do need a single patient IND and it goes down a clinical trial pathway. They come in the day before, they get treated the next morning. They spend that night in the ICU, here at Moffitt, just because we don't have a step-down unit, but a step-down unit would be appropriate.

Then I would say, the overwhelming vast majority of patients go home the next day. They would go home post-op day one, straight from the ICU, after morning labs. Make sure everything looks okay, they're tolerating a diet and walking around; they go home.

I can see in the future, us doing this as, come in the same day of surgery, get your procedure done, and go home post-op day one. Only one-night stay in the hospital. That usually is the vast majority of the patients. They usually feel well after the procedure. They see me, if I do the procedure, usually on a Tuesday or Wednesday, they're going home Wednesday or Thursday; they see me the following Monday, sometimes with minor complaints of just a little fatigue.

Then they see me the following week again, so about 14 days after the procedure, just to check labs to make sure all their labs are in order. By that time, they're already feeling back to themselves.

I've also noticed that, as the treatments go on, between PHP-1, PHP-2, and all the way up to PHP-6, that it is better tolerated for the patient. If they have this fatigue or any complaints after procedure number one, those seem to fall off by procedure three, four, five, and six. They literally feel great after the procedure. I don't know if it's the anxiety of the first procedure that kind of makes them feel fatigued and not themselves for the first few days after discharge or whatnot, but as the treatment goes on and we proceed down the line of giving them six PHPs at every six to eight-week intervals, they seem to do better and better.

Hogan Mullally:
Okay, that's interesting. You think that in the future, it could foreseeably be a 24-hour, in that morning, out the following morning procedure. A lot of the contemporary data we're getting out of Europe, where obviously PHP is approved and the medical device is CHEMOSAT, we're seeing data come in quite regularly. It appears that their stays are longer. A lot of the published literature for them is two to four days, three to five days.

What are they doing in Europe? Is that just more of a socialized medicine phenomena as opposed to the United States? How do we reconcile what you think, or your experience as opposed to the European experience?

Jonathan Zager, M.D.:
I've given a lot of talks about this in Europe, and talked to my colleagues in Europe about it as well. There's a couple of things. One, we remove the lines in the post-anaesthesia recovery unit as soon as the platelet count and any coagulation abnormalities are fixed and reversed, the lines come out. Sometimes in Europe, they're not removing those lines until the next day; for one reason or the other, I'm not sure why, and maybe they've changed their practices.

I don't know why they keep the patients for so many days. It's certainly not because the patient needs to be in the hospital. There's nothing that's acutely going on with these patients that you're monitoring that you can't monitor as an outpatient, even if it's labs, or that the patient acutely needs to be in the hospital for. There's no pain associated with the procedure, so there's no pain medicine. There's really no bowel dysfunction associated with the procedure, so there's no waiting for GI function to return.

Once the lines come out, that means you're—obviously, all of your blood parameters are pretty much back to normal or at least towards baseline, and there's really no monitoring that needs to be in the hospital at that point. It could be done as an outpatient, and like I said, I don't see the patient back after they leave for three to five days later with additional labs. They know they can call me at any time and we can have them pop back in to our little emergency room type unit, at Moffitt Cancer Centre. But for the most part, I see them again in clinic the following week with labs, and they do just fine.

I can't explain why the Europeans haven't capitalized on sending the patients home, freeing up that bed and lessening the use of resources in the hospital. But it is what it is.

Hogan Mullally:
Yes, okay. The multidisciplinary approach that's required for a PHP procedure itself, I mean, can you speak a little bit to the procedure itself and who's in the room with you, and who's the leader of the process? I know there's a number of specialists that are involved. If you just walk us through what that procedure looks like and who's all involved?

Jonathan Zager, M.D.:
I'll give what's involved in my centre, and there can be some variations in other centres. In my centre, we need a perfusionist, because the patient's on veno-veno bypass; obviously the double-balloon catheter upshocks the liver. The veno-veno bypass extracts the effluent from the hepatic veins. It gets filtered outside the body through the proprietary filters, then through veno-veno bypass and a bypass machine, gets pushed back into a jugular catheter, the chemo-filtrated blood.

You need a perfusionist to set up the system, set up the bypass system, run the machine, and troubleshoot any issues with the machine while the procedure is ongoing. You need an interventional radiologist. These guys can put catheters in anything. This is not a very hard procedure for them; there's much harder interventional oncology procedures. This is pretty straightforward; it's putting a catheter in the hepatic arteries, and embolizing any possible collaterals off the hepatic arteries or other collaterals that might see some chemotherapy-laden blood that would

divert it to intestines or the stomach. They embolize these vessels; again, a straightforward procedure for the interventional radiologist, but they are instrumental.

