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ViralClear Pharmaceuticals, Inc.
Data Review from Phase 2 Trials of Merimepodib in Combination with Remdesivir in Adult Patients with Advanced COVID-19
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Q&A Participants
Yale Jen – Laidlaw and Company
Jeremy Roe -- Integra
Gary Zwetchkenbaum – Plum Tree Consulting
Ted Lovejoy – Ladd Capital Management

Operator
Greetings, and welcome to the ViralClear update call. At this time, all participants are in a listen-only mode. A question and answer session will follow the formal presentation. If anyone should require operator assistance during the conference, please press "*0" on your telephone keypad. As a reminder, this conference is being recorded.

I would now like to turn the conference over to your host, Mr. Andy Ballou, Vice President, Investor Relations. Thank you. You may begin.

Andrew Ballou
Thank you, Operator, and thank you all for participating in today's conference call and webcast. On today's call, we're pleased to have Ken Londoner, Founder, Chairman, and CEO of BioSig Technologies, Dr. Jerry Zeldis, Chief Medical Officer of ViralClear Pharmaceuticals, and Steve King, Chief Operating Officer of ViralClear Pharmaceuticals.

Before we begin, I'll remind everyone that on this call, the presenters may make forward-looking statements. Such statements may be preceded by the words intends, may, will, plans, expects, anticipants, projects, predicts, estimates, aims, believes, hopes, potential, or similar words. Forward-looking statements are not guaranteed. Our future performance is based on certain assumptions and is subject to various known and unknown risks and uncertainties, many of which are beyond the

company's control and cannot be predicted or quantified, and consequently, actual results may differ materially from those expressed or implied by such forward-looking statements.

Such risks and uncertainties include, without limitation, risks and uncertainties associated with the geographic, social, and economic impact of COVID-19 on our ability to conduct our business and raise capital in the future when needed, our inability to manufacturer our products and product candidates on a commercial scale on our own or in collaboration with third parties, difficulties in obtaining financing on commercially reasonable terms, changes in the size and nature of our competition, the loss of one or more key executives or scientists, and difficulties in securing regulatory approval to market our products and product candidates. More detailed information about the company and the risk factors that may affect the realization of forward-looking statements is set forth in the company's filings with the Securities and Exchange Commission, SEC, included in the company's annual report on Form 10-K and its quarterly reports on Form 10-Q. Investors and security holders are urged to read these documents free of charge on the SEC's website at www.SEC.gov. The company assumes no obligation to publicly update or revise its forward-looking statements as a result of new information, future events, or otherwise.

I'll now turn the call over to Ken Londoner.

Ken Londoner
Good morning, everyone, and thank you for joining. Similar to last week's clinical update call for our PURE EP business, today, we will be providing a detailed update for ViralClear. I'd like to briefly recap our short history with ViralClear.

On March 25th, BioSig agreed to enact the purchase agreement to bring two drug assets in from Trek Pharmaceutical: VX-497 of Merimepodib and VX-222. Both these assets were originally developed by Vertex Pharmaceutical, and Vertex put a significant amount of financing into these programs.

Because of this, we were able to get an IND from the FDA to enable us to go from a standing start into a Phase 2 trial. And, we were also able, because of the quality of our team, to produce enough drug to be provided to the trial. In addition to that, leveraging off of the joint capabilities of the teams, we attracted Mayo Clinic to become the principal investigator for our trial, and we were able to complement Mayo with an additional footprint of centers around the United States.

As stated in our prior calls, BioSig's core objective in getting into this business was to fully support Dr. Zeldis and his team in order to meet the needs of the pandemic, given the confidence in Merimepodib and its pre-clinical activity, especially at the biodefense lab down in Galveston, Texas, with Dr. Paessler. I'm very pleased with the progress that has been made in less than six months. We

have only owned this business for five-and-a-half months, and we look very much forward to the next six months.

I'd like to also note that there have been some interesting articles that I think are worthy of mentioning here in my introduction. There was a recent New York Times article called "What the Fall and Winter of the Pandemic Will Look Like," and basically, I'd like to quote one of the lead researchers at the University of Minnesota. It was the Director for Infectious Disease Research. He was quoted as saying that 'the pandemic is like a forest fire. We have suppressed it in some places, but we have not put it out completely. It is going to keep burning as long as it has wood, and in this case, wood are humans that are susceptible to infection,' and there have been a lot of perceptions that we have our arms around this, and we don't. But if you look around the world today, as we're speaking, we have the pandemic raging in India, coming back significantly in Europe, and we're seeing signs of what hopefully is not but may be the next wave.

So, with that said, I'm going to turn it over to Jerry for his update.

Jerry Zeldis
Thank you, Ken. As Ken talked about, we've accomplished quite a bit since the end of March, and basically, what we've done is we've quickly repositioned Merimepodib for COVID-19 from a drug that had, in the past, been looked at for hepatitis C viral infections and immunological diseases, and we've raised the supporting capital to allow us to finish our Phase 2 program and to go forward with our Phase 3.

We have an established and accomplished development and management team. A very good point about this is that despite the fact that from the end of March until now, we've been working extremely hard to move things forward, and none of us have met face to face with each other.

We respond to the changing COVID-19 landscape, and I'll go into that in a minute. We anticipate having our topline data on our expanded Phase 2 trial the fourth quarter of this year, and very quickly turning around and starting our pivotal trial that same quarter, which would get us to filing the NDA for Merimepodib by the third quarter of next year.

Now a quick word on our Phase 2 study. The Phase 2 study is a signal seeking trial of hospitalized patients who require oxygen in combination with remdesivir. Remdesivir is now the standard of care for all COVID-19 patients who are hospitalized who require oxygen.

We've had to amend the protocol because recently, a number of other drugs have received what's called emergency use authorization besides remdesivir: Dexamethasone and convalescent plasma.

All centers now are using remdesivir. The use of the other two drugs is inconsistent between centers. It depends on what doctors believe, whether it's of use or not.

The good news for the United States, but the bad news for the study, is that enrollment has slowed, and this reflects that hospitalizations have decreased across the country. In response to this, we've expanded the number of sites from five to seven. However, some of these sites have sub-sites. So, we have a total of 11 centers that can now enroll patients.

When we look at the blinded data, what we discovered is quite surprising. There are two types of hospitalized patients who were not intubated, who require supplemental oxygen. Using the NIAID grading score, those who are grade 4s require either a nasal prong or a ventilator mask to maintain a good oxygenation level. However, those who are grade 3 are in respiratory distress, and they are very close to being intubated, and those people require a high percentage of oxygen and a high flow of oxygen in order to oxygenate.

What we've discovered is that the grade 4 patients, those who do not require this type of intensive oxygenation, oxygen therapy, they all do well. They all leave the hospital, and they don't relapse. Since this is a placebo-controlled trial, half of them receive our drug versus placebo. The outcome, we don't see a clinical outcome, which is any different between the two [arms].

Now, I'll just say parenthetically that Lilly recently reported that their kinase inhibitor can decrease the amount of hospitalizations in this type of population of patients when used on top of remdesivir, and they can decrease in the amount of hospitalizations by one day. But that required 1,000 patients to be studied. We're only looking at 40 patients' worth of data and half of whom are—were—NIAID grade 4s.

On the other hand, the grade 3s, when we look at in a blinded fashion, they are separating within that group. A certain percentage of those people are either doing worse or not improving, and the rest are getting better, some very quickly, some not so quickly, and once they leave the hospital and we follow those people for 28 days or longer, the ones who leave the hospital are doing well, thank you.

So, we believe that that is the group where we'll see a difference if indeed those who do well segregate with our drug versus placebo. At this point, the numbers are too small for us to say we now have a definitive signal to go to the FDA and to go pivotal.

Based on conversations that we've had with a variety of consultants and potential funding organizations—so that includes people with extensive previous experience in the government,

people who work for non-government organizations—we've been advised to expand the number of patients we have in our Phase 2 trial.

So, on that basis, we've expanded the trial to no more than 80 patients, and I say no more than 80 because we will be reviewing the data on an ongoing basis as it becomes available, and if the numbers of grade 3s, who are doing well, increases to a certain point, then we say ah-ha, perhaps we have the signal we're looking at. Then it'll be unblinded, and we will then discuss with the FDA because we will now have the power to phase--to power the Phase 3 study appropriately with the number of patients needed.

While this is going on, what we're going to be discovering studying markers for inflammation is how they change vis-à-vis our drug versus placebo. That includes cytokines and other markers that are associated with macrophage activation.