Then an anaesthesiology team. Now, I think that our results at Moffitt are so good, because I've used the same two anaesthesiologists and the same two to three CRNAs for all 120+ procedures, so we have it down to a science. We know what meds to give when, and pretty much have seen any possible issues throughout the case, which are predictable and treatable. It's nice to have a dedicated anaesthesiology team who is comfortable with the case in the room.

Then as far as myself, I hold the catheter in place and just run the show, making sure that there's direct communication between all members of the team: anaesthesia, perfusionist, and interventional radiologist. Just making sure everybody's on board as the step-wise progression of the case moves along. You just want to make sure everybody's ready for the next step, ready for the filters to be opened, ready for the balloons to be inflated, ready for the bypass line to be clamped, so on and so forth. My job is just to talk the whole time and hold the catheter.

Hogan Mullally:
It's interesting. You don't describe it as a complicated procedure, yet there's a lot of people involved in it. I guess, is that the complication, is just making sure everyone knows their part? I guess that's something that just improves over time, and the more you do it—you talk about your dedicated anaesthesiology team.

I was watching a YouTube video from Dr. Gupta who's an anaesthesiologist at Southampton, U.K., and he talked about how the performance of PHP just got better over time, because they became a more well-oiled machine. I guess that's what you're describing as well, is that the technology works, but it's just about getting that team flowing right. Am I summarizing that correctly?

Jonathan Zager, M.D.:
Yes, absolutely. That's why I'm saying, the constants in the procedure, I have had the same perfusionist each and every time, maybe except one; the same interventional radiologist every time except one; the same anaesthesia team, and I have been in every single procedure. It is nice to have the same team, and I would say that there are other procedures in the medical world, transplants, cardiac procedures and other complicated procedures where you have the same team in there. Once you have the same team in there, you get used to everybody's nuances and you understand the procedure better. With experience comes better familiarity with the procedure. It flows nicer.

The answer to the question, the long-winded answer to that question is yes. If you have a dedicated team with experience, it's going to become easier and easier. It's hard to teach perfusionists each time, when to clamp the bypass line, how quickly to open up the filters or the anaesthesiologist, when to start pushing some of the blood pressure medication, because we're going to see a little dip in the blood pressure. These guys know what to do, when, without me saying it, even though I still do. But again, a dedicated team helps out a lot.

Hogan Mullally:
Do you think PHP, if approved by FDA in the future, do you think it's more suited towards high-volume cancer centres like Moffitt? Or do you think community teaching hospitals could also be doing PHP procedures? How do you foresee it being rolled out throughout the United States if approved? Again, do you think it's more focused on centres of excellence, or could it be used more widely?

Jonathan Zager, M.D.:
Just so we're on the same page, there's 60 or so NCI-designated cancer centres and there's 30 or so NCCN cancer centres; a lot of them are the same. That's already covering the country, our country, pretty thoroughly, these large, academic cancer centres that do see the hardest of cases. This is a rare tumour, so yes, it's seen in the community,

and almost always referred to the cancer centre, except in some cases where the community oncologist might not know the best way to treat it and they start with immunotherapy, so on and so forth.

I think that sending it to the 60 NCI-designated cancer centres, is one, already a huge amount of cancer centres that cover the entire country that can field all the PHPs that are needed. Yes, as time goes on, it's going to be available, and it should be available, in other regional and local community medical centres, as long as the team has been appropriately educated on the procedure, proctored on the procedure or so on. But I think that, just like some other major types of surgery and transplants and so on and so forth, it's not like every single community hospital does transplant surgery, or heart transplants or whatnot. They're done at dedicated centres that are comfortable with the procedure and have experience with this procedure.

I think the same thing could be said with PHP. It's going to start out in the large, academic NCI centres, and then eventually will be available in the other community and regional centres, as other folks become familiar and comfortable with the procedure.

Hogan Mullally:
Great, okay, that makes sense. I'd like to go back in time a little bit here to the first Phase III study with PHP, when you were an investigator. In your opinion, what went right with that study, what went wrong, and do you think the safety issues that FDA highlighted in their previous review of PHP have been addressed with the filter change, to the GEN 2 filter?