We continue to look at combination therapies not only with new molecular entities but also with monoclonal antibodies. And the monoclonal antibodies, it's just worth a quick aside. At least three companies right now are looking at monoclonal antibodies that will neutralize the virus. The difficulty that they all have is that the amount of antibody they have to give to a single patient is quite large, and there's quite frankly not enough antibody around to treat the pandemic. So, anything which could be added to a monoclonal antibody, which would decrease the amount of antibody needed to treat a particular person, would be of great benefit.

So, we are now performing experiments to see if we can decrease the amount of monoclonal antibody that's needed. First, we'll do this in hamsters, and then if it looks promising, it will go to humans.

The monotherapy trials that we wanted to do we have to delay. The difficulty we've run into is now that remdesivir and other drugs are considered the standard of care for hospitalized patients, we cannot do monotherapy anymore in that setting. So, we will wait until the end of our current trial and then do a monotherapy trial in outpatients.

At this juncture, I'd like Steve King, who's our Chief Operating Officer, to discuss our business development and chemical manufacturing controls. Steve?

Steve King
Thank you, Jerry, and good morning, everyone. Since our last call, the ViralClear team has been working on many fronts, including business development and chemistry manufacturing and controls.

On the business development front, we were able to work with Vertex to offset the scheduled milestone payments to the start of Phase 2 and Phase 3 studies in return for a small increase in back-end sales royalty. The team at Vertex has also supported many of our needs in providing historical technical information.

We have also been talking with many companies to discuss possible Merimepodib drug combinations. These collaborations are ongoing, and we'll start with testing in vitro cells, as we did with remdesivir, and in animal models such as hamsters. And discussions with various organizations also continue in relation to non-diluted funding for both COVID-19 and other viral diseases.

On the CMC side, we continue to put in place the supply chain for both the NDA filing and subsequent commercial launch. In July, we contracted with AMRI to manufacture the Merimepodib drug substance for Phase 3 registration batches. These will be required for the NDA filing and also to scale up. This material will be used to produce the drug product, which is the solution for the Phase 3 trial.

In addition, we have contracted with another API supplier to produce large quantities of key ingredients to make the Merimepodib drug substance. These have been converted into the Merimepodib material, which goes into the solution. As mentioned, we have produced sufficient supplies of active and placebo to the Phase 2 study. In parallel, we're working on flavoring and taste masking for the pivotal Phase 3 trial.

A CDMO, or contract manufacturing organization, has been selected to produce Phase 3 registration batches of the solution and scale up to the commercial launch. The team has also been working on a tablet formulation, which should be available in the next six months.

This concludes the updates of the CMC and B.D., and I'll hand back to Jerry for closing remarks.

Jerry Zeldis
Thank you, Steve. I'll summarize that from the beginning, our mantra has been focus and speed, and we have focused on COVID-19, and we've accomplished quite a bit since the end of March. We have quickly repositioned Merimepodib for this horrible disease, and we've raised supporting capital to allow us to get to the end of Phase 2 and to negotiate to Phase 3.

We've established an accomplished development and management team, which has worked very well together, despite the fact that none of us have ever met face to face. We responded to the changing COVID-19 landscape by amending the protocol as the standard of care has evolved, and by increasing the number of centers so that we can keep up with the enrollment of our trial.

So, despite all these—or because of all these efforts—we believe that we'll have topline data on our Phase 2 trial, the expanded trial, the fourth quarter of this year and that within a four week period, we'll be able to rotate into our pivotal trial hopefully that same quarter, which would lead to a filing of the NDA for Merimepodib by the third quarter of next year.

At this point, I'd like to hand this call over to the Operator. Thank you.

Operator
Thank you. At this time, we'll be conducting a question and answer session. If you'd like to ask a question over the phone, please press "*1" on your telephone keypad. A confirmation tone will indicate your line is in the question queue. You may press "*2" if you'd like to remove your question from the queue. For participants using speaker equipment, it may be necessary to pick up your handset before pressing the "*" keys.

You may also submit a question via the webcast by typing into the Ask a Question box on the left side of your screen.

One moment, please, while we poll for questions.

Andrew Ballou
Thanks, Melissa. While we're waiting for the questions to poll, I'll throw one out to the team. Can you describe the relationship with Vertex? Why were they willing to give up milestone payments at this stage for more on the back-end?

Steve King
Thanks, Andy. I'll take this call. It's Steve King. Firstly, I want to say the Vertex team has been very helpful and supportive. Vertex wants to do something to help with the COVID-19 pandemic, and helping ViralClear was a way to achieve this. I also think it's a good example of the pharmaceutical companies working together to fight the COVID-19 pandemic.

Andrew Ballou
Great, thank you. Melissa, we're ready for questions from the line.

Operator
Thank you. Our first question comes from the line of Yale Jen with Laidlaw and Company. Please proceed with your question.

Yale Jen
Good morning and thanks for taking the questions. I have two here. The first question applies to the data, how many—among the 40 patients—how many are grade 3 and how many are grade 4, so we can estimate how many grade 4 and grade 3 patients may be in by the end of the study.

Jerry Zeldis
I'll take this. We're not going to give specific numbers yet. Just as I revealed, we've had 40 people randomized in the trial, and at this point, approximately half of each type of grade. But I think it's irrelevant if it's 18 versus 22 or whatever it is. But it's about the same number of patients.

The problem that we faced is that because the outcomes of the grade 4s were very different than the grade 3s, and we saw that all the grade 4s did well, we have to bring in more patients to beef up the number of grade 3s. So, this separation, we saw an outcome; we can get a stronger signal.

Yale Jen
Okay, maybe one more. One follow up question here is what percentage of the patients do you think may have taken the convalescent plasma or Dexamethasone? What is complicating the data reading, and do you intend to stratify a little bit to get a better picture when you have the Phase 2 data in the fourth quarter of this year? Thanks.

Jerry Zeldis
As you'll recall, the convalescent plasma received its authorization approximately a month ago, and so we don't have many patients who took that. And, Dexamethasone is an interesting story because some—many—clinicians don't really believe that it's of great use, unlike remdesivir. And the reason for that is very straightforward.

In England, where the work was done with Dexamethasone, the ICU mortality dropped from about 37 percent to around 20 percent or 22 percent. At the Mayo Clinic—and we are in three different sites—our principal investigator is at the Mayo Clinic—their ICU mortality is in the low teens at worst, and so they've said, well all that happened in England was that they started moving towards what they were doing at the Mayo Clinic, and therefore we don't see any need to have Dexamethasone. The majority of patients we've admitted were not on Dexamethasone, but of course, we're going to look at this, and we'll go from there.

Yale Jen
Okay, great, thanks, and I'll get back to the queue. I appreciate it and congrats on the positive progression at this moment.

Jerry Zeldis
Yeah, well our fingers are crossed.

Operator
Thank you. Our next question comes from the line of Jeremy Roe with Integra. Please proceed with your question.

Jeremy Roe
Hey, guys. Good morning. Thanks for taking my question. I appreciate it. So, I've done some digging into the science with some friends on this company, as well as a handful of others who are doctors and researchers, and feel particularly with this one we're on pretty solid ground. What I'm curious about is the bigger picture regarding corporate plans. Do you plan to keep ViralClear as a sub? Are we going to spin it out to its own public entity or sell it privately? And, then a quick follow up would be to that end, where are we at with this process, if that's what we're doing with this.

Ken Londoner
Yeah, hi Jeremy--

Jerry Zeldis
Do you want to take this?

Ken Londoner
Yeah--

Jeremy Roe
Jerry, this is for Ken.

Ken Londoner
Yeah, thanks for the question. We have been working consistently on the process, and we have a board meeting coming up this Thursday, where we're going to be discussing the process further. There is a path forward for the spin-out. There are certain inputs that have to go into it that I can't really discuss on today's call, but we think within the next 30 days, we'll be in a position to socialize more about it.

I mean, at the end of the day, what we said on the last call and the call prior was that we see Jerry and his team as outstanding leaders in drug development with a great track record. They have a fantastic drug platform that Vertex spent quite a bit of money on and was willing to forego milestone payments for which we thought was a good sign. And, we're preparing it for its own

independent life, and in order to do that, you need to go through a number of steps. But you'll be hearing about that soon, and we're heading in that direction. Thanks, Jeremy.

Jeremy Roe
Got it. Thanks very much.

Operator
Thank you. Our next question comes from the line of Gary Zwetchkenbaum with Plum Tree Consulting. Please proceed with your question.

Gary Zwetchkenbaum
Thank you. My question is for you, Dr. Zeldis, and for Ken Londoner. What does ViralClear Pharmaceutical have to do to receive emergency authorization for our antiviral drug? And, the second part of my question is, are there any combination therapy partners out there that we have identified or are talking with now for our drug? Can you expand on that, please?