Jonathan Zager, M.D.:
A lot went right; I think the last Phase III was—there's, I guess, a couple issues. One, just so we're on the same page, it met its goal of prolonging hepatic progression-free survival. There was a five-times increase in progression-free survival, so it was a positive trial in terms of its treatment goal.

There were some toxicity issues; it was a previous filter. All those toxicity issues and some of the higher-grade toxicities, I think, have been mitigated, both at the time of the Phase III trial. There were protocol modifications after certain toxicities were seen, and those toxicities never happened again after the protocol modifications. Those have been mitigated, both in terms of protocol and approach to the procedure, as well as a change to the second-generation filters, which have definitely helped filter out more of the chemotherapy and allowed patients to get a higher median number of PHPs since the advent of the second-generation filter.

I think that it is a positive study. Obviously, the FDA has its reasons and rationale of why they didn't accept it back then, and it was mostly based on the toxicity, which I think has been mitigated and dealt with. Hopefully we'll see, in this current Phase III trial, a lot less toxicity when the data comes out and we have a chance to present it to the FDA.

Hogan Mullally:
Terrific. Maybe a question I should've asked you previously when we were talking about the actual procedure itself; but because it was also an issue in the past, in the previous Phase III. How manageable are the haematological side effects with PHP? We see it as Grade 3, Grade 4 haematological side effects. I was reading a recent paper from Leiden, they talked about these side effects being very manageable, though.

In your experience, I'm assuming that you find these haematological side effects, which the FDA did highlight in their previous Phase III with the old GEN filter, with the new GEN filter and how you manage these patients. Do you feel like those haematological side effects are manageable?

Jonathan Zager, M.D.:

Yes, they're totally manageable. I would say, in my experience, 97%+ of the time, as outpatients, extremely rarely are we bringing the patient in for some sort of transfusion or whatnot. Even at that point, it's still an outpatient procedure. They're very manageable. There's really no major toxicity emergencies that necessitate the patients to be readmitted.

I think that the overwhelming, vast majority of these toxicities are, again, manageable as an outpatient, over the phone. Obviously, I don't know if you're familiar, but we give Neulasta as an injection within 72 hours of the PHP, so that helps mitigate some of the bone marrow toxicity, so completely manageable as an outpatient.

Hogan Mullally:
Terrific, okay. Kind of move to the current FOCUS Study, in preparation for this call I was looking at the different—a bunch of different information on PHP, and I stumbled across a series of YouTube videos on a conference from 2017 put on by the Ocular Melanoma Foundation, called the Eye Am Not Alone Conference. I believe you were a speaker there, watched your presentation.

There were a lot of patients and caregivers, ocular melanoma patients and caregivers in the audience, and I was actually really touched by some of their comments. I think it was more so when Dr. Saries (phon) and Dr. Wong from Sinai's, presentation, about how—and this was 2017—about patients' angst and reservation about the prospects of being randomized into that FOCUS Study. First, protocol, where they had a chance of being randomized, either the PHP or to best alternative care; a lot of them were very anxious about the potential or the prospects of being put onto the best alternative care arm.

Can you speak to the difficulty, from the old protocol enrolling patients, and how that influenced the change that came about in 2018 which took FOCUS from a randomized study to a single arm study?

Jonathan Zager, M.D.:
Yes. As the lead PI and the discussions with the Company, we wanted to change it to a single arm. If I recall, it was more that the FDA was a little resistant and wanted it to be a randomized study. But what we were doing is creating a socioeconomic disparity in the study, in that patients who were randomized to best alternative care, who have the means, were flying to Europe and getting their procedures done in Europe because it's CE mark approved, and paying for it in cash. Whereas those that didn't have the socioeconomic status to do so were stuck with best alternative care. We were losing patients. Some patients didn't even want to be randomized, because they were like, "If I have a 50% chance of getting best alternative care, I'm just going to go to Europe. Why do I have to go through all these screening procedures and the randomization process? I'm just going to go now." They would even not entertain the study any further at that point.

I had more than a few patients, randomized to best alternative care, that decided to go to Europe. They just decided that, I'm not going to get best alternative care, I'm going to go pay for it on my own. I'm going to ask friends and family for help, financial help, and see you—and, never saw those patients again, even though they were signing consent for the trial. Rightfully so, in discussions with the FDA, we finally agreed that a single arm study was the best way to go, and to ensure that the patients get this treatment, and we can really, hopefully, have a positive impact on their disease and follow them for hepatic progression-free, overall progression-free, and overall survival as a single arm study.

Hogan Mullally:
As part of that, the endpoint change to a primary endpoint of objective response rate, and I'm curious, from your opinion, this is still a very meaningful endpoint for a Phase III study ORR?