Jerry Zeldis
Okay, the first question is about emergency use authorization. It's fairly straightforward. Once we engage the FDA to review what we have seen, it's a series of considerations. One is, is the signal such that it would justify going pivotal and most likely, depending on what we see as we're moving forward, in the eyes of the regulators, is this truly a breakthrough that's of significance? And, I put quotes on that because it's in the eyes of the beholder that the FDA would say, "Yes, this is urgent, we want--people should have access to it, and we'll therefore grant an emergency use authorization."

If the answer is yes, then we will prepare the application with that in mind. If the answer is no, but it is--you have a positive trial, you can submit the NDA, then we'll go through the appropriate hoops we need to jump through and file an NDA. I'll just say parenthetically that emergency use authorization also requires an extensive application. It isn't as if you get a phone call and, "Congratulations, you've just won emergency use authorization." The FDA has to look with good scientific rigor over the data to make certain that it stands up to what we believe we've seen, and so that's a process.

The second question you asked--give me one second--make sure I recall--if you could repeat the second question, please.

Gary Zwetchkenbaum
Yes. I asked if there are any combination therapy partners that we are talking to that we have identified or that are talking to us now or recently to partner with our drug or drugs.

Jerry Zeldis
Okay, there's a couple levels. We are, as I'm talking to you, combining other company's antivirals, antibodies in tissue culture, and ultimately into the hamster, which will not be that long from now, to see how active their agent is with our agent in addressing this infection. We've also done much business development activity. We are reaching out to more companies to either partner or whatever.

Of course, I can't really talk about that. I'll just say so far, the major bottom line is they want to see data in the clinic or in an animal, and we're moving in that direction.

Gary Zwetchkenbaum
So, there are several companies that we're in talks with now that we are doing some form of trial in a lab with these companies and their products?

Jerry Zeldis
Yes.

Gary Zwetchkenbaum
Thank you. And, on the authorization, is there a timeline on that for where we are right now? How long does it take to get emergency authorization from where we are right now?

Jerry Zeldis
I don't know because we have to--as I said, this fourth quarter is when we're going to have the data on our Phase 2 trial, and at that point, we will engage the agency to discuss what we've found, and we anticipate or hope that this will lead to the FDA agreeing with us that we should go into a pivotal trial.--

Gary Zwetchkenbaum
--All right, the fourth quarter begins in a week and a half. Can you give any closer timeline of where in the fourth quarter? Are we looking at October and November?

Jerry Zeldis
I can't. But, right now, that's our timeline.

Andrew Ballou
Thanks, Gary. So, we'll take one from the webcast here, and it's on a topic of EUA. Is there sufficient inventory of MMPD for initial use by healthcare personnel in the event of emergency use authorization by the FDA?

Ken Londoner
Steve, do you want to handle this?

Steve King
Yeah, we--as I mentioned in my earlier comments--we have API that we are making now, which we would expect to happen in the fourth quarter, which will build up our inventory of materials. And we have further materials being delivered in the first quarter, second quarter of next year. So, depending on when that comes, we will have inventory.

Andrew Ballou
Jerry, we'll take another from the webcast here. It seems like it took a long time to enroll 40 patients. Do you expect that it will take the same amount of time to enroll the next 40?

Jerry Zeldis
Well, we've just activated a number of--two more-principal investigators, which are associated with a number of locations. As you know, this epidemic is coming in waves. We think we're now in centers where, unfortunately, the wave is going up. It's not going down. So, it's a double-edged sword. On the one hand, I'm very pleased when I find out that in a certain area which was quite active with COVID-19, all of a sudden, the number of hospitalizations and people in ICUs has gone down. It's good for us in general. Obviously, it's not good for the trial.

So, I think we'll get there. But the other thing is that we are partnering with the Hospital Corporation of America and their COVID taskforce and, as you know, they have hospitals across America, and we are beginning to evaluate hospitals where things are going—where the number of infections are going up, not down. We are trying to get them online as fast as possible so that we can be ahead of the wave. Of course, people are also expecting a second wave of infection, and we're already in place in case this thing happens.

Andrew Ballou
Thanks, Jerry. Another question from the webcast. Can you describe the drug pricing, cost of goods sold? Steve, maybe that's for you.

Steve King
Sure. As we go through the development process, the cost of goods will go down as we scale up both the merimepodib drug substance and also the oral solution. It's anticipated the cost will be consistent with other products in the market and will allow us to get margins consistent with the products of this type for the treatment of COVID-19.

Andrew Ballou
Great, thank you, Steve. All right, another question from the webcast. If you're fortunate enough to get to Phase 3, what's the estimate on the number of patients and the time you'll need to enroll?

Jerry Zeldis
That's a great question. Right now, we are evaluating contract research organizations who run clinical research outside of the United States. We will use the centers we already have in the United States as well, and unfortunately, as you know, watching the news, there are certain places in the world, Europe, but also it's never really abated, India, South Africa in particular, where--Brazil--where there's many, many people unfortunately who are quite ill from this disease. And our intention is to go international as well as stay in the United States, both places, to get the number of patients we need.

Andrew Ballou
Thank you. Question from the webcast for Ken. Ken, what are the upcoming capital commitments?

Ken Londoner
Could you--capital commitments with respect to--

Andrew Ballou
With respect to ViralClear.

Ken Londoner
The terms of investment?

Andrew Ballou
Yes.

Ken Londoner
Thank you, Andy. ViralClear happens to have a decent amount of cash on the books. We're about to close out the third quarter, and they have ample funds to take them well forward. In terms of BioSig's balance sheet, again, the quarter is coming up. Last month, we had about $36 million on the balance sheet, and we're doing very well from a capital positioning standpoint. So, we're able to handle the activity without additional stock issuances.

Andrew Ballou
Thanks, Ken. Melissa, can we take another from the line now?

Operator
Yes. Our next question comes from the line of Ted Lovejoy with Ladd Capital Management. Please proceed with your question.

Ted Lovejoy
Yeah, hi guys. Just a question, I understand the results were inconclusive. You're going to expand the trial. But, with the patients that did receive the drug, how did they tolerate it? Were there any adverse reactions, that sort of thing? And, then just a follow-up. I mean, any plans of doing a study where somebody gets tested as positive and before they get to the hospital, trying to treat them with an oral version, something like that, as opposed to hitting them later on when they're sicker?

Jerry Zeldis
That's an interesting question. Our intent has always been to do an outpatient study to study the population you're talking about. Because we didn't know--merimepodib had never been used to treat people with COVID-19--we felt the better part of valor, the right thing to do was to treat people in the hospital where things were much more well-controlled, and we could address our concerns. The good news is that the drug is very well tolerated, and the adverse events we saw were consistent with what was known about merimepodib--or consistent with what to expect with COVID-19 infection.

We've had no unexpected adverse events, and we're monitoring the trial very, very closely for this. So, it's not like we're looking the other way, and something slips through.

There are certain things that we did to be very careful, which we now think we can lighten up a little bit, such as timing of administration of merimepodib vis-à-vis remdesivir. We now think that that's less of an issue, and in our latest amendment to the protocol, which is now active, we are allowing people to start in the trial if they only had one dose of remdesivir. Before, they had to receive our drug first and then remdesivir, and that's no longer the case.

So, we feel much more comfortable, and we anticipate when we do our Phase 3 trial that some of the restrictions we had just to be on the safe side we no longer will need to do. We also think that based on what we've observed so far, that we can then go into the outpatient setting and see if we can affect people who have been exposed or are symptomatic or asymptomatic with this infection. So, we're quite further along than where we were even a month ago.

Ted Lovejoy
Okay, great. Thanks for the update.

Operator
Thank you.

Andrew Ballou
Thank you--go ahead, Melissa.

Operator
Thank you. Ladies and gentlemen, as a reminder, if you'd like to ask a question via the phone, please press "*1" on your telephone keypad. You may also submit questions via the webcast by typing into the Ask a Question box on the left side of your screen. Please go ahead.

Andrew Ballou
Thanks, Melissa. A common question we're getting on the webcast here is, BARDA, NIH, non-diluted funding, will you be receiving any non-diluted funding?

Jerry Zeldis
We've contacted and have had meaningful exchanges with a variety of non-diluted financing mechanisms that include BARDA. We've even chatted with the White House Operation Warp Speed program, even though, for the moment, that program is focusing on vaccines. They're also keeping an eye out on antivirals. We've talked to also a number of non-government organizations who also are funding development in this pandemic. So, you can imagine the names because they're in the news almost every day.