Jonathan Zager, M.D.:

Yes. I do think it is a meaningful—especially in this patient population with this procedure. I honestly don't see how we could have any other type of primary objective here, other than that. It is meaningful, so we'll have to see what the results are.

Hogan Mullally:
Okay, terrific. Looking at the future, if PHP is approved and the Company is thinking about its next path forward with PHP, outside of metastatic ocular melanoma, a lot of us think of it as a platform technology that can be used in other tumours of the liver, other—to isolate other organs. Do you have any thoughts on other areas that you think PHP could be used, where you think it would have the most merits, the best application for it? Just curious as to where you think it could and should go next.

Jonathan Zager, M.D.:
As you know, in Europe, it's CE mark approved, I'm pretty sure, for any malignancy, metastatic, to the liver.

Hogan Mullally:
Yes.

Jonathan Zager, M.D.:
I can see that being the same thing here in the U.S. Obviously, first the FDA is going to approve it for ocular melanoma to the liver, but once it's on the shelves and we realize that it's a powerful therapy to treat isolated or predominant disease in the liver, I can't imagine other physicians and multidisciplinary cancer groups aren't going to start trying to use this, with insurance approval, for other malignancies in the liver, when, either, one, options are exhausted for those patients, or options might be contraindicated or the patient who is now a very educated part of this multidisciplinary team, is going to come in and they're going to talk to us about these procedures that they read about online, that isolates the liver. You have very minimal systemic toxicity with a good quality of life, and so on.

I can't see that it won't move in that direction, where it's going to be used more and more for other histologies to the liver, but obviously, FDA approval will be for ocular melanoma.

Hogan Mullally:
Right, okay. This is maybe a little bit of an unfair question, but I know reimbursement and drug pricing is not an area that you focus on. But I'm just curious about your thoughts on where PHP could or should be priced at. We just talked at the beginning of our conversation about these novel and expensive immunotherapies that are being tried with response rates in the 5% to 10% range.

Assuming we see a strong response rate from the Phase III FOCUS Study and FDA approves this product, do you think this product can be priced like an immunotherapy? Can it be priced—I guess, again, it's a loaded question, because I know that's not an area of your focus. But where do you…

Jonathan Zager, M.D.:
Yes, it's a great question and I can't answer it. I mean, I am a simple surgeon. I am paid by the hospital. I've heard $60,000 per treatment thrown around, I don't know if that's true or not, I honestly don't know. I would have to defer to the coding and reimbursement specialist, as well as the Company, for what they're going to do. I honestly don't know. I don't know any of the procedures I do and what the hospital gets paid for it. I just work here.

Hogan Mullally:
Right, well, I knew it was a bit of an unfair question, but I thought I would ask and see if you had an opinion on where it could or should be priced. Is it safe to say, as we start to get into the close of this Q&A, I think at the beginning of the call you had mentioned that you think that PHP, once FDA approved, should be a frontline therapy for patients

who have a new diagnosis of metastatic disease to the liver with ocular melanoma. Is this, in your mind, the first line therapy that you would go with for those patients?

Jonathan Zager, M.D.:
A hundred percent. If it's approved, in my practice, that would be the first line therapy, assuming there's no contraindications to it.

Hogan Mullally:
Okay. I think that just about summarizes everything. I'm just looking at any questions I may have received at the last minute here, but look. Really, really appreciate your time and your insights. We're obviously, as investors, anxiously awaiting the Phase III FOCUS data. Appreciate you giving us your time here, and unless there's anything else on your end, I'll just say thank you. I guess we look forward to hearing from you and your fellow investigators when the Phase III FOCUS data are available.

Jonathan Zager, M.D.:
Yes, I'm anxiously awaiting the data too, and I'm hoping that everything's positive. Just to summarize, it's a great procedure, the patients tolerate it well. Given the team that has some familiarity with the procedure, it's easy to do. I'm excited for the future; I'm hoping that everything just turns out positive, and the next time we talk, you'll know how much the procedure gets paid, reimbursed, and we can talk more about how to get more than the 60 NCI centres on-board.

Hogan Mullally:
Terrific. Thanks, Dr. Zager, really appreciate your time.

Jonathan Zager, M.D.:
All right, you take care.

Hogan Mullally:
Thank you, Operator. I think we're finished here.

Operator:
Thank you. This concludes today's conference call. You may disconnect your lines. Thank you for participating, and have a pleasant day.