Essentially what everyone has told us is please come back when you have the signal in Phase 2. So, I think we're working on the assumption that once we get a signal in Phase 2 that we are having meaningful activity in the drug, that it would merit us and be pivotal, then we would probably qualify for a variety of non-diluted funding mechanisms.

Andrew Ballou
Great. Thank you, Jerry. Another question that we're getting from the webcast regards viral reduction. With bloodwork that you're seeing, are you seeing viral reduction, and what about the speed of viral clearance? Is there anything you can share there?

Jerry Zeldis
At this point, no. We're still analyzing the data, and we also feel that we need more patient data before we can draw a conclusion.

Andrew Ballou
Thank you. Another question from the webcast that we're getting is, What other indications are you considering for merimepodib?

Jerry Zeldis
Okay, well as you know, or maybe you don't know, the first investors conference we've had--and also I believe it was on our website--this drug in tissue culture has been shown to be active against basically every virus that it's ever been looked at with. And that includes DNA viruses, RNA viruses. It's a host-directed therapy.

We are now beginning to look at--and so some of the viruses where we've seen activity include Zika, herpes simplex, a number of the hemorrhagic fever viruses. So, we're now going to look at Dengue fever, which, as you know, has now entered the United States. There have been cases in Florida, as well as Hawaii, and so it's less of a theoretical thing. Well, it's out there, but it's not a U.S. issue. It's becoming a U.S. issue.

So, we'll look at Dengue. We're also going to look at West Nile Fever and a variety of other viruses, and more importantly, we're going to go into appropriate animal models to see if we affect these infections in the animal. So, once we go through that, we'll then talk to a variety of organizations. There are the Department of Defense, the NIH, and other parts of the government that have programs to look at some of these infections, because not only is it national security, but we have troops and officers, soldiers, out where these infections exist, and so there are programs to try to protect our soldiers.

So, we'll talk to those programs that could lead to some non-diluted funding to do development in that arena. We also have a variety of other ideas as to how this drug might be active with certain types of infections that occur in a variety of clinical settings, and we'll begin to model those as well. So, stay tuned.

Andrew Ballou
Thanks, Jerry. Melissa, why don't we take one more question from the line?

Operator
Thank you. Our next question is a follow up from the line of Yale Jen with Laidlaw and Company. Please proceed with your question.

Yale Jen
Thanks for taking the follow-up question. Just a quick one that in terms of the new patients added--so, roughly in total of 40 to60 patients going forward, are you still going to have the same 1 to 1

randomization between remdesivir alone versus the combo, or could you change that to a different sort of randomization level to read the data later on?

Jerry Zeldis
It still would be a 1 to 1 randomization, but now, we're going to concentrate on enrolling grade 3 patients because we need to beef up the numbers so that the sense we're getting that grade 3s do differentiate--they do bifurcate in your outcomes--we'll see whether that bifurcation segregates with our drug or placebo. So, and I said in my opening remarks, on an ongoing basis, we're going to be observing what's going on. So, if we bring in another 10 or 15 grade 3 patients and we feel that things are really--the numbers are looking very good, at that point, we can do an unblinding. We look, and if we see that things behave the way we hope they will behave, then we'll go into a dialogue with the FDA.

Yale Jen
Okay, maybe just tag on one last question, which is are you seeing increasingly more elderly patients in the trial at this moment, or are you still seeing age distribution still more broadly in terms of the age?

Jerry Zeldis
We have a spectrum of ages. I think the youngest patient in the trial is 31.

Yale Jen
And do they generally account for a lower portion—percentage--versus the elderly patients, because--

Jerry Zeldis
--Let me--the impression I have, and I haven't really done--it's more eyeballing the list of patients. I think it's distributed amongst the age groups. We have people--I said the youngest is 31. I forget how old the oldest was, but we have many people who are in their 40s, as well as 50s.. So it isn't like they're all octogenarians.

Yale Jen
Okay, great, thanks, Dr. Zeldis. Appreciate it.

Andrew Ballou
Thank you, Yale. Thanks, Jerry, Steve, and Ken, and thank all of you for participating on today's call. That will be our last question. For more information, please don't hesitate to reach out to us or visit www.biosig.com, and you can find information on ViralClear there too. Have a good day.

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Operator
Thank you. This concludes today's conference. You may disconnect your lines at this time. Thank you for your participation.